



CERTIFICATE OF ANALYSIS

Chain of Custody: 300396
Client: US Food & Drug Administration
Address: Office of Cosmetics & Colors
 4300 River Road
 College Park, MD 20740
Attention: John Gasper

Job Name: Task 3 - Analysis of Official Samples
Job Location: 1st Group - 8 Samples
Job Number: CLIN 1 - Task 3 (8 Samples)
PO Number: HHSF223201810337P

Date Submitted: 3/14/2019
Date Analyzed: 3/29/2019 - 4/18/2019
Report Date: 10/25/2019
Date Sampled: Not Provided
Person Submitting: Steve Wolfgang
Revised:

SUMMARY OF ASBESTOS IN TALC ANALYSIS

AMA Sample ID	Client Sample ID	TEM LOD Using ASTM D5756 Mass Calculation	TEM LOQ Using ASTM D5756 Mass Calculation	% Tremolite by TEM Using ASTM D5756 Mass Calculation	% Chrysotile by TEM Using ASTM D5756 Mass Calculation	% Total Tremolite & Chrysotile by TEM Using ASTM D5756 Mass Calculation	% Asbestos by PLM	% Organics	% Acid Soluable	% Other	Comments
300396-7	D-38	0.0000134%	0.0000536%	ND	ND	ND	ND	0.0%	3.1%	96.8%	
300396-7A	D-38	0.0000173%	0.0000694%	ND	ND	ND	ND	0.1%	2.4%	97.5%	
300396-7B	D-38	0.0000135%	0.0000539%	ND	ND	ND	ND	0.0%	2.5%	97.4%	

LOD = Limit of Detection

LOQ = Limit of Quantification

ND = Not Detected

PLM = Polarized Light Microscopy

TEM = Transmission Electron Microscopy

Analytical Method(s): PLM by Modified NY ELAP 198.6
 TEM by Modified NY ELAP 198.4/ASTM D5756

Analyst(s): PLM
 TEM

(b) (6)

Technical Director: Andreas Saldivar

All results are to be considered preliminary and subject to change unless signed by the Technical Director or Deputy

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CFSAN
Office of Cosmetics and Colors
CHAIN OF CUSTODY FORM

Case/Lab No: 300396
 Submitter: Steven Wolfgang
 Assignment No./ Contract No.: HHSF 223201810337P
 Entry No./Lab No.: 300396
 Date Sealed: 3/14/19 Sample Type: 8 samples - first group

Description of Evidence



8	1	Sample ID #: D-39

Chain of Custody

Item #	Date	Received by	Received by	Comments/Location
1-8	3/14/19	(b) (6)(b) (6)(b) (6)(b) (6)	(b) (6)(b) (6)(b) (6)(b) (6)	S/O @ HMA



Case Narrative

Client Name: FDA Office of Cosmetics & Colors Contact: John Gasper
 PO Number: HHSF223201810337P Phone: (240) 402-1133
 Job Name/Location: Task 3 – Analysis of Official Samples (1st 8 Samples) Email: john.gasper@fdsa.hhs.gov
 AMA COC Number: 300396-7, 7A, 7B/D-38 Date Received: March 14, 2019

AMA Sample No.	Client Sample No.	Sample Description	Analytical Method
300396-7	D-38	Fine white powder	Mod. PLM ELAP 198.6/TEM ELAP 198.4
300396-7A	D-38		Mod. PLM ELAP 198.6/TEM ELAP 198.4
300396-7B	D-38		Mod. PLM ELAP 198.6/TEM ELAP 198.4

Requested Analyses: PLM and TEM Analysis for asbestos fibers conducted by Modified NY ELAP Method 198.6 and Modified NY ELAP Method 198.4

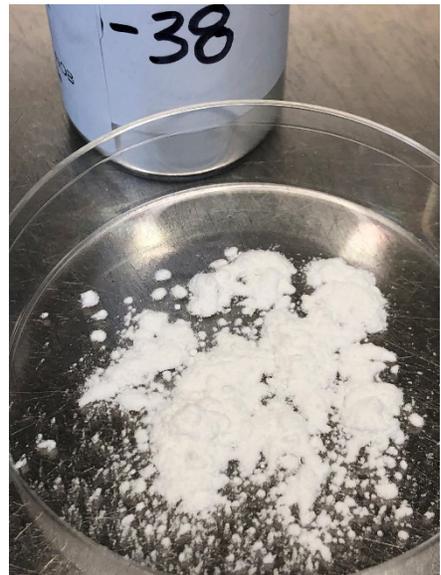
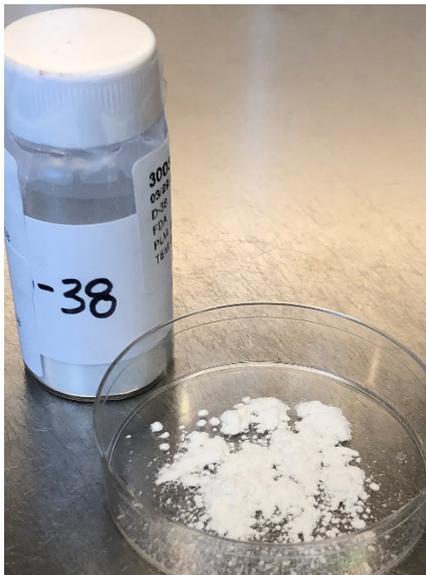
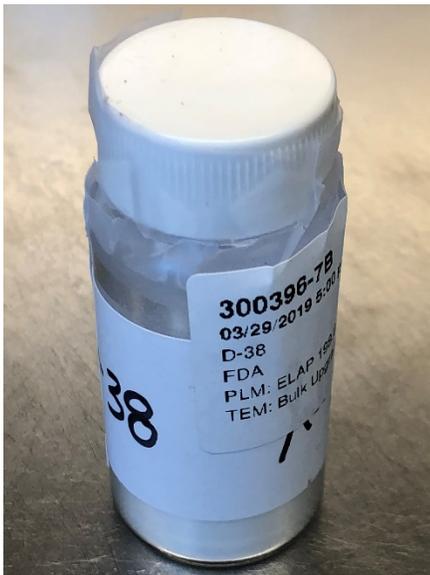
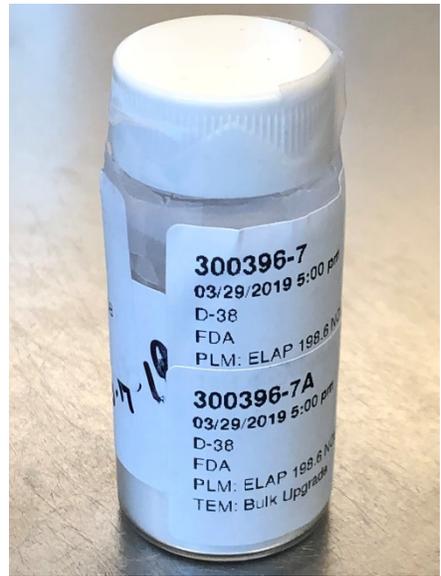
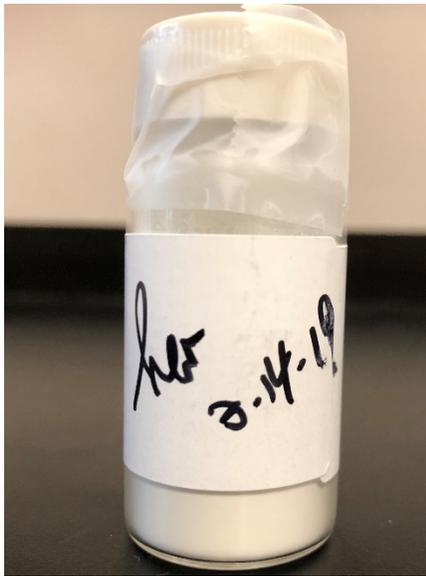
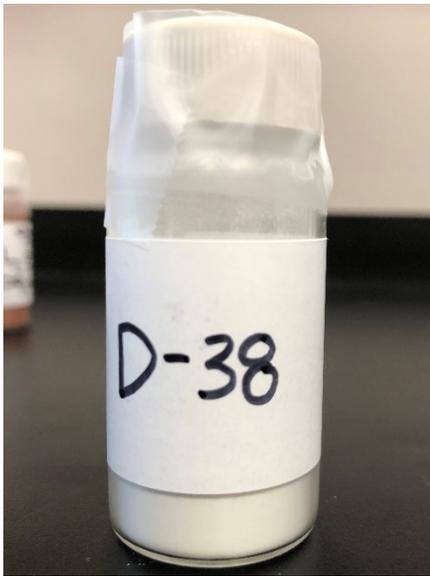
Sample Receipt:

The samples were received by AMA Analytical Services, Inc. on March 14, 2019 at 1640 via in-person drop-off by FDA representative, Steven Wolfgang. The set consisted of 8 (eight) samples submitted in ~2oz, glass jars sealed with scotch tape. Conditions were checked upon receipt and all sample containers were intact. Most jars were filled approximately ½ to ¾ full. The sample set was processed on AMA Chain-of-Custody (COC) number 300396. This COC number served as the internal laboratory job number for tracking purposes. The samples were entered into the AMA laboratory database on March 14, 2019 at 1734 by (b) (6). The samples were logged in for analysis in triplicate and each sample aliquot was assigned a unique laboratory identification number as shown in the table above. After the sample login, the set was transferred to AMA’s lock-box for storage.

The following pictures document the condition of each sample upon receipt at AMA:



300396-7, 7A, 7B/D-38



Sample Preparation

Samples were prepared for PLM and TEM bulk analysis by (b) (6) on March 15, 2019 through March 29, 2019. Sample preparation consisted of the following steps:

- 1) Label and weigh two 8mL glass vials for each sample in the set – one vial for the PLM preparation and one vial for the TEM preparation.
- 2) Weigh out 0.1 to 0.8 grams of material and place in corresponding 8mL glass vial. Record weight.
- 3) Burn samples at 480° C for at least 12 hours.
- 4) Record Post-Ash Weight.
- 5) Treat ashed sample with concentrated hydrochloric acid.
- 6) Filter acid reduced material onto a pre-weighed 47mm 0.4um PolyCarbonate filter.
- 7) Place filter into drying oven for 30 minutes and then record Post-Acid Reduced weight.
- 8) Make four PLM slide preparations from the PLM residual ash for each sample in 1.550 dispersion oil. Make additional preparations in 1.605, 1.625, 1.680 and 1.700 dispersion oil as necessary for particle identification.
- 9) Weigh a portion of the residue from the TEM residual ash and place it into the corresponding pre-weighed 100ml jar.
- 10) Fill the 100ml jar with deionized water
- 11) Sonicate the jars for approximate 5-minutes.
- 12) Filter 0.2ml to 1ml of the solution onto a 47mm 0.22um MCE filter.
- 13) Dry the filter for 10 minutes then collapse, carbon coat, and place on a 3 TEM grids.

PLM Analysis

Analysis was performed in accordance with NY ELAP 198.6 protocols. The analysis was conducted using an Olympus BH-2 polarized light microscope (PLM) equipped with a dispersion staining objective. All four slide preparations for each aliquot were examined. 400-point count was performed for those samples on which asbestos was observed. If no asbestos was detected on any of the slides, the percentage of fibrous components was determined by visual estimation. The results of this analysis are detailed below in the *Discussion and Interpretation of Analytical Findings* section for each individual sample.

TEM Analysis

Analysis was performed in accordance with modified NY ELAP Method 198.4 protocols. The analysis was performed using a JEOL JEM-100CX II transmission electron microscope (TEM), equipped with a Thermo Fisher Quest Energy Dispersive X-Ray Analyzer (EDXA), at magnifications of 19,000x. Two grids for each aliquot were examined. Twenty (20) grid openings were examined per sample.

Modifications to the NY ELAP 198.4 Method were:

- 1) The residue was not placed in alcohol and prepared using the quick drop method. To obtain a more uniform preparation, the residue was placed in a jar and filled with 100ml of deionized water. The jar was sonicated, and a portion of the solution was filtered onto a 47mm 0.22um MCE filter.
- 2) The tremolite and chrysotile were not visually estimated. The length and width of the observed particles were measured, and the mass of each amphibole particle was calculated using the ASTM D5756 method.
- 3) All particles identified as tremolite were included with the counts/concentrations, regardless of size and aspect ratio.

The results of this analysis are detailed below in the *Discussion and Interpretation of Analytical Findings* section for each individual sample.

Calculations

ASTM D5756 Mass

$$M = \pi/4 L * W^2 * D * 10^{-12}$$

M = mass

L = length



W = width

D = density

Percent Calculation

$$\frac{EFA(\text{mm}^2) * 100\text{ml} * MA(\text{g}) * RW(\text{g})}{VF(\text{ml}) * IW(\text{g}) * AA(\text{mm}^2) * RJ(\text{g})}$$

The calculated value is then multiplied by 100 to convert it to percent.

EFA – Effective filter area

MA – Mass of asbestos

RW – Weight of residue

VF – Volume filtered

IW – Initial weight of the sample

AA – Area analyzed

RJ – Weight of residue placed into the jar

Limit of Detection and Quantification

We used the mass of a 0.5 x 0.04-micron tremolite or chrysotile fiber, depending on what was found in each sample, as the basis for our calculations. Limit of detection was defined as 1 fiber and limit of quantification was defined as 4 fibers. For samples without tremolite or chrysotile, tremolite was used to determine the LOD and LOQ.

Discussion and Interpretation of Analytical Findings:

300396-7, 7A, 7B, Client Sample D-38

PLM

All three aliquots of sample D-38 were analyzed by **(b) (6)(b) (6)** on March 29, 2019. No asbestos or non-asbestos amphibole variants were detected the samples. The results were calculated using the equations detailed in the calculations section.

300396-7	NAD
300396-7A	NAD
300396-7B	NAD

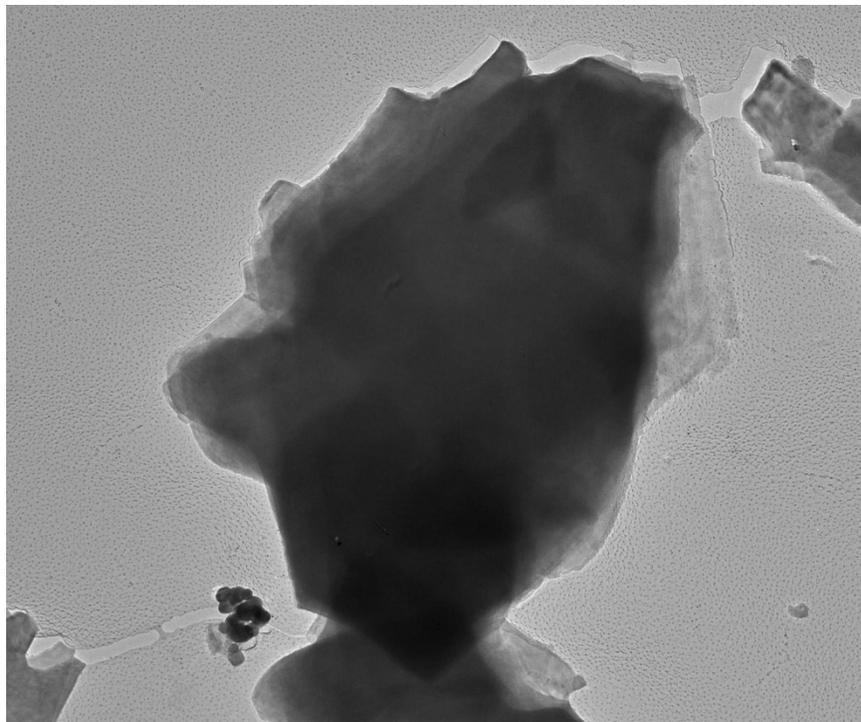
TEM

(b) (6)(b) (6) analyzed Sample 7 on April 11, 2019 and sample 7B on April 18, 2019. **(b) (6)** analyzed sample 7A on April 18, 2019. The sample consisted primarily of talc particles. These were mostly talc flakes but numerous talc fibers and ribbons were also observed. A few mica particles were observed. No asbestos or non-asbestos amphibole variants were detected in the samples. The results were calculated using the equations detailed in the calculations section.

300396-7	NAD
300396-7A	NAD
300396-7B	NAD

Below are pictures, diffraction patterns, and chemistry from some of the observed particles. The unidentified peaks in chemistry spectra are copper, zinc, and carbon. Those peaks are from the TEM specimen holder and specimen grid.

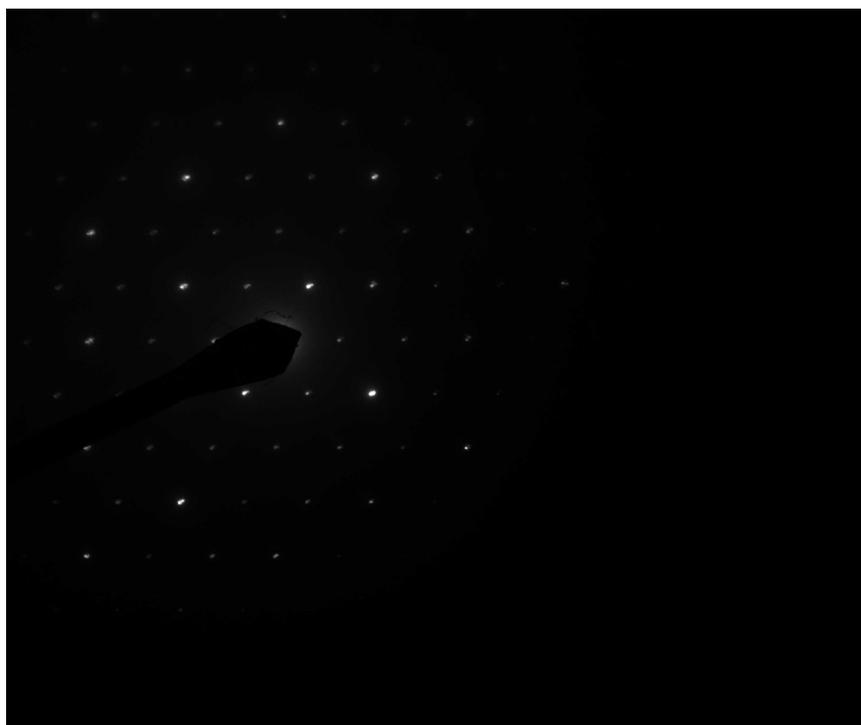
Sample 300396-7 Talc particle



300396 FDA_054.jpg
Talc Particle
Cat: 0.002858 $\mu\text{m}/\text{pix}$
19:46 4/10/2019
Microscopist: MG
Camera: NANOSPRT5, Exposure: 800 (ms) x 5 std. frames, Gain: 1, Bin: 1
Gamma: 1.00, No Sharpening, Normal Contrast

800 nm
HV=100kV
Direct Mag: 3600 x
AMA Analytical Services, Inc

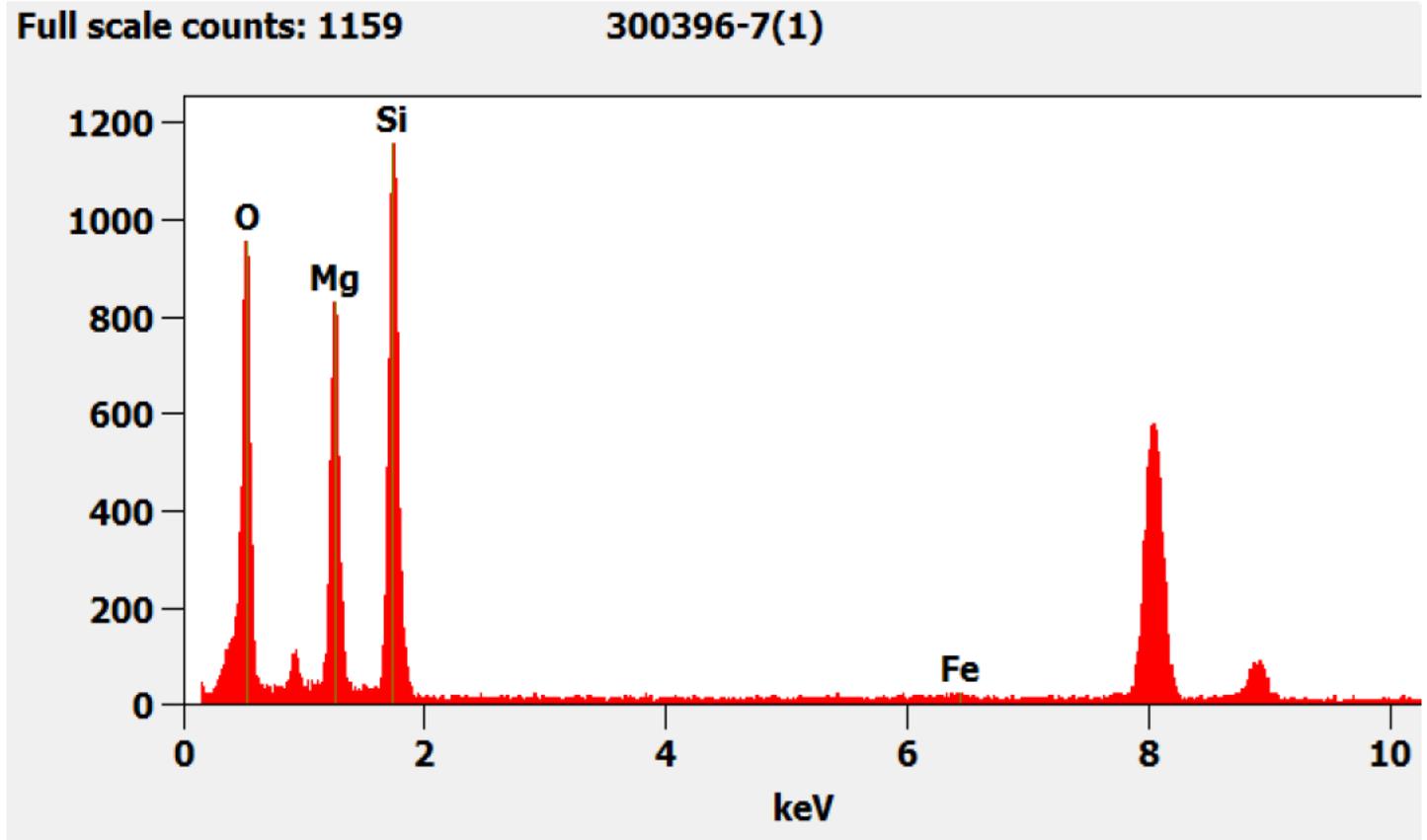
Sample 300396-7 Diffraction pattern from talc particle pictured above.



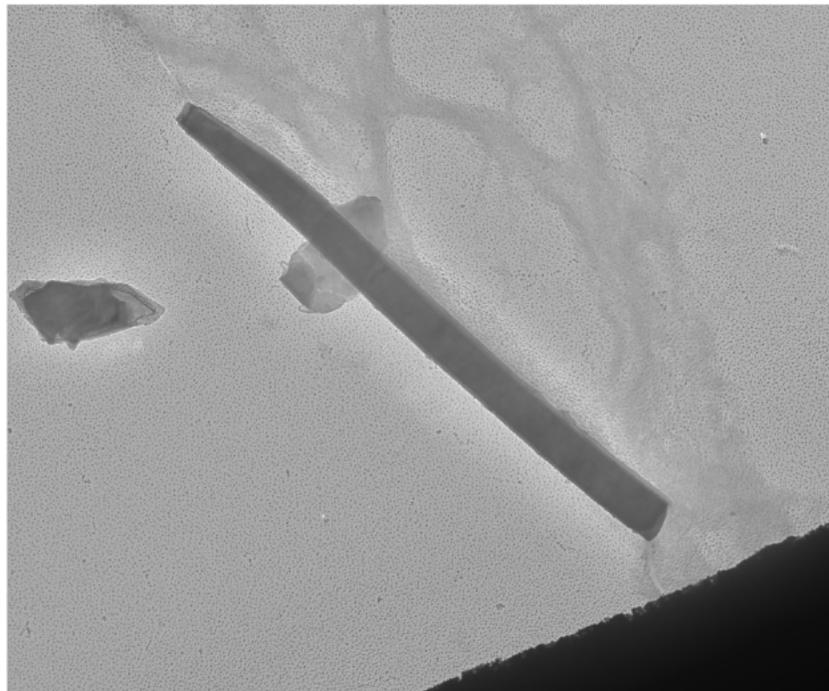
300396 FDA_055.jpg
Talc Particle Diff
19:47 4/10/2019
Microscopist: MG
Camera: NANOSPRT5, Exposure: 800 (ms) x 5 std. frames, Gain: 1, Bin: 1
Gamma: 1.00, No Sharpening, Normal Contrast

100 (1/Å)
HV=100kV
Cam Len: 0.2200 m
AMA Analytical Services, Inc

Sample 300396-7 Chemistry from talc particle pictured above



Sample 300396-7A Talc fiber



Sample 7a_002.tif
Sample 7a 7.0 x 0.42 microns
Talc fiber
Cal: 0.003548 µm/pix
12:20 4/18/2019
TEM Mode: Imaging
Microscopist: (b) (6)
Camera: NANOSCOPY, Exposure: 800 (ms) x 5 drift frames, Gain: 1, Bin: 1
Gamma: 1.00, No Sharpening, Normal Contrast

1 µm
HV=100kV
Direct Mag: 2900 x
AMA Analytical Services, Inc

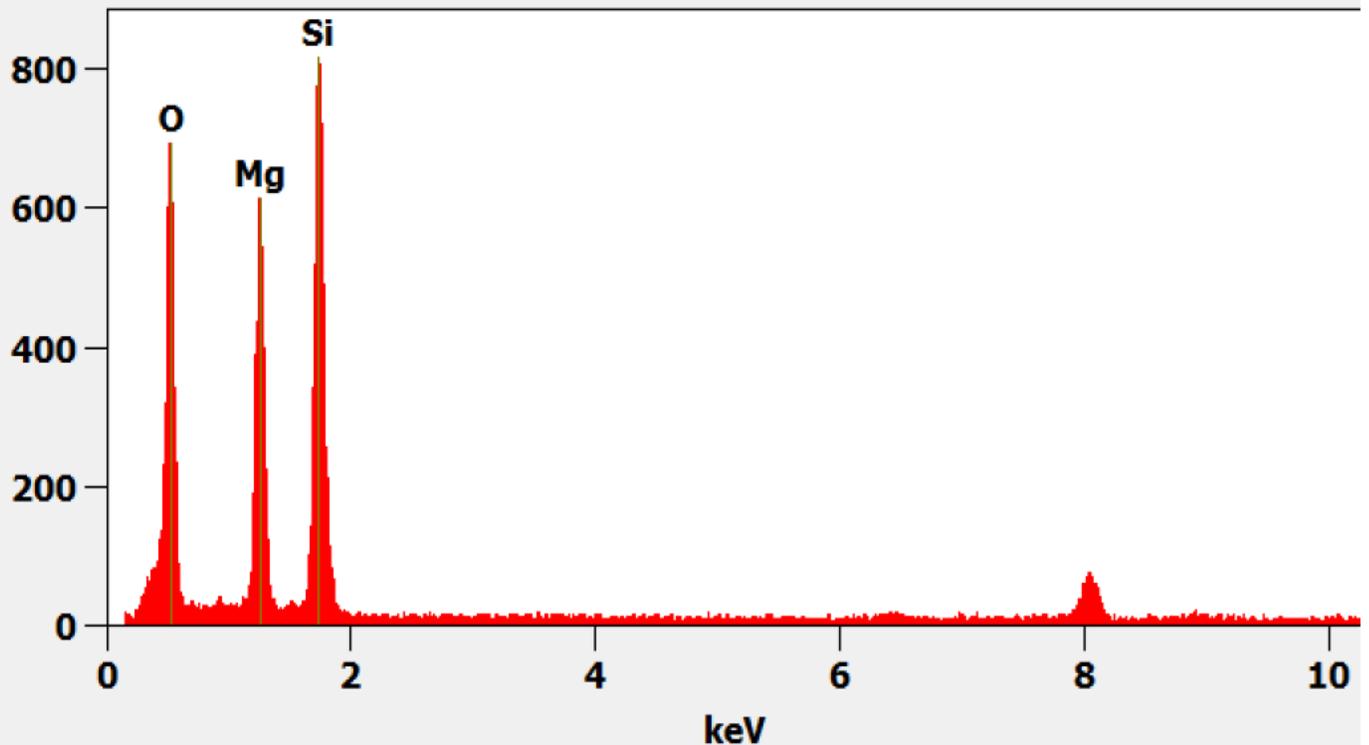
Sample 300396-7A Diffraction pattern from talc fiber pictured above.



Sample 7a_001.tif
Sample 7a
Talc fiber diffraction
12:17 4/18/2019
TEM Mode: Diffraction
Microscopist: (b) (6)(b) (6)(b) (6)
Camera: NANOSPRT5, Exposure: 800 (ms) x 5 drift frames, Gain: 1, Bin: 1
Gamma: 1.00, No Sharpening, Normal Contrast
100 (1/A)
HV=100kV
Cam Len: 0.2200 m
AMA Analytical Services, Inc

Sample 300396-7A Chemistry from talc fiber pictured above.

Full scale counts: 818 300396-7a(1)



QC Discussion:

During preparation, one blank control sample and one reference control sample were prepared. These samples were prepared alongside the customer samples. The blank sample was prepared using Sigma-Aldrich Talc Powder, <10 micron (Product No. 643604-500G; Batch No. 10830AJ) and was analyzed by (b) (6)(b) (6) on April 25, 2019. No asbestos was detected on the blank sample. The reference sample was made from the same Sigma-Aldrich talc powder spiked with 10% Chrysotile. The reference sample was analyzed by (b) (6)(b) (6) on April 25, 2019 and found to be within acceptable limits.

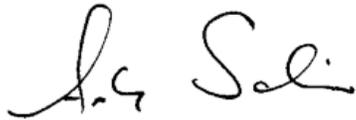
Our laboratory information management systems (LIMS) randomly selected (b) (4) additional replicate QC analysis. Separate preparations were made for PLM and TEM analysis. The replicate QC analysis was performed by (b) (6)(b) (6) on March 29, 2019, 2019 for PLM analysis and by (b) (6)(b) (6) on April 25, 2019 for TEM analysis. The Chrysotile found in the replicate QC sample for (b) (4) consistent with the findings of (b) (4) (b) (4) and (b) (4)

Attachments:

The following items are attached to this case narrative for your reference:

- 1) Sample Log-In Sheet
- 2) Daily PLM Scope Calibration Log
- 3) Refractive Index Oil Calibration Log
- 4) Daily TEM Scope Calibration Log
- 5) QC Results Summary
- 6) Replicate & Duplicate QC Chart for (b) (6)(b) (6) for samples analyzed between 9/1/2018 and 3/31/2019
- 7) Replicate & Duplicate QC Chart for (b) (6)(b) (6) for samples analyzed between 9/1/2018 and 4/19/2019
- 8) Replicate & Duplicate QC Chart for (b) (6) for samples analyzed between 9/1/2018 and 4/19/2019
- 9) Raw Data Sheets
 - a. Gravimetric Data
 - b. Filtration Worksheets
 - c. PLM Analysis
 - d. TEM Analysis
 - e. QC Samples

I certify that all information contained in this report pertaining to laboratory events, procedures, and protocols accurately describes the handling of this project by AMA Analytical Services, Inc. and its personnel and is true to the best of my knowledge .



10/25/2019

Andreas Saldivar
Laboratory Director

Date

AMA Sample Number	Client Sample Number	Analysis Type(s) and Sample Type(s)
300396-6	D-37	PLM: ELAP 198.6 NOB TEM: Bu k Upgrade
300396-6A	D-37	PLM: ELAP 198.6 NOB TEM: Bu k Upgrade
300396-6B	D-37	PLM: ELAP 198.6 NOB TEM: Bu k Upgrade
300396-7	D-38	PLM: ELAP 198.6 NOB TEM: Bu k Upgrade
300396-7A	D-38	PLM: ELAP 198.6 NOB TEM: Bu k Upgrade
300396-7B	D-38	PLM: ELAP 198.6 NOB TEM: Bu k Upgrade
		PLM: ELAP 198.6 NOB TEM: Bu k Upgrade
		PLM: ELAP 198.6 NOB TEM: Bu k Upgrade
		PLM: ELAP 198.6 NOB TEM: Bu k Upgrade
		PLM: ELAP 198.6 NOB TEM: Bu k Upgrade

Special Instructions:

Samples are in AMA lock box See **(b) (6)(b) (6)** for key. Follow FDA specific protocols.

Daily Calibrations for PLM Scope # 2

Date: 3/29/19
Analyst Initials: **(b) (6)**

Cleaning:

Oculars Objectives Field Lens Mechanical Stage Main Body

Alignment:

- Kohler Illumination (or as close to it as scope allows)
- Polarizer & Analyzer at 90 degrees to one another
- Polarizer & Analyzer aligned with reticule cross hairs
- Axis of rotation of stage centered in field of view
- Central stop of the D.S. objective aligned with condenser aperture

Refractive Index Colors of Permanent 1,680 Amosite:

2060 Parallel wavelength 660 Perpendicular wavelength

Comments/other procedures performed:

Daily Calibrations for PLM Scope # 2

Date: 4/1/19
Analyst Initials: **(b) (6)**

Cleaning:

Oculars Objectives Field Lens Mechanical Stage Main Body

Alignment:

- Kohler Illumination (or as close to it as scope allows)
- Polarizer & Analyzer at 90 degrees to one another
- Polarizer & Analyzer aligned with reticule cross hairs
- Axis of rotation of stage centered in field of view
- Central stop of the D.S. objective aligned with condenser aperture

Refractive Index Colors of Permanent 1,680 Amosite:

2060 Parallel wavelength 660 Perpendicular wavelength

Comments/other procedures performed:

Daily Calibrations for PLM Scope # 9

Date: 4/2/19
Analyst Initials: **(b) (6)**

Cleaning:

Oculars Objectives Field Lens Mechanical Stage Main Body

Alignment:

- Kohler Illumination (or as close to it as scope allows)
- Polarizer & Analyzer at 90 degrees to one another
- Polarizer & Analyzer aligned with reticule cross hairs
- Axis of rotation of stage centered in field of view
- Central stop of the D.S. objective aligned with condenser aperture

Refractive Index Colors of Permanent 1,680 Amosite:

2740 Parallel wavelength 660 Perpendicular wavelength

Comments/other procedures performed:

REFRACTIVE INDEX OIL CALIBRATION

DATE	ANALYST	RI OIL	BOTTLE ID	LAB ID	RI BEAD	TEMP (Deg. C)	Dispersion Staining Color/ Becke Line Observations	Matching Wavelength	Measured R.I.
2-4-19	(b) (6)	1.550	1.550 #4		1.55	25.7°	Red, Blue Magenta	580	1.5505
"	"	1.680	1.680 #4		1.68	"	Blue, Green	620	1.6816
"	"	1.605	1.605 #4		1.60	"	Blue, Lt Green	660	1.6041
"	"	1.625	1.625 #4		1.62	"	Blue, Magenta	560	-
2-4-19	"	1.700	1.700 #4		1.70	"	Blue, Green, Purple	580	-

(b) (4)

1-1-19	(b) (6)	1.550	1.550 #3		1.55	25.0°	Red, Blue Magenta	580	1.5505
"	"	1.680	1.680 #3		1.68	"	Blue, Green	620	1.6816
"	"	1.605	1.605 #3		1.60	"	Blue, Light green	660	1.6041
"	"	1.625	1.625 #3		1.62	"	magenta	560	-
"	"	1.700	1.700 #3		1.70	"	Blue, Green, Purple	580	-

DAILY TEM CALIBRATION LOG

Every analyst should confirm alignment prior to analyzing samples.
 X-ray analyzer must be calibrated prior to each day's use.
 Dewar for x-ray detector is to be filled each Tuesday and Friday.

Note: Please enter code letters in Type Column
 Type of Analysis: Routine Analysis A
 Quality Control QC
 Training T
 Research R
 Other (Explain) O

TRANSMISSION ELECTRON MICROSCOPE <i>Scope 1</i>							X-RAY ANALYZE		
DATE	NAME	SYSTEM/ ALIGN. CHECK	ACTUAL "BEAM TIME" USED			TOTAL # SAMPLES	TYPE	EDXA CAL. (AL/CU)	DEWAR LN2 (INIT)
			ON	OFF	TOTAL MINUTES				
4/8/19	(b) (6)	OK							
4/9/19	(b) (6)	OK							
4/10/19	(b) (6)	OK							
4/11/19	(b) (6)	OK							
4/13/19	(b) (6)	OK	0800						
4/14/19	(b) (6)	OK							
4/15/19	(b) (6)	OK							
4/16/19	(b) (6)	OK							
4/17/19	(b) (6)	OK	0740						
4/18/19	(b) (6)	OK							

Chain Of Custody #300396

[+ Add CoC](#)

General Samples Documents **QC Results**

QC Samples

Date Analyzed	Sample Number	Original PLM Analyst	Original PLM Result	PLM QC Result	PLM QC Analyst	PLM R Value	Original TEM Analyst	Original TEM Result	TEM QC Result	TEM QC Analyst	TEM R Value	Comments
03/21/2019	(b) (4)	(b) (6) (b) (6)	0.00		(b) (6) (b) (6)	0.00	(b) (6) (b) (6)	0.00	0.01	(b) (6) (b) (6)	-2.00	(b) (6) (b) (6) (b) (4) (b) (4) Analytical time = 1hr 20 mins Grid A - E1, E2, E5, E7, E8, D9, D7, D6, D3, C1 Grid B - H2, H3, H4, H5, G5, G4, G3, G2, F2, F3

Reference Samples

Sample Number	Tile #	Analyst	Asbestos Type	Percent Asbestos	Result	Created Date	Comments
Talc Ref	Talc Ref 10%	(b) (6)(b) (6)	Chrysotile	10.00	Pass	04/25/2019	Associated with COC 300396

Blanks

Blank Number	Date	Analyst	Asbestos Percentage	Asbestos Type	Comments
Talc Blank 358	04/25/2019	(b) (6)	0.0		Associated with 300396

PLM Error(s)

No Results

TEM NOB Error(s)

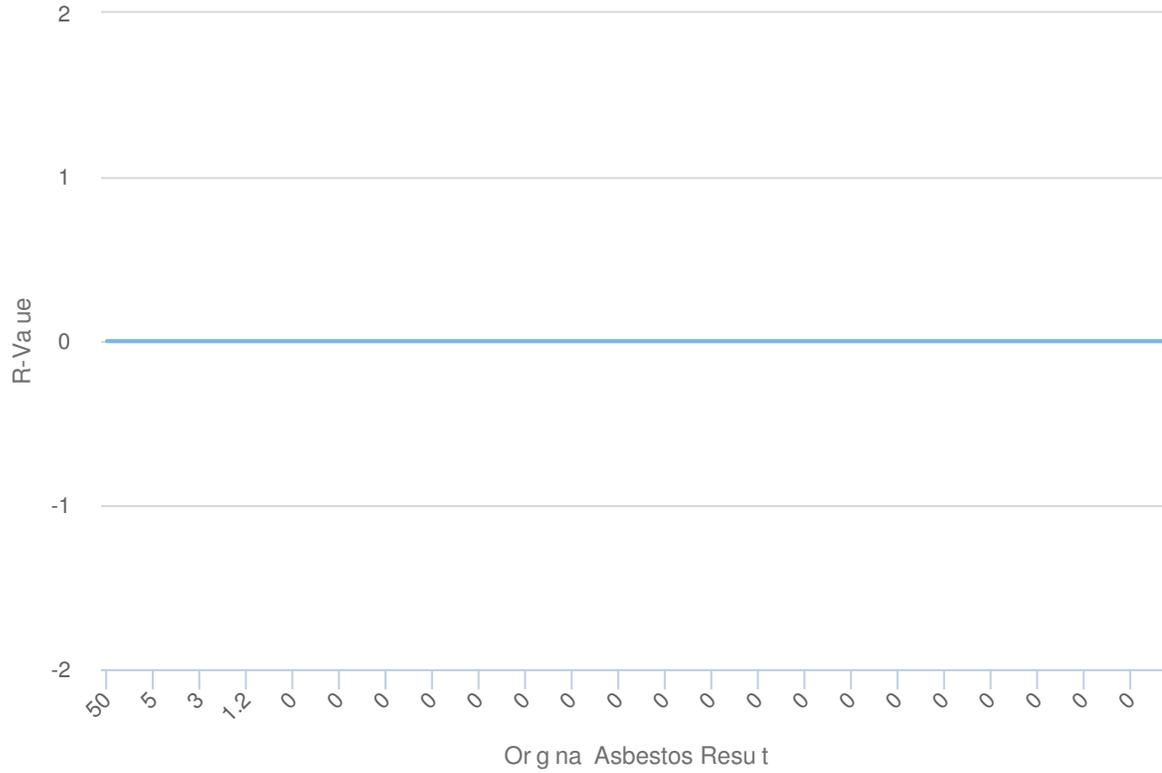
No Results

PLM QC Chart

QC Type: Duplicate

Analyst: (b) (6)(b) (6)(b) (6)

Dates Analyzed: 09/01/2018 - 03/31/2019



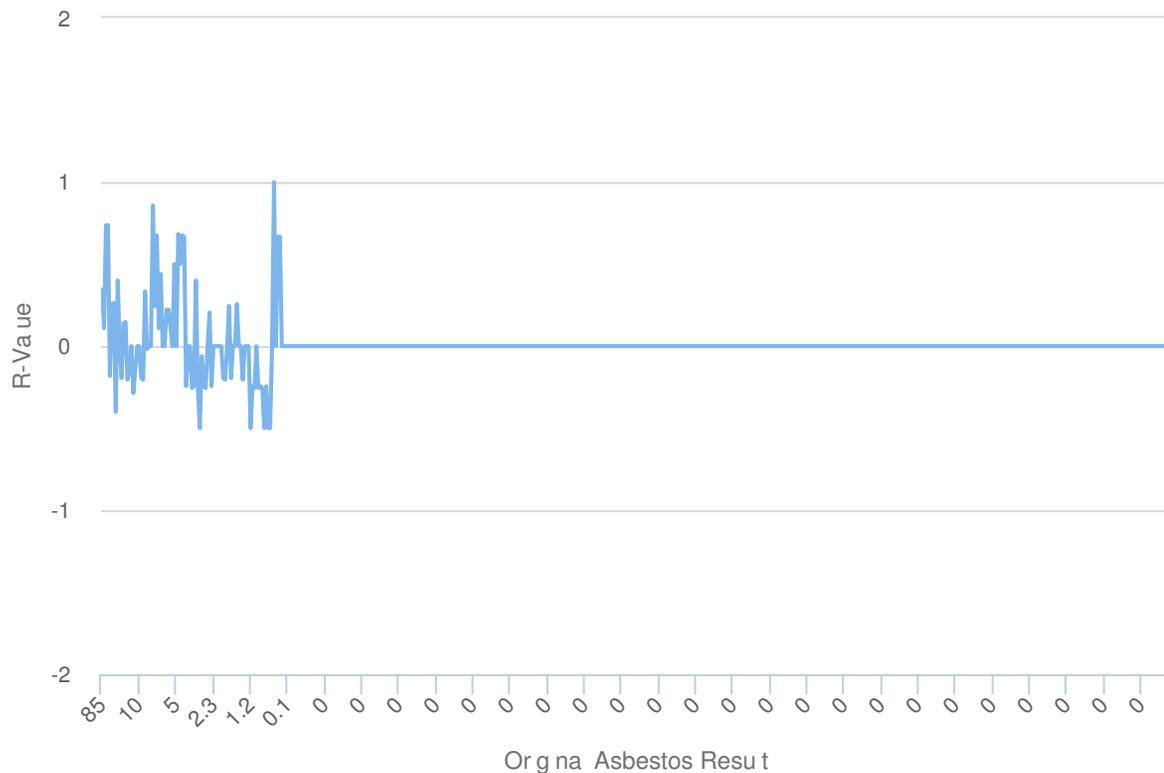
$$R = [\text{Organ Result}] - [\text{QC Result}] / [\text{Average}]$$

PLM QC Chart

QC Type: Replicate

Analyst: (b) (6)(b) (6)

Dates Analyzed: 09/01/2018 - 03/31/2019



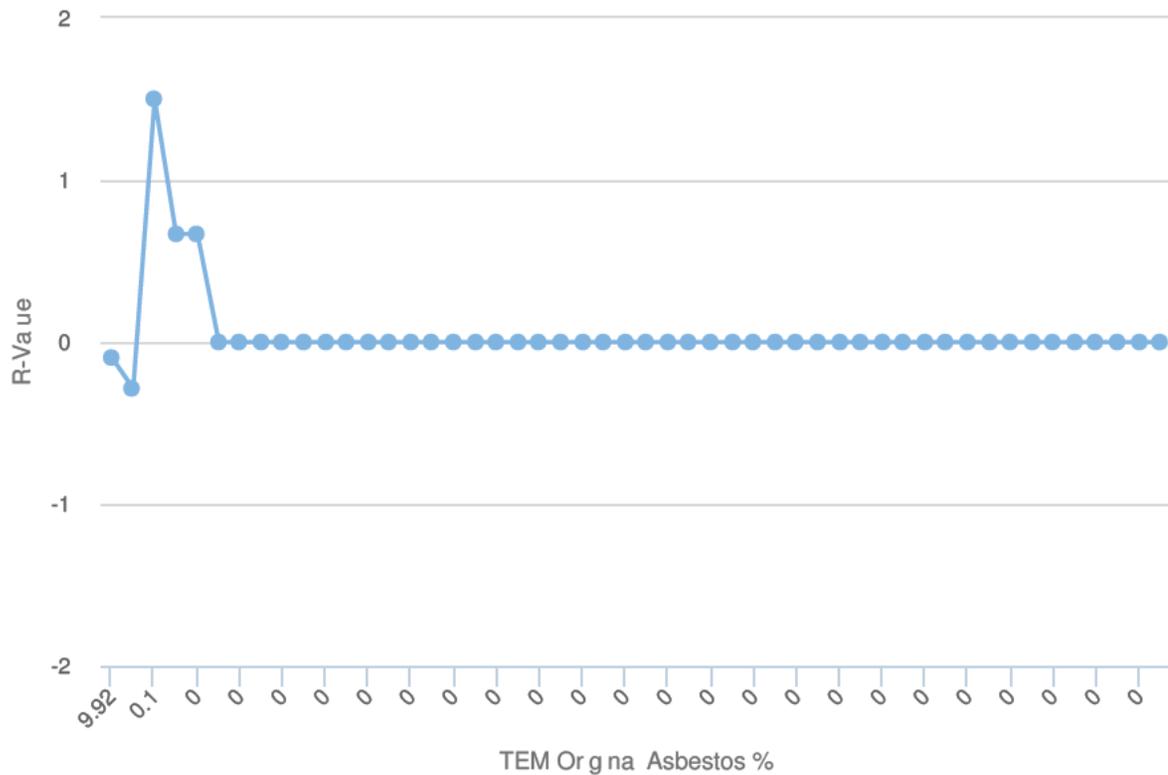
$$R = \frac{[\text{Organ Result}] - [\text{QC Result}]}{[\text{Average}]}$$

NOB QC Chart

QC Type: Duplicate

Analyst (b) (6)(b) (6)

Dates Analyzed: 09/01/2018 - 04/19/2019



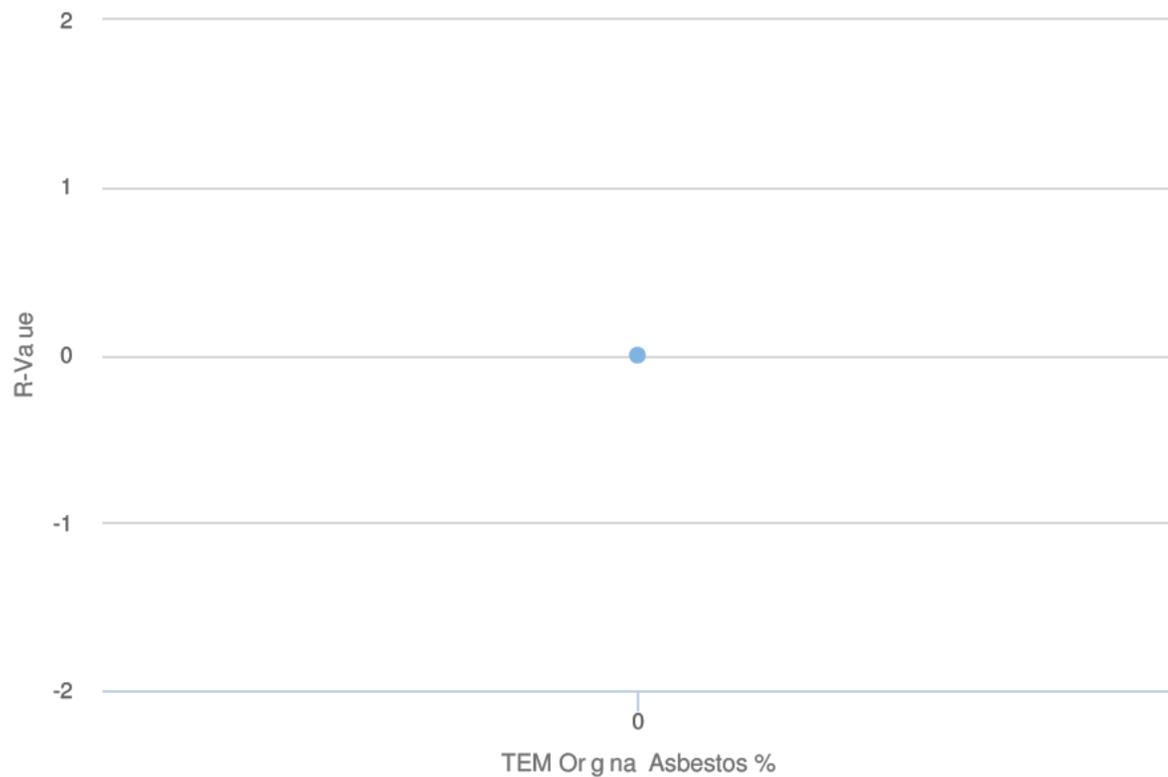
$$R = \frac{[\text{Or g na Resu t}] - [\text{QC Resu t}]}{[\text{Average}]}$$

NOB QC Chart

QC Type: Duplicate

Analyst: (b) (6)(b) (6)

Dates Analyzed: 09/01/2018 - 04/19/2019



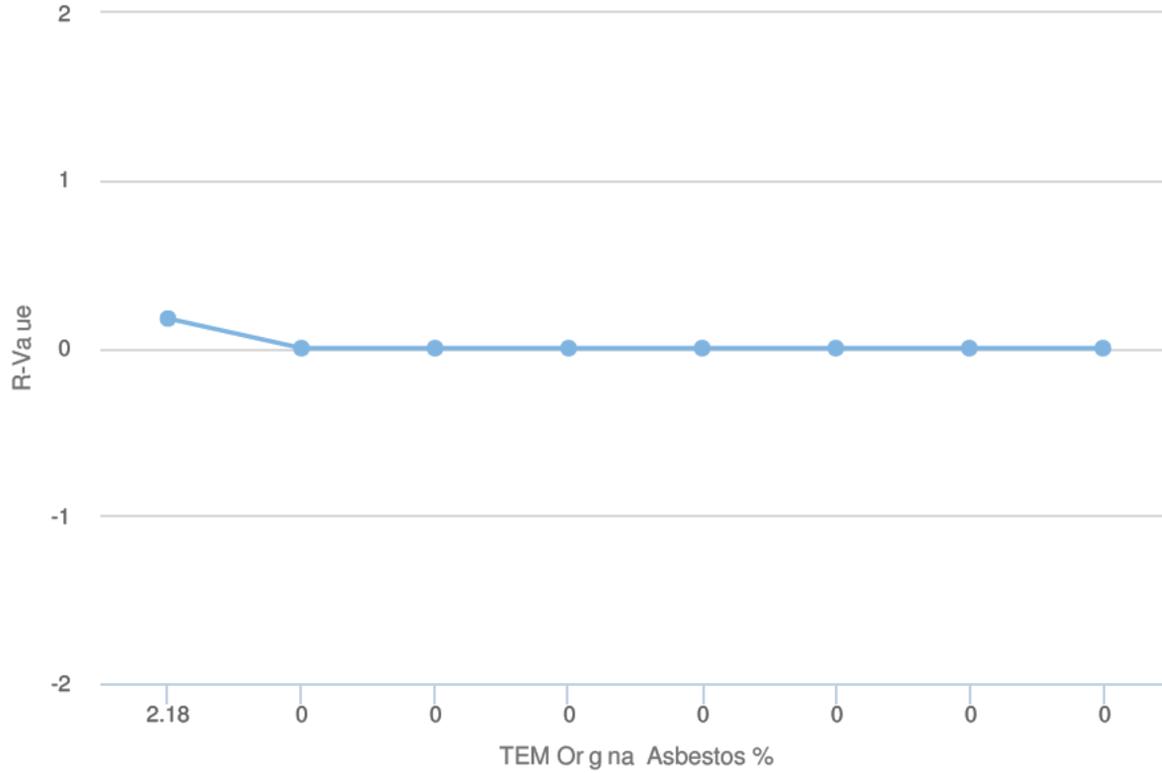
$$R = [\text{Or g na Resu t}] - [\text{QC Resu t}] / [\text{Average}]$$

NOB QC Chart

QC Type: Replicate

Analyst: (b) (6)(b) (6)

Dates Analyzed: 09/01/2018 - 04/19/2019



$$R = \frac{[\text{Organics Result}] - [\text{QC Result}]}{[\text{Average}]}$$



TEM Preparations

COC #: 300396

Date: 3/22/19

Client: FDA

Prep By: (b) (6)

Filter Type: 47 mm, 0.22 µm, MCE EFA: 1047 mm²

Filtered By: (b) (6) Lot #: R2NA36919; Date: 3/22/19

AMA Sample ID	Gravimetric Reduction Weights			Filtration Weights				Filtration Volumes					
	Mass (g) Vial	Mass (g) Vial & Sample	Mass (g) Post Ash Vial & Sample	Mass (g) Filter & Petri Dish	Mass (g) Post Acid Wash Filter & Petri Dish	Mass (g) 100mL Jar w/ Lid	Mass (g) 100mL Jar w/ Lid & Sample Residue	Initial Volume (mL)	Volume Filtered (mL)	Serial Dilution Initial Volume (mL) (if left blank, no serial dilution performed)	Serial Dilution Volume Filtered (mL) (if left blank, no serial dilution performed)	Serial Dilution Final Volume (mL) (if left blank, no serial dilution performed)	
-7B	7.1169	7.6366	7.6364	6.1380	6.6443	19.8586	20.1154	100mL	-2			=	
(b) (4)									-2			=	
									-2			=	
									-2			=	
									-2			=	
									-2			=	
(b) (4)									-2			=	
									10%			=	
												=	
													=
													=
													=
													=
													=
													=
													=
													=
													=
													=
													=
													=
													=

Edit Sample #300396-7 (D-38)

General PLM: ELAP 198.6 NOB TEM: Bulk Upgrade

Initial Sample Weight Vial Weight: 7.1142 Vial + Sample Weight: 7.6112 Initial Sample Weight: 0.497	Post Ash Weight Vial + Ashed Sample Weight: 7.611 Ashed Sample Weight: 0.497	Post Acid Treatment Filter Tare: 6.147 Gross Filter Weight: 6.6283 Weight Residue: 0.481
Visual Estimations Estimated Asbestos PLM: 0.0	Final Asbestos Percents Percent Asbestos PLM: NAD	Final Non-Asbestos % Percent Organics: 0.04 Percent Acid Soluble: 3.119 Percent Other: 96.841

Material Type: Powder
Color: White
Homogeneity: Homogeneous
Sample Type: Whole
Texture: Powdery

Sample was not analyzed
 Fibrous
 Scanning Negative Option
 Stratified Point Count
 400 Point Count

Macro Asbestos % Chrysotile Percent Amosite Percent Crocidolite Percent Other Asbestos Percent	Macro Non Asbestos % Mineral Wool Percent Fiberglass Organic Synthetic Other	Macro Non Fibrous % Particulate: 100.0 Other Non-Fibrous
---	--	---

Macroscopic Comments

Temperature (°C): 25.0
Microscope #: 2

Morphology	Color	Elongation	Ext. Ang	DSC ⊥	DSC	Ref Index ⊥	Ref Index	Pleo	Birefringence	Refractive Index Oil	Ident.
Add Row											

Slide 1	Slide 2	Slide 3	Slide 4	Slide 5	Slide 6	Slide 7	Slide 8
Ident.	Fiber #						
Add Row							

Asbestos Points

Chrysotile Points: Pending Trace Detected but no points
 Amosite Points: Pending Trace Detected but no points
 Crocidolite Points: Pending Trace Detected but no points
 Other Asbestos Points: Pending Trace Detected but no points
 Total Asbestos Points: Pending NAD < 0.25%
 Total Points: Pending

Non Asbestos Fiber Percentages Mineral Wool + Fiberglass Combined Organic Synthetic Other	Non Fibrous Percentages Particulate: 100.0 Other Non-Fibrous <input type="checkbox"/> Recommend TEM <input type="checkbox"/> Recommend Matrix Reduction
--	--

Microscopic Comments

Report Comments

Error(s) Found During Review

Edit Sample #300396-7 (D-38)

General PLM: ELAP 198.6 NOB TEM: Bulk Upgrade

Initial Sample Weight Vial Weight: 7.1142 Vial + Sample Weight: 7.6112 Initial Sample Weight: 0.497	Post Ash Weight Vial + Ashed Sample Weight: 7.611 Ashed Sample Weight: 0.497	Post Acid Treatment Filter Tare: 6.147 Gross Filter Weight: 6.6283 Weight Residue: 0.481
Visual Estimations Estimated Asbestos PLM: 0.0 Estimated Asbestos TEM: 0.0	Final Asbestos Percents Percent Asbestos PLM: NAD Percent Asbestos TEM: NAD	Final Non-Asbestos % Percent Organics: 0.04 Percent Acid Soluble: 3.119 Percent Other: 96.841

Sample Type Whole	Material Type Powder	Sample Color White
Grid Box A19-216	Row and Slots 9ab	Microscope # 1
Working Mag. High (K) 15	Working Mag. Low (K)	Accelerating Voltage (KV) 100

Sample was not analyzed

Structure Crystallographic and Photographic Data

Structure #	SAED	Elements	Neg. #	Camera Length / Mag.	Ident.
9	hex, 5 x 4.2	Mg Al Si Fe, Mica F			
8	neg, 2.25 x 1.75	Mg Al Si Fe, Mica F			
7	hex, 4 x 3.5	Si Mg, Talc Particle			
6	hex, 6 x 0.6	Si Mg, Talc Fiber			
5	hex	Si Mg			
4	hex	Mg Al Si Fe			
3	hex	Si Mg			
2	neg	Mg Al Si Fe			
1	hex	Si Mg			

Grid #1 Estimated Asbestos 0.0	Grid #2 Estimated Asbestos 0.0	Estimated Asbestos % 0.0%
--	--	-------------------------------------

Analyst Comments
 Grid A done - 45 Minutes, Grid B- 40 mins. Total - 1 hour 25 mins. Analyzed 4/11/19
 Mostly talc particles, few talc fibers, few mica

(b) (6) 4/18/2019

Report Comments
 Mostly talc particles, few talc fibers, few mica particles

Error(s) Found During Review

Edit Sample #300396-7A (D-38) i

General PLM: ELAP 198.6 NOB TEM: Bulk Upgrade

Initial Sample Weight Vial Weight: 7.0438 Vial + Sample Weight: 7.4686 Initial Sample Weight: 0.425	Post Ash Weight Vial + Ashed Sample Weight: 7.4683 Ashed Sample Weight: 0.425	Post Acid Treatment i Filter Tare: 6.1458 Gross Filter Weight: 6.5599 Weight Residue: 0.414
Visual Estimations Estimated Asbestos PLM: 0.0	Final Asbestos Percents Percent Asbestos PLM: NAD	Final Non-Asbestos % Percent Organics: 0.071 Percent Acid Soluble: 2.448 Percent Other: 97.481

Material Type Powder	Color White	Homogeneity Homogeneous
Sample Type Whole	Texture Powdery	
<input type="checkbox"/> Sample was not analyzed <input type="checkbox"/> Fibrous <input checked="" type="checkbox"/> Scanning Negative Option <input type="checkbox"/> Stratified Point Count <input type="checkbox"/> 400 Point Count		
Macro Asbestos % Chrysotile Percent: <input type="text"/> Amosite Percent: <input type="text"/> Crocidolite Percent: <input type="text"/> Other Asbestos Percent: <input type="text"/>	Macro Non Asbestos % Mineral Wool Percent: <input type="text"/> Fiberglass: <input type="text"/> Organic: <input type="text"/> Synthetic: <input type="text"/> Other: <input type="text"/>	Macro Non Fibrous % Particulate: 100.0 Other Non-Fibrous: <input type="text"/>
Macroscopic Comments <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>		

Temperature (°C) 25.0	Microscope # 5																									
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Morphology</th> <th>Color</th> <th>Elongation</th> <th>Ext. Ang</th> <th>DSC ⊥</th> <th>DSC </th> <th>Ref Index ⊥</th> <th>Ref Index </th> <th>Pleo</th> <th>Birefringence</th> <th>Refractive Index Oil</th> <th>Ident.</th> </tr> </thead> <tbody> <tr> <td colspan="12" style="text-align: right;">Add Row</td> </tr> </tbody> </table>			Morphology	Color	Elongation	Ext. Ang	DSC ⊥	DSC	Ref Index ⊥	Ref Index	Pleo	Birefringence	Refractive Index Oil	Ident.	Add Row											
Morphology	Color	Elongation	Ext. Ang	DSC ⊥	DSC	Ref Index ⊥	Ref Index	Pleo	Birefringence	Refractive Index Oil	Ident.															
Add Row																										
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Slide 1	Slide 2	Slide 3	Slide 4	Slide 5	Slide 6	Slide 7	Slide 8																			
Ident.	Fiber #	Ident.	Fiber #	Ident.	Fiber #	Ident.	Fiber #																			
Add Row																										
Asbestos Points Chrysotile Points: <input type="text"/> Pending <input type="checkbox"/> Trace Detected but no points Amosite Points: <input type="text"/> Pending <input type="checkbox"/> Trace Detected but no points Crocidolite Points: <input type="text"/> Pending <input type="checkbox"/> Trace Detected but no points Other Asbestos Points: <input type="text"/> Pending <input type="checkbox"/> Trace Detected but no points Total Asbestos Points: Pending NAD <input type="checkbox"/> < 0.25% Total Points: Pending																										
<table style="width:100%;"> <tr> <td style="width:50%; padding: 5px;"> Non Asbestos Fiber Percentages Mineral Wool + Fiberglass Combined: <input type="text"/> Organic: <input type="text"/> Synthetic: <input type="text"/> Other: <input type="text"/> </td> <td style="width:50%; padding: 5px;"> Non Fibrous Percentages Particulate: 100.0 Other Non-Fibrous: <input type="text"/> <input type="checkbox"/> Recommend TEM <input type="checkbox"/> Recommend Matrix Reduction </td> </tr> </table>			Non Asbestos Fiber Percentages Mineral Wool + Fiberglass Combined: <input type="text"/> Organic: <input type="text"/> Synthetic: <input type="text"/> Other: <input type="text"/>	Non Fibrous Percentages Particulate: 100.0 Other Non-Fibrous: <input type="text"/> <input type="checkbox"/> Recommend TEM <input type="checkbox"/> Recommend Matrix Reduction																						
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Report Comments <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>																										
<input type="checkbox"/> Error(s) Found During Review																										

Edit Sample #300396-7A (D-38)

General PLM: ELAP 198.6 NOB TEM: Bulk Upgrade

Initial Sample Weight

Vial Weight: 7.0438

Vial + Sample Weight: 7.4686

Initial Sample Weight: 0.425

Post Ash Weight

Vial + Ashed Sample Weight: 7.4683

Ashed Sample Weight: 0.425

Post Acid Treatment

Filter Tare: 6.1458

Gross Filter Weight: 6.5599

Weight Residue: 0.414

Visual Estimations

Estimated Asbestos PLM: 0.0

Estimated Asbestos TEM: 0.0

Final Asbestos Percents

Percent Asbestos PLM: NAD

Percent Asbestos TEM: NAD

Final Non-Asbestos %

Percent Organics: 0.071

Percent Acid Soluble: 2.448

Percent Other: 97.481

Sample Type: Whole

Material Type: []

Sample Color: []

Grid Box: A19-216

Row and Slots: 10ab

Microscope #: 1

Working Mag. High (K): 15

Working Mag. Low (K): []

Accelerating Voltage (KV): 100

Sample was not analyzed

Structure Crystallographic and Photographic Data

Structure #	SAED	Elements	Neg. #	Camera Length / Mag.	Ident.
4	hex, talc fiber	O,Mg,Si			[]
3	hex, talc	O,Mg,Si			[]
2	hex, talc	O,Mg,Si			[]
1	hex, talc	O,Mg,Si			[]

Grid #1 Estimated Asbestos: 0.0 **Grid #2 Estimated Asbestos**: 0.0 **Estimated Asbestos %**: 0.0%

Analyst Comments

4/18/19 Mostly talc flakes with numerous talc fibers and some talc ribbons.

Report Comments

[]

Error(s) Found During Review

Edit Sample #300396-7B (D-38) i

General PLM: ELAP 198.6 NOB TEM: Bulk Upgrade

Initial Sample Weight Vial Weight: 7.1169 Vial + Sample Weight: 7.6366 Initial Sample Weight: 0.520	Post Ash Weight Vial + Ashed Sample Weight: 7.6364 Ashed Sample Weight: 0.519	Post Acid Treatment i Filter Tare: 6.138 Gross Filter Weight: 6.6443 Weight Residue: 0.506
Visual Estimations Estimated Asbestos PLM: 0.0	Final Asbestos Percents Percent Asbestos PLM: NAD	Final Non-Asbestos % Percent Organics: 0.038 Percent Acid Soluble: 2.54 Percent Other: 97.422

Material Type Powder	Color White	Homogeneity Homogeneous
Sample Type Whole	Texture Powdery	
<input type="checkbox"/> Sample was not analyzed <input type="checkbox"/> Fibrous <input checked="" type="checkbox"/> Scanning Negative Option <input type="checkbox"/> Stratified Point Count <input type="checkbox"/> 400 Point Count		
Macro Asbestos % Chrysotile Percent Amosite Percent Crocidolite Percent Other Asbestos Percent	Macro Non Asbestos % Mineral Wool Percent Fiberglass Organic Synthetic Other	Macro Non Fibrous % Particulate: 100.0 Other Non-Fibrous
Macroscopic Comments <div style="border: 1px solid #ccc; height: 30px; width: 100%;"></div>		

Temperature (°C) 25.0	Microscope # 2																									
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Morphology</th> <th>Color</th> <th>Elongation</th> <th>Ext. Ang</th> <th>DSC ⊥</th> <th>DSC </th> <th>Ref Index ⊥</th> <th>Ref Index </th> <th>Pleo</th> <th>Birefringence</th> <th>Refractive Index Oil</th> <th>Ident.</th> </tr> </thead> <tbody> <tr> <td colspan="12" style="text-align: right;">Add Row</td> </tr> </tbody> </table>			Morphology	Color	Elongation	Ext. Ang	DSC ⊥	DSC	Ref Index ⊥	Ref Index	Pleo	Birefringence	Refractive Index Oil	Ident.	Add Row											
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Report Comments <div style="border: 1px solid #ccc; height: 30px; width: 100%;"></div>																										
<input type="checkbox"/> Error(s) Found During Review																										

Edit Sample #300396-7B (D-38) i

General PLM: ELAP 198.6 NOB TEM: Bulk Upgrade

Initial Sample Weight

Vial Weight 7.1169

Vial + Sample Weight 7.6366

Initial Sample Weight 0.520

Post Ash Weight

Vial + Ashed Sample Weight 7.6364

Ashed Sample Weight 0.519

Post Acid Treatment i

Filter Tare 6.138

Gross Filter Weight 6.6443

Weight Residue 0.506

Visual Estimations

Estimated Asbestos PLM 0.0

Estimated Asbestos TEM 0.0

Final Asbestos Percents

Percent Asbestos PLM NAD

Percent Asbestos TEM NAD

Final Non-Asbestos %

Percent Organics 0.038

Percent Acid Soluble 2.54

Percent Other 97.422

Sample Type

Whole ▾

Material Type

Powder ▾

Sample Color

White ▾

Grid Box

A19-2

Row and Slots

1AB

Microscope

1

Working Mag. High (K)

15

Working Mag. Low (K)

Accelerating Voltage (KV)

100

 Sample was not analyzed

Structure Crystallographic and Photographic Data

Structure #	SAED	Elements	Neg. #	Camera Length / Mag.	Ident.	
3	hex	O, Mg, Si				▾ ×
2	neg	O, Si, Ti				▾ ×
1	HEX	O, Mg, Si, Fe				▾ ×

Grid #1 Estimated Asbestos

0.0

Grid #2 Estimated Asbestos

0.0

Estimated Asbestos %

0.0%

Analyst Comments

4/18/19, 1 hr

Report Comments

 Error(s) Found During Review

Edit TEM NOB Blank Result

Blank Number

Talc Blank 358

Analyst

(b) (6)(b) (6)

Date Analyzed

04-25-2019



Percent Asbestos

0.0

Asbestos Type

NAD

Comments

Associated with 300396

Save Changes

Edit NOB Reference Sample Result

Sample Number

Talc Ref

Analyst

(b) (6)

Reference Sample

Tile #

Talc Ref 10% ▼

Reference Value

10

Asbestos Type

Chrysotile

Lower Limit

5

Upper Limit

25

Vial Weight	<input type="text" value="0.0"/>	Post Acid Weight	<input type="text" value="1.0"/>	Asbestos Type	<input type="text" value="Chrysotile"/>
Vial and Sample Weight	<input type="text" value="1.0"/>	Filter Tare	<input type="text" value="0.0"/>	Estimated Asbestos	<input type="text" value="10.0"/>
Vial and Ashed Sample Weight	<input type="text" value="0.0"/>	Ashed Weight	<input type="text" value="0"/>	Percent Asbestos	<input type="text" value="10"/>
Initial Sample Weight	<input type="text" value="1"/>	Residue Weight	<input type="text" value="1"/>	Result	<input type="text" value="Pass"/>

Comments

Associated with COC 300396

Save Changes

From: [Dewan, Kapal](#)
To: [Katz, Linda](#); [Lewis, Kathleen](#); [Smegal, Deborah](#); [Wolfgang, Steven](#); [Sadrieh, Nakissa](#); [Roosevelt, Michael](#)
Cc: [Gasper, John](#)
Subject: Fwd: Johnson Baby Powder lot #22318RB
Date: Friday, October 18, 2019 8:55:22 PM

FYI— see below J&J's email. They will be coming in at 11:00 am.

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Date: October 18, 2019 at 8:14:48 PM EDT
To: Gasper, John <John.Gasper@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>, Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>
Subject: Re: Johnson Baby Powder lot #22318RB

Hello John,

Derek Smith and Jeff Jenner are planning to be at your facility at 11:00am. Should they go to:

Center for Food Safety and Applied Nutrition
5001 Campus Dr
College Park, MD 20740
(888) 723-3366

Please let me know if this is the correct location or if there is a special entry to meet you. They will have ID and sample collection tools/containers.

Thank you, Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: +(b) (6)(b) (6)

pedson@its.jnj.com
<http://www.jnj.com>

From: Paul Edson <PEDSON@its.jnj.com>
Date: Friday, October 18, 2019 at 6:14 PM
To: "Gasper, John" <John.Gasper@fda.hhs.gov>
Cc: "Dewan, Kapal" <Kapal.Dewan@fda.hhs.gov>, Venessa Piper-Givler <VPiperG@its.jnj.com>
Subject: Re: Johnson Baby Powder lot #22318RB

We plan to be onsite to pick up the sample late morning. I do not yet have the name of the individual. We will notify you of the individuals ASAP. Thank you!

Paul

On Oct 18, 2019, at 5:16 PM, Gasper, John <John.Gasper@fda.hhs.gov> wrote:

Mr. Edson,

Please bring your own container to use for sample collection. Thank you.

Regards,

John Gasper

CFSAN
Office of Cosmetics and Colors
U.S. Food and Drug Administration
Tel: 240-402-1133

john.gasper@fda.hhs.gov

[<image007.png>](#)

[<image008.jpg>](#)

[<image009.jpg>](#)

[<image010.jpg>](#)

[<image011.jpg>](#)

[<image012.jpg>](#)

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>

Sent: Friday, October 18, 2019 3:42 PM

To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal
<Kapal.Dewan@fda.hhs.gov>

Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>

Subject: Johnson Baby Powder lot #22318RB

Hello John and Kapal,

Pursuant to FDA's agreement to help facilitate materials for our investigation of Johnson's Baby Powder lot #22318RB, we request support for the following:

- 75grams of J&J Baby Powder from the original J&J Baby Powder bottle lot #22318RB
- Access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing (to determine authenticity)
- A Picture of the original container sampled, prior to opening
- Picture or evidence the original tamper seals were intact prior to sampling
- A sample from any remaining J&J Baby Powder from the blinded sample containers (D58 308006-6A; D58 308006-6B) tested by AMA
- AMA Labs Talc Testing SOP & Protocol
- AMA sample preparation methods for preparation of reference control standard using Sigma-Aldrich spike with 10% chrysolite
- Analysis and/or TEM photos of the Sigma-Aldrich spiked with 10% chrysolite
- Any asbestos environmental testing for the area used in FDA blinded sample preparation and at AMA laboratories testing labs
- FDA's Standard operating procedure for preparation of samples for Blind testing of Talc (D58 308006 series)
- Documentation for the chain of custody including any invoices for the purchase of the samples from the online retailer

As the investigation is of the utmost importance, we will be available to receive any of the above material, as soon as each of them are available and at the earliest convenience.

I look forward to hearing from you soon,

Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: **(b) (6)(b) (6)**

pedson@its.jnj.com
<http://www.jnj.com>

From: [Sadrieh, Nakissa](#)
To: [Katz, Linda](#); [Dewan, Kapal](#); [Wolfgang, Steven](#)
Cc: [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: D38 J&J sample report
Date: Thursday, October 10, 2019 4:52:52 PM

Yes, that must have been a typo. (b) (5)

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Sent: Thursday, October 10, 2019 4:49 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: D38 J&J sample report

Thanks – (b) (5)(b) (5)(b) (5)(b) (5)(b) (5)(b) (5)(b) (5) ?

From: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Sent: Thursday, October 10, 2019 4:48 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: D38 J&J sample report

(b) (5)(b) (5)(b) (5)(b) (5)

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)

Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Sent: Thursday, October 10, 2019 4:48 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: D38 J&J sample report

For clarification (b) (5)(b) (5)(b) (5)(b) (5) ? I have emails (b) (5)(b) (5)
(b) (5)(b) (5)

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Wednesday, September 25, 2019 2:31 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: RE: D38 J&J sample report

Baby powder.

From: Katz, Linda
Sent: Wednesday, September 25, 2019 1:23 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: D38 J&J sample report

Was it (b) (5)(b) (5)(b) (5)(b) (5) ?

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Wednesday, September 25, 2019 1:23 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: D38 J&J sample report

Yes, that was sent in the 4th batch.

From: Katz, Linda

Sent: Wednesday, September 25, 2019 1:22 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: D38 J&J sample report

Thanks. Have we sent another J&J sample for analysis to AMA in the last batch?

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Wednesday, September 25, 2019 1:19 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: D38 J&J sample report

Linda,

John has requested AMA for a separate report for D38 (J&J) sample. They have agreed to send a separate report. Just wanted to inform you.

Kapal Dewan
Team Lead, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
College Park, MD 20740

Phone: 240-402-2908
Fax: 301-436-2975

From: [Sadrieh, Nakissa](#)
To: [Wolfgang, Steven](#); [Katz, Linda](#)
Cc: [Lewis, Kathleen](#); [Dewan, Kapal](#); [Smegal, Deborah](#); [Gasper, John](#)
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample
Date: Friday, October 18, 2019 2:42:45 PM

Can (b) (4)

(b) (4)

(b) (4)

I am answering the latest inquiry from Gloria. Can I get this information asap? Thanks.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 2:37 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

Linda,

John and I spoke with Dana at AMA about 45 minutes ago and right this minute I think John is tied up collecting the sample from AMA and making sure we have all the documentation to go along with the change in possession. We have a plan and John and I will be communicating throughout the remainder of the day. Will give you an update later.

Steve

From: Katz, Linda
Sent: Friday, October 18, 2019 2:19 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Smegal, Deborah

<Deborah.Smegal@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>

Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

There was supposed (b) (5)

You also need to (b) (5)

This needs to be done today.

From: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>

Sent: Friday, October 18, 2019 2:10 PM

To: Gasper, John <John.Gasper@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>

Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

Hi John,

I thought we were good with this:

(b) (5)(b) (5)

Did I miss anything?

Kay Lewis

Senior Advisor

OCAC/CFSAN/FDA

240-402-1129 office

240-825-9944 bb

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From: Gasper, John <John.Gasper@fda.hhs.gov>

Sent: Friday, October 18, 2019 2:05 PM

From: [Sadrieh, Nakissa](#)
To: [Dewan, Kapal](#); [Gasper, John](#); [Katz, Linda](#); [Smegal, Deborah](#); [Lewis, Kathleen](#); [Wolfgang, Steven](#)
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample
Date: Friday, October 18, 2019 3:07:56 PM

Have we drafted (b) (6) ? It would be good if we could collect the sample today. maybe John is already getting the sample.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Friday, October 18, 2019 3:04 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

Hello,

Linda asked me to call Paul. I talked to him. He wanted to know where we are located and misunderstood that we are in Philadelphia. I told him that we are in Maryland. He will send his questions via email to John and Ruark as they relate to sample/ aliquot collection. J&J will come over for sample collection on Monday. Details of when, where, and what time will be indicated in the email that J&J will send us. NO rush for sample to aliquot for J&J today.

Steve,

Linda has asked that you come in early on Monday morning.

This is for now!
Kapal

From: Gasper, John
Sent: Friday, October 18, 2019 2:05 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>;

Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>

Subject: RE: J&J Has Contacted Me About Logistics of Providing Sample

To All:

Please note that a (b) (5) . (b) (5)
(b) (5) (b) (5) (b) (5)
(b) (5) We should discuss (b) (5) . Thank you.

Regards,
John G

From: [Dana Hudson Nicodemus](#)
To: [Gasper, John](#); [Wolfgang, Steven](#); [Dewan, Kapal](#)
Cc: [Andreas Saldivar](#)
Subject: 308006-6, 6A, 6B/D-58 Final Data Package - Revision 2
Date: Friday, October 11, 2019 1:45:27 PM
Attachments: [308006 FDA 6, 6A, 6B-D58 Final Data Package_Rev2.pdf](#)
[308006 FDA Worksheet Calculations Revised 10-10-2019.xlsx](#)

Attached, please find the 2nd revision for the above referenced report.

I've also attached an updated Worksheet Calculations spreadsheet.

Please let me know if you need anything else.

Also – My goal is to finish the final report package for the remaining samples in 308006 next week & for the samples in 310123 no later than 10/25/2019.

Thanks!!

Dana Nicodemus Hudson
Client Services Director



AMA Analytical Services, Inc.
Focused On Results.

4475 Forbes Boulevard
Lanham, MD 20706
(301) 459-2640 / (800) 346-0961
(410) 491-2738 Cell
dhudson@amalab.com
www.amalab.com

From: [Dana Hudson Nicodemus](#)
To: [Gasper, John](#)
Subject: Accepted: FDA Project - Telecon to Discuss the Results on 308006-6/D-58
Start: Monday, October 07, 2019 2:00:00 PM
End: Monday, October 07, 2019 3:00:00 PM
Location: Room 1044 and WebEx Call In

From: [Gasper, John](#)
To: [Dana Hudson Nicodemus](#); [Andreas Saldivar](#); [Wolfgang, Steven](#)
Subject: Discuss D-58 Report
Start: Wednesday, October 09, 2019 3:00:00 PM
End: Wednesday, October 09, 2019 4:00:00 PM
Location: WebEx Call In - FDA in Steve's Office

Dana, Andreas, and Steve,

This meeting is to go over some more questions we have on the D-58 report. A WebEx call in is provided below. Thank you.

Regards,

John G

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When it's time, join your Webex meeting here.

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Meeting password: **(b) (6)**

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S Toll Free

Global call-in numbers <<https://fda1.webex.com/fda1/globalcallin.php?MTID=m58f38bd9a09aeb0eac7e15275654a81e>> | Toll-free calling restrictions <https://e-meetings.verizonbusiness.com/global/pdf/Verizon_Audio_Conferencing_Global_Access_Information_August2017.pdf>

Need help? Go to <http://help.webex.com> <<http://help.webex.com>>

From: [Dana Hudson Nicodemus](#)
To: [Gasper, John](#); [Wolfgang, Steven](#); [Dewan, Kapal](#)
Cc: [Andreas Saldivar](#)
Subject: Final Data Package for 308006-6, 6A, 6B/D58 - Revision 1
Date: Tuesday, October 08, 2019 12:40:13 PM
Attachments: [308006 FDA 6, 6A, 6B-D58 Final Data Package Rev1.pdf](#)

Attached, please find the revised report package for the above referenced analysis.

It includes all of the changes that we discussed yesterday.

With regards to the missing the gravimetric data for 308006-16 & 308006-17, the data had been recorded, but our technician accidentally recorded it a photocopy of the of the bench sheet instead of on the original bench sheet. He makes a photocopy of bench sheets whenever he's preparing a large set of samples where analysis is being performed before all samples are prepared as back-up.

Dana Nicodemus Hudson

Client Services Director



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(410) 491-2738 Cell
dhudson@amalab.com
www.amalab.com

From: [Dana Hudson Nicodemus](#)
To: [Gasper, John](#); [Wolfgang, Steven](#); [Dewan, Kapal](#)
Cc: [Andreas Saldivar](#)
Subject: Final Data Package for 308006-6, 6A, 6B/D-58
Date: Thursday, October 03, 2019 5:13:57 PM
Attachments: [308006 FDA 6, 6A, 6B-D58 Final Data Package.pdf](#)

The final data package for the above referenced sample analysis is attached for your review.

Please do not hesitate to contact us with any questions or concerns that you may have.

Thank you,

Dana Nicodemus Hudson
Client Services Director



AMA Analytical Services, Inc.
Focused On Results.

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(301) 459-2640 / (800) 346-0961
(410) 491-2738 Cell
dhudson@amalab.com
www.amalab.com

From: [Gasper, John](#)
To: [Dana Hudson Nicodemus](#); [Wolfgang, Steven](#)
Subject: How D-58 was Handled at AMA, Transfer of D-58 Back to FDA
Start: Friday, October 18, 2019 1:15:00 PM
End: Friday, October 18, 2019 1:45:00 PM
Location: WebEx Call In

Dana and Steve,

This call is to go over a document we want from AMA that details how D-58 was handled from initial receipt, through testing, preparing the 4th aliquot, and release back to FDA. We envision just a paragraph or two that explains it. Also, we will talk about me going to AMA later today to obtain this sample.

A WebEx call in is provided below. Thank you.

Regards,

John G

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(b) (6) JS Toll
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Need help? Go to <http://help.webex.com> <<http://help.webex.com>>

From: [Gasper, John](#)
To: [Dana Hudson Nicodemus](#); [Andreas Saldivar](#)
Cc: [Wolfgang, Steven](#)
Subject: RE: FDA - Additional Information Requested
Date: Friday, October 18, 2019 7:03:00 PM

Hi Dana and Andreas,

If you would, please provide us with the following information for sharing with the party disputing D-58:

- With regard to the (b) (5) [redacted] (b) (5) [redacted]
[redacted]
 - [redacted]
 - [redacted]
 - [redacted]
- [redacted]
 - [redacted]
 - [redacted]
 - [redacted]
 - [redacted]
 - [redacted]

We would appreciate this as soon as possible. Please let us know if you have any questions.
Thank you.

Regards,
John

From: [Gasper, John](#)
To: [Dana Hudson Nicodemus](#); [Andreas Saldivar](#)
Cc: [Wolfgang, Steven](#); [Dewan, Kapal](#)
Subject: RE: FDA Project - Do Not Do Another Aliquot Test of D-58 (6C)
Date: Tuesday, October 01, 2019 10:26:00 AM
Importance: High

Dana and Andreas,

(b) (5)

Please let me know if you have any questions. Thank you.

Regards,
John

(

From: [Gasper, John](#)
To: [Dana Hudson Nicodemus](#); [Andreas Saldivar](#)
Cc: [Wolfgang, Steven](#); [Dewan, Kapal](#)
Subject: RE: FDA Project - Report for Sample D-58 (AMA ID 308006-6)
Date: Wednesday, October 02, 2019 9:15:00 AM

Hello Dana and Andreas,

We'd like to request the report for sample D-58 (AMA ID 308006-6) as soon as possible and ideally today. Please let me know when you think you can get that to us. Please let me know if you have any questions. Thank you.

Regards,
John

From: [Lewis, Kathleen](#)
To: [Lewis, Kathleen](#)
Subject: 2019-10237 FOIA Request
Date: Friday, November 01, 2019 3:12:50 PM
Attachments: [2019_11_01_15_11_39.pdf](#)

From: [Kuntz, Thomas](#)
To: [Katz, Linda](#); [Dewan, Kapal](#); [Sadrieh, Nakissa](#); [Wolfgang, Steven](#); [Jabs, Alexandra](#); [Jasperse, Carie](#); [Roosevelt, Michael](#); [Dooren, Jennifer](#); [Lanham, Ruark](#); [Pack, Randy](#); [Darlington, Leonora](#); [Barringer, Amy](#)
Cc: [Correll, William A](#); [Mayne, Susan](#); [Musser, Steven M](#); [Stearn, Douglas](#); [Beckerman, Peter](#); [Stone, Dyana](#); [Lewis, Kathleen](#); [Gasper, John](#); [Ingram, Shannon](#); [ORA Recall OE](#)
Subject: FW: Follow up from today's 29 October call
Date: Tuesday, October 29, 2019 4:15:37 PM
Attachments: (b) (4)(b) (4)

Documents from J&J as promised during today's call.

From: Szczepaniak, Lynne [CPCUS] [mailto:lszczepa@ITS.JNJ.com]
Sent: Tuesday, October 29, 2019 3:02 PM
To: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>
Cc: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>; Zuyev, Natasha [CPCUS] <nzuyev@ITS.JNJ.com>; Williams, Bobette [MCCUS] <BWilli10@its.jnj.com>; Scott, Elizabeth G. [MCCUS] <EGiulian@its.jnj.com>
Subject: FW: Follow up from today's 29 October call

Mr. Kuntz

We want to thank you again for scheduling the meeting to discuss results from our investigation of Johnson's Baby Powder recalled Lot #22318RB. As we discussed on the call, attached please find the following reports:

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(b) (4)

We would like to discuss these reports and findings, along with details of our full investigation. As we discussed, our investigation is on-going and we are in the process of doing additional testing. We will update you once we have additional results.

We also confirm, as we noted on today's call, that the samples tested by FDA were authentic. On the call, you asked about any discrepancies we noted in the sampling conducted by AMA based upon the AMA report. We will provide you with a detailed description of those discrepancies and information about the methods that you requested.

I have copied only you on this message per Dr Mayne's request to work with a single point of contact, however please forward this message to others who were on the call and anyone else who needs this information.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: **(b) (6)**
e-mail: lszczepa@its.jnj.com



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From: [Dewan, Kapal](#)
To: [Katz, Linda](#); [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Wolfgang, Steven](#); [Smegal, Deborah](#); [Roosevelt, Michael](#); [Scarborough, Kim](#)
Cc: [Gasper, John](#)
Subject: FW: Johnson Baby Powder lot #22318RB
Date: Friday, October 18, 2019 6:57:27 PM

FYI—As per email below, J&J plans to be onsite on Monday late morning.

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Friday, October 18, 2019 6:15 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>
Subject: Re: Johnson Baby Powder lot #22318RB

We plan to be onsite to pick up the sample late morning. I do not yet have the name of the individual. We will notify you of the individuals ASAP. Thank you!

Paul

On Oct 18, 2019, at 5:16 PM, Gasper, John <John.Gasper@fda.hhs.gov> wrote:

Mr. Edson,

Please bring your own container to use for sample collection. Thank you.

Regards,

John Gasper

CFSAN
Office of Cosmetics and Colors
U.S. Food and Drug Administration
Tel: 240-402-1133

john.gasper@fda.hhs.gov

[<image007.png>](#)

[<image008.jpg>](#)

[<image009.jpg>](#)

[<image010.jpg>](#)

[<image011.jpg>](#)

[<image012.jpg>](#)

From: [Gasper, John](#)
To: [Dana Hudson Nicodemus](#); [Andreas Saldivar](#)
Cc: [Wolfgang, Steven](#); [Dewan, Kapal](#)
Subject: RE: FDA Project - Telecon to Discuss the Results on 308006-6/D-58 - Monday 10/7
Date: Friday, October 04, 2019 2:24:00 PM

Dana and Andreas,

Would you have time for a 1 hour telecon, between noon and 2 pm on Monday, 10/7, to discuss the results on 308006-6/D-58? Please let me know and I can schedule a meeting. Thank you.

Regards,
John

From: [Dana Hudson Nicodemus](#)
To: [Gasper, John](#); [Andreas Saldivar](#)
Cc: [Wolfgang, Steven](#); [Dewan, Kapal](#)
Subject: RE: FDA Project - Telecon to Discuss the Results on 308006-6/D-58 - Monday 10/7
Date: Friday, October 04, 2019 3:07:23 PM

John,

Andreas has some off-site meetings Monday morning and won't be in the office until about 1:45PM. He can do a meeting from 2-3PM on Monday 10/7/2019. Will that work for you?

Thank you,

Dana Nicodemus Hudson

Client Services Director



AMA Analytical Services, Inc.
Focused On Results.

4475 Forbes Boulevard
Lanham, MD 20706
(301) 459-2640 / (800) 346-0961
(410) 491-2738 Cell
dhudson@amalab.com
www.amalab.com

From: Gasper, John <John.Gasper@fda.hhs.gov>
Sent: Friday, October 4, 2019 2:24 PM
To: Dana Hudson Nicodemus <dhudson@amalab.com>; Andreas Saldivar <andreas@amalab.com>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: FDA Project - Telecon to Discuss the Results on 308006-6/D-58 - Monday 10/7

Dana and Andreas,

Would you have time for a 1 hour telecon, between noon and 2 pm on Monday, 10/7, to discuss the results on 308006-6/D-58? Please let me know and I can schedule a meeting. Thank you.

Regards,
John

From: [Gasper, John](#)
To: [Edson, Paul \[JJCUS\]](#); [Dewan, Kapal](#)
Cc: [Piper-Givler, Venessa \[MCCUS\]](#)
Subject: RE: Johnson Baby Powder lot #22318RB
Date: Friday, October 18, 2019 5:16:00 PM
Attachments: [image007.png](#)

Mr. Edson,

Please bring your own container to use for sample collection. Thank you.

Regards,

John Gasper

CFSAN
Office of Cosmetics and Colors
U.S. Food and Drug Administration
Tel: 240-402-1133

john.gasper@fda.hhs.gov



From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Friday, October 18, 2019 3:42 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>
Subject: Johnson Baby Powder lot #22318RB

Hello John and Kapal,

Pursuant to FDA's agreement to help facilitate materials for our investigation of Johnson's Baby Powder lot #22318RB, we request support for the following:

- 75grams of J&J Baby Powder from the original J&J Baby Powder bottle lot #22318RB
- Access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing (to determine authenticity)
- A Picture of the original container sampled, prior to opening

Picture or evidence the original tamper seals were intact prior to sampling

- A sample from any remaining J&J Baby Powder from the blinded sample containers (D58 308006-6A; D58 308006-6B) tested by AMA
- AMA Labs Talc Testing SOP & Protocol
- AMA sample preparation methods for preparation of reference control standard using Sigma-Aldrich spike with 10% chrysolite
- Analysis and/or TEM photos of the Sigma-Aldrich spiked with 10% chrysolite
- Any asbestos environmental testing for the area used in FDA blinded sample preparation and at AMA laboratories testing labs
- FDA's Standard operating procedure for preparation of samples for Blind testing of Talc (D58 308006 series)
- Documentation for the chain of custody including any invoices for the purchase of the samples from the online retailer

As the investigation is of the utmost importance, we will be available to receive any of the above material, as soon as each of them are available and at the earliest convenience.

I look forward to hearing from you soon,

Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: (b) (6)

pedson@its.inj.com
<http://www.inj.com>

From: [Edson, Paul \[JJCUS\]](#)
To: [Gasper, John](#)
Cc: [Dewan, Kapal](#); [Piper-Givler, Venessa \[MCCUS\]](#)
Subject: Re: Johnson Baby Powder lot #22318RB
Date: Friday, October 18, 2019 8:27:28 PM

John, for clarity, what sample material is being made available. Powder from the original container or powder from the blinded samples? Or both? Thanks for the clarification.

Best regards, Paul

> On Oct 18, 2019, at 8:14 PM, Edson, Paul [JJCUS] <PEDSON@its.jnj.com> wrote:

>

From: [Haake, Lindsay](#)
To: [Mayne, Susan](#); [Stearn, Douglas](#); [Musser, Steven M](#); [Kux, Leslie](#); [Katz, Linda](#); [Correll, William A](#); [Roosevelt, Michael](#)
Cc: [Dooren, Jennifer](#); [Naum, Marianna](#); [CFSAN-OCD-CPES-MGRS](#)
Subject: Asbestos in Cosmetics links are LIVE!
Date: Friday, October 18, 2019 1:45:20 PM
Attachments: [image001.png](#)

<https://www.fda.gov/food/cfsan-constituent-updates/baby-powder-manufacturer-voluntarily-recalls-product-asbestos>

<https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-advises-consumers-stop-using-certain-cosmetic-products>

(b) (5)




Thanks,

Lindsay Haake

Health Communication Specialist

Communications and Public Engagement Staff

Center for Food Safety and Applied Nutrition

U.S. Food and Drug Administration

5001 Campus Drive, College Park, MD 20740

Phone: 301-796-3007

Cell: 202-309-7277

Follow us on Twitter @FDAfood; @FDACosmetics; and @FDAanimalhealth



From: [Dewan, Kapal](#)
To: [Katz, Linda](#)
Cc: [Sadrieh, Nakissa](#)
Subject: D38 J&J sample report
Date: Wednesday, September 25, 2019 1:18:48 PM

Linda,

John has requested AMA for a separate report for D38 (J&J) sample. They have agreed to send a separate report. Just wanted to inform you.

Kapal Dewan
Team Lead, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
College Park, MD 20740

Phone: 240-402-2908

Fax: 301-436-2975

Gloria Sánchez-Contreras

International Press Officer

Spanish-Language Communications Lead

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 301-796-7686 / Cell: 301-500-8888

gloria.sanchez-contreras@fda.hhs.gov



From: [Katz, Linda](#)
To: [Chopko, Jane](#); [Flamm, Eric](#); [Colonius, Tristan](#); [Hodnette, Jonathan](#)
Cc: [Glasner, Aliza](#)
Subject: follow-up on inspection question
Date: Wednesday, February 13, 2019 3:48:17 PM
Attachments: [e90189.doc](#)

From a quick search, two records were found in eNspect. J&J Consumer Products inspection was conducted in 2002 and 2005 that included both medicated and non-medicated baby powders containing **talc**. The investigations have been closed. For your reference a copy of the EIR from 2005 inspection is attached. From the 2002 inspection, no documents are available. Only inspection endorsement text is available. I have requested additional information about whether or not any of the products were actually evaluated for asbestos.

Inspected FEI: 1046432
Firm Name: Johnson & Johnson Consumer Prd
Address: Royston GA 30662-4321 US

Additionally, at least one sample of J&J Baby Powder was analyzed as part of the 2009-2010 FDA survey, which did not have any asbestos.

If I get any additional information, I will pass it along.

Linda

From: [Wolfgang, Steven](#)
To: [Katz, Linda](#)
Cc: [Sadrieh, Nakissa](#)
Subject: further discussions on FDA's analytical methods
Date: Friday, October 18, 2019 8:38:34 AM
Attachments: [RE Agenda for meeting J and J Conference Call.doc.msg](#)

Linda,

Not sure if you have awareness of the email that is attached. It refers to (b) (5) to (b) (5)(b) (5)(b) (5)(b) (5)(b) (5)(b) (5)(b) (5)(b) (5)

I assume th (b) (5)(b) (5)(b) (5)(b) (5)(b) (5)(b) (5)(b) (5)(b) (5)(b) (5) (b) (5) here are about 5 grams of the product remaining in the possession of AMA (same vial) based on my calculations (amount sent – amount used to prepare PLM and TEM aliquots). We also have the bottle that was opened and tested in the locked cabinet as well as 2 bottles of product from same batch/lot that are unopened.

Steve

*Steven Wolfgang, Ph.D.
Consumer Safety Officer
Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
College Park, MD
301-796-3264
240-328-9827*

From: [Sadrieh, Nakissa](#)
To: [Katz, Linda](#)
Subject: FW: AMA Results
Date: Tuesday, October 15, 2019 12:02:52 PM
Attachments: [308006 FDA_6, 6A, 6B-D58 Final Data Package_Rev2.pdf](#)

Here is the final report that the COR has obtained from the AMA. This is what Steve is reviewing to make sure that it's fine and meets the requests made for revisions. This is what will have to get redacted, once Steve says it's OK. I am not sure if we are to share this with others until we hear from Steve.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Gasper, John <John.Gasper@fda.hhs.gov>
Sent: Tuesday, October 15, 2019 11:59 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: AMA Results

Nakissa, please see attached. John G

From: Sadrieh, Nakissa
Sent: Tuesday, October 15, 2019 11:40 AM
To: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: FW: AMA Results

John,

Please send me the draft AMA report. Linda needs it now. Thanks.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive

Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Sent: Tuesday, October 15, 2019 11:34 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: AMA Results

Please send me a copy of the draft memo and the AMA report now. When will Steve have the final memo?

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Tuesday, October 15, 2019 11:30 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: AMA Results

Linda,

We have received the report from AMA on 10/11. Steve is working on the memo.

Kapal

From: Katz, Linda
Sent: Tuesday, October 15, 2019 11:21 AM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: AMA Results

Also, please send me a draft memo and copy of the preliminary AMA report ASAP.

From: Katz, Linda
Sent: Tuesday, October 15, 2019 11:17 AM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Subject: AMA Results

Have we received the final report from AMA so that we can finalize our memo? If not, when are we expected to received it and how long will it take for us to finalize the memo?

Also, has anyone (b) (5) ?

Linda

From: [Scarborough, Kim](#)
To: [Haake, Lindsay](#); [Naum, Marianna](#)
Cc: [Katz, Linda](#); [Sadrieh, Nakissa](#); [Dewan, Kapal](#); [Matos, Carmen](#); [Smegal, Deborah](#)
Subject: FW: Asbestos in Cosmetics links are LIVE!
Date: Friday, October 18, 2019 2:51:17 PM
Attachments: [image001.png](#)

Hello Lindsay and Marianna,

(b) (5)

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

I can put in the web ticket for the verbiage on the talc page to be updated with today's date. However, (b) (5) [Redacted], I thought it would be helpful if we coordinated the submission of the web tickets so that the Web Team doesn't get confused, and can hopefully make all necessary updates in unison.

Let me know how you want to proceed.

Thanks,
Kim

From: Katz, Linda
Sent: Friday, October 18, 2019 1:47 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Subject: FW: Asbestos in Cosmetics links are LIVE!

FYI

From: Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>
Sent: Friday, October 18, 2019 1:45 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>; Katz, Linda

<Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>; Roosevelt, Michael <Michael.Roosevelt@fda.hhs.gov>

Cc: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Naum, Marianna <Marianna.Naum@fda.hhs.gov>; CFSAN-OCD-CPES-MGRS <CFSAN-OCD-CPES-MGRS@fda.hhs.gov>

Subject: Asbestos in Cosmetics links are LIVE!

<https://www.fda.gov/food/cfsan-constituent-updates/baby-powder-manufacturer-voluntarily-recalls-product-asbestos>

<https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-advises-consumers-stop-using-certain-cosmetic-products>

(b) (5)

Thanks,

Lindsay Haake

Health Communication Specialist

**Communications and Public Engagement Staff
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration**

5001 Campus Drive, College Park, MD 20740

Phone: 301-796-3007

Cell: 202-309-7277

Follow us on Twitter @FDAfood; @FDACosmetics; and @FDAanimalhealth



From: [Sadrieh, Nakissa](#)
To: [Tsai, Victoria](#); [Gasper, John](#); [Wolfgang, Steven](#); [Dewan, Kapal](#)
Subject: FW: Products purchase from the store
Date: Monday, November 04, 2019 5:13:35 PM

Please see below too. **(b) (5)**

[Redacted]

[Redacted]

[Redacted]

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Sadrieh, Nakissa
Sent: Tuesday, June 11, 2019 4:10 PM
To: Moghaddam, Sarvin <Sarvin.Moghaddam@fda.hhs.gov>
Subject: FW: Products purchase from the store

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Dewan, Kapal
Sent: Tuesday, June 11, 2019 2:26 PM
To: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lowther, Donnie K <Donnie.Lowther@fda.hhs.gov>

Subject: RE: Products purchase from the store

Thank you Kay. John and Steve will (b) (5) (b) (5) .

Kapal

From: Lewis, Kathleen
Sent: Tuesday, June 11, 2019 2:02 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lowther, Donnie K <Donnie.Lowther@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Subject: RE: Products purchase from the store

Hi Everyone,

Here's what OC says (b) (5) :

(b) (5)

(b) (5)

So, if (b) (5) we should (b) (5) (b) (5)

Kay Lewis
Senior Advisor
OCAC/CFSAN/FDA
240-402-1129 office
240-825-9944 bb

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From: Dewan, Kapal
Sent: Tuesday, June 11, 2019 1:56 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lowther, Donnie K <Donnie.Lowther@fda.hhs.gov>
Subject: FW: Products purchase from the store

John, Steve,

Please see below Kay's email. Just wanted to keep you posted.

If (b) (5)

(b) (5)

Thank you,
Kapal

From: Lewis, Kathleen
Sent: Tuesday, June 11, 2019 10:20 AM
To: Lowther, Donnie K <Donnie.Lowther@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: Products purchase from the store

Good Morning,

(b) (5)

(b) (5)

I have an

email but haven't read it yet. I'll get back to you all shortly.

Kay Lewis
Senior Advisor
OCAC/CFSAN/FDA
240-402-1129 office
240-825-9944 bb

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From: Lowther, Donnie K
Sent: Tuesday, June 11, 2019 9:58 AM
To: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: FW: Products purchase from the store
Importance: High

From: Sadrieh, Nakissa
Sent: Monday, June 10, 2019 4:51 PM
To: Lowther, Donnie K <Donnie.Lowther@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Subject: RE: Products purchase from the store

(b) (5)

Thanks.

Regards,

Nakissa

From: Lowther, Donnie K
Sent: Monday, June 10, 2019 4:43 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Subject: RE: Products purchase from the store
Importance: High

Hi Kapal,

Yes, I can. **(b) (5)**

Donnie

From: Dewan, Kapal

Sent: Monday, June 10, 2019 4:38 PM

To: Lowther, Donnie K <Donnie.Lowther@fda.hhs.gov>

Cc: Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>

Subject: Products purchase from the store

Donnie,

Can you (b) (5)

?

(b) (5)

Kapal Dewan
Team Lead, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
College Park, MD 20740

Phone: 240-402-2908

Fax: 301-436-2975

From: [Sadrieh, Nakissa](#)
To: [Gasper, John](#); [Wolfgang, Steven](#); [Dewan, Kapal](#); [Tsai, Victoria](#)
Subject: RE: J&J
Date: Monday, November 04, 2019 4:57:45 PM

I have notes in my notebook from a 1:1 (b) (5) (b) (5)
(b) (5)

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Sent: Monday, November 4, 2019 4:52 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Tsai, Victoria <Victoria.Tsai@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: FW: J&J

I just found what Steve asked me to look for. It took a while, but I found it. It's for a FOIA request. Please see below.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Sadrieh, Nakissa
Sent: Wednesday, June 26, 2019 1:58 PM
To: Dewan, Kapal (Kapal.Dewan@fda.hhs.gov) <Kapal.dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>

Subject: J&J

Linda has asked **(b) (5)**

Thanks.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: [Musser, Steven M](#)
To: [Katz, Linda](#)
Subject: FW: Follow-up communications
Date: Friday, September 20, 2019 8:55:29 AM
Attachments: [image001.png](#)

See email contact info below.

On 9/16/19, 9:25 AM, "Bradshaw, Sheldon" <SBradshaw@KSLAW.com> wrote:

Dr. Musser,

Welcome back from vacation. I just wanted to follow up **(b) (5)**

(b) (5)

As you can imagine **(b) (5)**

Take care,

Sheldon

Sent from my iPhone

On Aug 15, 2019, at 3:05 PM, Musser, Steven M
<Steven.Musser@fda.hhs.gov<<mailto:Steven.Musser@fda.hhs.gov>>> wrote:

Thanks Lisa – we'll address any correspondence to Lynne.

From: "Dwyer, Lisa" <LDwyer@KSLAW.com<<mailto:LDwyer@KSLAW.com>>>
Date: Thursday, August 15, 2019 at 1:17 PM
To: "Musser, Steven M" <Steven.Musser@fda.hhs.gov<<mailto:Steven.Musser@fda.hhs.gov>>>
Cc: "Bradshaw, Sheldon" <SBradshaw@KSLAW.com<<mailto:SBradshaw@KSLAW.com>>>
Subject: Follow-up communications

Dr. Musser – as a follow-up, we wanted to mention that any communication related to J&J should be sent to Lynne Szczepaniak, Vice President and Head of Global Regulatory Affairs, at lszczepa@ITS.JNJ.com<<mailto:lszczepa@ITS.JNJ.com>>.

Best,

Lisa

.

—
Lisa M. Dwyer
Partner

T: +1 202 626 2393 | E: ldwyer@kslaw.com<<mailto:ldwyer@kslaw.com>> |
www.kslaw.com<<http://www.kslaw.com>>

BIO<<https://www.kslaw.com/people/lisa-dwyer>> | vCARD<<https://www.kslaw.com/people/lisa-dwyer.vcf>>

King & Spalding LLP
1700 Pennsylvania Avenue, NW
Suite 200
Washington, D.C. 20006

<image001.png><<https://www.kslaw.com/>>

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From: [Katz, Linda](#)
To: [Dooren, Jennifer](#); [Naum, Marianna](#)
Subject: FW: Photos of D-58 positive asbestos sample
Date: Tuesday, October 15, 2019 3:00:00 PM
Attachments: [IMG_4080.JPG](#)
[IMG_4081.JPG](#)
[IMG_4082.JPG](#)

Attached are the photos of the + sample.

From: [Smegal, Deborah](#)
To: [Musser, Steven M](#); [Mayne, Susan](#)
Cc: [Katz, Linda](#)
Subject: FW: Photos of D-58 positive asbestos sample
Date: Friday, October 18, 2019 10:09:46 AM
Attachments: [IMG_4080.JPG](#)
[IMG_4081.JPG](#)
[IMG_4082.JPG](#)
[image001.png](#)

Hi,

As requested, attached are the photos of the product. I confirmed the product was (b) (5) ^{b) (5)}
(b) (5) .

Regards

debbie

Deborah Smegal, MPH

Associate Director, Office of Cosmetics and Colors (OCAC)

**Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration**

Tel: 240-402-1818

Deborah.smegal@fda.hhs.gov



From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Tuesday, October 15, 2019 2:57 PM
To: Naum, Marianna <Marianna.Naum@fda.hhs.gov>
Cc: Katz, Linda <Linda.Katz@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Photos of D-58 positive asbestos sample

Marianna,

FYI- We have a positive sample (cosmetics contaminated with asbestos). I am forwarding you the photos of the product. Let me know (b) (5) . I have cc'ed Kim who can assist.

Thanks,
Kapal

From: [Sadrieh, Nakissa](#)
To: [Katz, Linda](#)
Subject: FW: recall of baby powder
Date: Friday, October 18, 2019 12:30:16 PM

For your records.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Field, John (HC/SC) <john.field@canada.ca>
Sent: Friday, October 18, 2019 12:28 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: Re: recall of baby powder

Thanks for the heads up, Nakissa. Very much appreciated.

John

Sent from my Bell Samsung device over Canada's largest network.

----- Original message -----

From: "Sadrieh, Nakissa" <Nakissa.Sadrieh@fda.hhs.gov>
Date: 2019-10-18 12:16 PM (GMT-05:00)
To: "Field, John (HC/SC)" <john.field@canada.ca>
Cc: "Sadrieh, Nakissa" <Nakissa.Sadrieh@fda.hhs.gov>
Subject: recall of baby powder

Hello John,

I just left you a voice message because I wanted to let you know about the recall of a J&J baby powder because of chrysotile asbestos found upon FDA testing. The link to the J&J press release is below. We are **(b) (5)**

hope that all is well with you.

<https://www.jnj.com/johnson-johnson-consumer-inc-to-voluntarily-recall-a-single-lot-of-johnsons-baby-powder-in-the-united-states>

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: [Dewan, Kapal](#)
To: [Spence, Susan](#)
Cc: [Katz, Linda](#); [Sadrieh, Nakissa](#)
Subject: FW: Talc - letter due by 8/29 to Linda
Date: Wednesday, August 14, 2019 8:07:49 AM

Susan,

See below the request **(b) (5)**

This letter is due to **Linda by August 29th.**

Regarding the product - J&J Johnson's Baby Powder, lot# 00918RA (FDA Sample ID D-38) was tested as part of the 2nd batch. Test results were "ND", which is not detected, by both TEM and PLM. You can ask John Gasper for the report to refer.

I know you are very busy with multiple media inquiries, and **(b) (5)** August. Thank you for multitasking all the time to meet the demand of work.

Thank you,
Kapal

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Date: August 13, 2019 at 4:44:19 PM EDT
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: Talc

I would prefer **(b) (5)**

From: Dewan, Kapal
Sent: Tuesday, August 13, 2019 4:34 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: Talc

Okay. I am short staffed this month. In September, I will assign this to Susan **(b) (5)** **(b) (5)**. Is this time frame okay?

From: Katz, Linda
Sent: Tuesday, August 13, 2019 3:59 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>

Subject: RE: Talc

We do not. The request was sent to Steve Musser who is discussing (b) (5)

Linda

From: Dewan, Kapal

Sent: Tuesday, August 13, 2019 3:23 PM

To: Katz, Linda <Linda.Katz@fda.hhs.gov>

Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>

Subject: RE: Talc

Linda,

Do we have a FOIA request in and a number to reference in the letter? I have not seen one or any documentation related to this inquiry.

Kapal

From: Katz, Linda

Sent: Tuesday, August 13, 2019 2:24 PM

To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>

Subject: Talc

Kapal,

Please have someone draft a (b) (5)

If you have any questions, let me know.

Linda

From: [Sadrieh, Nakissa](#)
To: [Dewan, Kapal](#); [Wolfgang, Steven](#); [Scarborough, Kim](#); [Gasper, John](#)
Cc: [Lewis, Kathleen](#); [Smegal, Deborah](#); [Katz, Linda](#); [Sadrieh, Nakissa](#)
Subject: JJ Testing Questions DRAFT 10-18-19
Date: Friday, October 18, 2019 3:03:37 PM
Attachments: [JJ Testing Questions DRAFT 10-18-19.docx](#)

I was working on the attached and I need help with the comments in purple. This is from Gloria's last request for input.

From: [Wolfgang, Steven](#)
To: ["crane.dan@dol.gov" \(crane.dan@dol.gov\)](mailto:crane.dan@dol.gov)
Subject: Confidential: For 2nd opinion
Date: Monday, October 07, 2019 4:43:00 PM
Attachments: [Dan Crane 2nd opinion.docx](#)

Hi Dan,

Attached is TEM/EDXA/SAED from a recent analysis. Do you (b) (5)
(b) (5) ? (b) (5), so assume it (b) (5)
(b) (5).

Thanks,
Steve
Steven Wolfgang, Ph.D.
Consumer Safety Officer
Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
College Park, MD
301-796-3264
240-328-9827

From: [Dewan, Kapal](#)
To: [Gasper, John](#); [Wolfgang, Steven](#)
Cc: [Scarborough, Kim](#)
Subject: FW: Talc and talc issues - J&J letter due date to Linda by August 26th
Date: Thursday, September 19, 2019 9:11:20 AM
Attachments: [DRAFT letter to JJ talc on testing-SM pcb.doc \(005\).doc](#)
[Template for talc letters.doc](#)

Steve, John,

Please send me (b) (5) ? Based on the email from (b) (5) See highlighted.

Kapal

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Sent: Thursday, September 19, 2019 8:17 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: Talc and talc issues - J&J letter due date to Linda by August 26th

I decided to draft the (b) (5)

When I get back comments, I will forward them on to you and Kapal so (b) (5)

(b) (5)

Linda

From: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Sent: Wednesday, September 18, 2019 8:49 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: Re: Talc and talc issues - J&J letter due date to Linda by August 26th

I told Kapal that I will wait for you to send the revised letter tomorrow morning. Then we will draft the other letters.

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Date: September 18, 2019 at 7:42:11 PM EDT
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: Re: Talc and talc issues - J&J letter due date to Linda by August 26th

Don't have anyone do anything with it until I send the revised version.

From: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Date: September 18, 2019 at 7:16:36 PM EDT
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: Fwd: Talc and talc issues - J&J letter due date to Linda by August 26th

We will (b) (5)) (b) (5)

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Date: August 20, 2019 at 4:39:55 PM EDT
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Cc: Spence, Susan <Susan.Spence@fda.hhs.gov>
Subject: RE: Talc and talc issues - J&J letter due date to Linda by August 26th

Clean copy.

From: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Sent: Tuesday, August 20, 2019 12:21 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Spence, Susan <Susan.Spence@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: Talc and talc issues - J&J letter due date to Linda by August 26th

My edits and comment.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Dewan, Kapal
Sent: Tuesday, August 20, 2019 11:47 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Cc: Spence, Susan <Susan.Spence@fda.hhs.gov>
Subject: RE: Talc and talc issues - J&J letter due date to Linda by August 26th

Susan,

Looks fine had one comment. I have included Nakissa so she can check. Thanks.

Nakissa,

I had one comment rest is fine with me.

Thanks,
Kapal

From: Spence, Susan
Sent: Tuesday, August 20, 2019 11:38 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: Talc and talc issues - J&J letter due date to Linda by August 26th

Dear Kapal (and Nakissa),

I've attached a draft letter. I look forward to your edits.

Best wishes,

Susan

From: Sadrieh, Nakissa
Sent: Tuesday, August 20, 2019 9:34 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Spence, Susan <Susan.Spence@fda.hhs.gov>
Cc: Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: Re: Talc and talc issues - J&J letter due date to Linda by August 26th

I can help Susan if she needs my help. Both Susan and Steve have been assigned a lot of work on the (b) (5) while Debbie is (b) (6), and they were both working on that until late last night.

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: August 20, 2019 at 8:35:20 AM EDT
To: Spence, Susan <Susan.Spence@fda.hhs.gov>

Cc: Katz, Linda <Linda.Katz@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>

Subject: FW: Talc and talc issues - J&J letter due date to Linda by August 26th

Importance: High

Susan,

Please see below the request to draft (b) (5)
[Redacted]
[Redacted]. Let me know if you have any questions.

Thank you,
Kapal

From: Katz, Linda
Sent: Tuesday, August 20, 2019 8:28 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: Talc and talc issues

Kapal,

(b) (5) (b) (5). Given that, please make sure I have a draft on August 26. Again, this (b) (5)
[Redacted]

Linda

(b) (5)

Kapal

From: Katz, Linda
Sent: Friday, October 25, 2019 8:25 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Re: Copy of FDA Letter

Contact Doug Ticker and cc: Laura Pillsbury for clarification of some of the details needed in our response

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 25, 2019 at 8:11:17 AM EDT
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Steve,

See the attached letter. We can discuss once you review it.

Kapal

From: Katz, Linda
Sent: Thursday, October 24, 2019 6:53 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Please assign this. We will need (b) (5)(b) (5)(b) (5)(b) (5)(b) (5)(b) (5) .

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Date: October 24, 2019 at 5:29:46 PM EDT
To: Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>, Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>, Correll, William A <William.Correll@fda.hhs.gov>, Musser, Steven M <Steven.Musser@fda.hhs.gov>, Dooren, Jennifer

<Jennifer.Dooren@fda.hhs.gov>, Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>

Subject: FW: Copy of FDA Letter

Here is the actual incoming letter (sent after the original email sent earlier today).

Susan

From: Szczepaniak, Lynne [CPCUS] <lszczepa@ITS.JNJ.com>

Sent: Thursday, October 24, 2019 5:02 PM

To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>

Subject: Copy of FDA Letter

Dear Dr Mayne,

Please find attached the letter referenced in the e-mail sent to you earlier this afternoon. A hard copy of that letter has also been sent to you via Federal Express. We reiterate our interest in meeting with you as soon as it is convenient, even if that is tomorrow or over the weekend. I look forward to hearing from you.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: **(b) (6)(b) (6)**
e-mail: lszczepa@its.jnj.com



CONSERVE OUR RESOURCES. PLEASE DO NOT PRINT THIS E-MAIL UNLESS NECESSARY.

From: [Dewan, Kapal](#)
To: [Wolfgang, Steven](#)
Cc: [Sadrieh, Nakissa](#); [Smegal, Deborah](#); [Katz, Linda](#)
Subject: FW: Copy of FDA Letter
Date: Friday, October 25, 2019 8:11:18 AM
Attachments: [Dr mayne letter10-24-2019_5 pm16-51-20.pdf](#)

Steve,

See the attached letter. We can discuss once you review it.

Kapal

From: Katz, Linda
Sent: Thursday, October 24, 2019 6:53 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Please assign this. We will need a **(b) (5)** .

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Date: October 24, 2019 at 5:29:46 PM EDT
To: Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>, Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>, Correll, William A <William.Correll@fda.hhs.gov>, Musser, Steven M <Steven.Musser@fda.hhs.gov>, Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>, Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Here is the actual incoming letter (sent after the original email sent earlier today).

Susan

From: Szczepaniak, Lynne [CPCUS] <lszczepa@ITS.JNJ.com>
Sent: Thursday, October 24, 2019 5:02 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: Copy of FDA Letter

Dear Dr Mayne,

Please find attached the letter referenced in the e-mail sent to you earlier this afternoon. A hard copy of that letter has also been sent to you via Federal Express. We reiterate our interest in meeting with you as soon as it is convenient, even if that is tomorrow or over the weekend. I look forward to hearing from you.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: **(b) (6)(b) (6)**
e-mail: lszczepa@its.jnj.com



CONSERVE OUR RESOURCES. PLEASE DO NOT PRINT THIS E-MAIL UNLESS NECESSARY.

From: [Dewan, Kapal](#)
To: [Wolfgang, Steven](#)
Subject: FW: Follow up from today's 29 October call
Date: Wednesday, October 30, 2019 12:52:33 PM
Attachments: [\(b\) \(4\)](#)

Steve,

Please **(b) (5)**. I would appreciate if you can send me the information latest by **10:00 am tomorrow**.

Thank you,
Kapal

From: Wolfgang, Steven
Sent: Wednesday, October 30, 2019 10:00 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

I looked at the report/data from RJ Lee. **(b) (5)**

There are **(b) (5)**

How **(b) (5)**

Steve

From: Dewan, Kapal
Sent: Wednesday, October 30, 2019 9:13 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

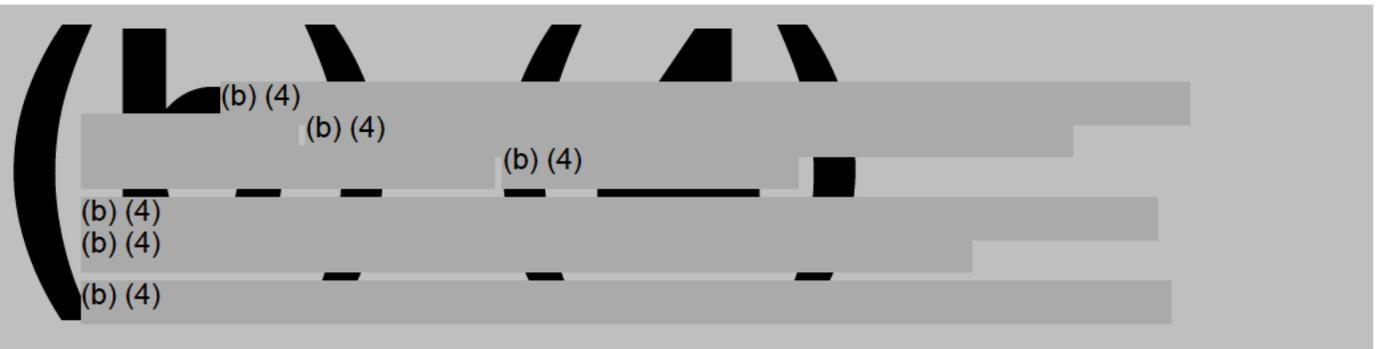
I have checked the incoming documents **(b) (5)**

Kapal

From: Szczepaniak, Lynne [CPCUS] [<mailto:lszczepa@ITS.JNJ.com>]
Sent: Tuesday, October 29, 2019 3:02 PM
To: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>
Cc: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>; Zuyev, Natasha [CPCUS] <nzuyev@ITS.JNJ.com>; Williams, Bobette [MCCUS] <BWilli10@its.jnj.com>; Scott, Elizabeth G. [MCCUS] <EGiulian@its.jnj.com>
Subject: FW: Follow up from today's 29 October call

Mr. Kuntz

We want to thank you again for scheduling the meeting to discuss results from our investigation of Johnson's Baby Powder recalled Lot #22318RB. As we discussed on the call, attached please find the following reports:



We would like to discuss these reports and findings, along with details of our full investigation. As we discussed, our investigation is on-going and we are in the process of doing additional testing. We will update you once we have additional results.

We also confirm, as we noted on today's call, that the samples tested by FDA were authentic. On the call, you asked about any discrepancies we noted in the sampling conducted by AMA based upon the AMA report. We will provide you with a detailed description of those discrepancies and information about the methods that you requested.

I have copied only you on this message per Dr Mayne's request to work with a single point of contact, however please forward this message to others who were on the call and anyone else who needs this information.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: (b) (6)
e-mail: lszczepa@its.jnj.com



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From: [Dewan, Kapal](#)
To: [Katz, Linda](#); [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Smegal, Deborah](#)
Cc: [Wolfqanq, Steven](#); [Gasper, John](#); [Scarborough, Kim](#)
Subject: FW: Johnson Baby Powder lot #22318RB - (b) (5)
Date: Friday, October 18, 2019 7:50:39 PM
Attachments: [IMG 4079.JPG](#)
[IMG 4080.JPG](#)
[IMG 4081.JPG](#)
[IMG 4082.JPG](#)
[IMG 4073.JPG](#)
[IMG 4074.JPG](#)
[IMG 4075.JPG](#)
[IMG 4076.JPG](#)
[IMG 4077.JPG](#)
[IMG 4078.JPG](#)
[FINAL OCAC Sample handling for testing by outside lab 05 21 19 10 18 19.docx..docx](#)
[analytical protocol for D58.pdf](#)

Importance: High

Hello,

Please see below in blue text what we have proposed (b) (5)

We are calling a day now. Team will reconvene on Monday morning.

My sincere thanks to Steve, John, and Kim who worked way more than I can ask for to plan for next week.

Kapal

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Friday, October 18, 2019 3:42 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>
Subject: Johnson Baby Powder lot #22318RB

Hello John and Kapal,

Pursuant to FDA's agreement to help facilitate materials for our investigation of Johnson's Baby Powder [lot #22318RB](#), we request support for the following:

- 75grams of J&J Baby Powder from the original J&J Baby Powder bottle lot #22318RB

OCAC's response: 75 grams of J&J Baby Powder in J&J provided container from the original J&J Baby Powder bottle lot #22318RB can be given to the firm.

- Access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing (to determine authenticity)

OCAC's response: FDA can provide access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing.

- A Picture of the original container sampled, prior to opening

OCAC's response: FDA has the photos of the front and back panel of original container sampled (attached)

- Picture or evidence the original tamper seals were intact prior to sampling

OCAC's response: FDA has the photo of the top seal (attached)

- A sample from any remaining J&J Baby Powder from the blinded sample containers (D58 308006-6A; D58 308006-6B) tested by AMA

OCAC's response: A sample from the remaining J&J Baby Powder from the blinded sample containers can be provided.

- AMA Labs Talc Testing SOP & Protocol

OCAC's response: Pages from AMA Lab report showing sample preparation, analysis, methods of calculations of asbestos fiber mass is attached (see file titled analytical protocol for D58).

- AMA sample preparation methods for preparation of reference control standard using Sigma-Aldrich spike with 10% chrysolite

OCAC's response: Team in not comfortable sharing the AMA QA Manual and reference control standards without AMA's permission.

- Analysis and/or TEM photos of the Sigma-Aldrich spiked with 10% chrysolite

Asked AMA - TEM was requested from AMA, and if available will provide.

Waiting for a response.

- Any asbestos environmental testing for the area used in FDA blinded sample preparation and at AMA laboratories testing labs

OCAC's response: FDA does not have any records for environmental testing for the area in which blinded samples were prepared; however, the D58 blinded sample was prepared on the same day as 14 other blinded samples were prepared with no indication that there was any contamination at the time D58 was prepared.

FDA's Standard operating procedure for preparation of samples for Blind testing of Talc (D58 308006 series)

OCAC's response: FDA's SOP - File titled Final OCAC Sample handling for testing by outside lab (attached)

- Documentation for the chain of custody including any invoices for the purchase of the samples from the online retailer

Both documents were sent to Kay for redaction.

As the investigation is of the utmost importance, we will be available to receive any of the above material, as soon as each of them are available and at the earliest convenience.

I look forward to hearing from you soon,

Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: +1 (b) (6)

pedson@its.inj.com
<http://www.inj.com>

From: [Dewan, Kapal](#)
To: [Gasper, John](#)
Cc: [Wolfgang, Steven](#)
Subject: FW: Johnson Baby Powder lot #22318RB - (b) (5)
Date: Saturday, October 19, 2019 9:45:44 PM
Importance: High

John,

First thing on Monday, (b) (5)

Thanks,
Kapal

From: Jasperse, Carie
Sent: Saturday, October 19, 2019 4:44 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

(b) (5)
(b) (5)
? Thanks, Carie

From: Dewan, Kapal
Sent: Saturday, October 19, 2019 2:04 PM
To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Importance: High

Thanks Carie. (b) (5) . I have added Bill to this email.

Bill,

Please see below the email from J&J that includes a number of materials that they have asked. They are planning to come on Monday, 10/21/2019 at 11:00 am to collect a sample of the retail container

product and blinded sample and other materials. OCAC's response is in blue font that is included in the email from J&J (b) (5)

Thank you,
Kapal

From: Jasperse, Carie
Sent: Saturday, October 19, 2019 12:07 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

(b) (5)

From: Dewan, Kapal
Sent: Saturday, October 19, 2019 7:53 AM
To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Importance: High

Carie,

(b) (5)

Thank you in advance!
Kapal

From: Katz, Linda
Sent: Friday, October 18, 2019 9:21 PM

From: [Dewan, Kapal](#)
To: [Jasperse, Carie](#)
Cc: [Katz, Linda](#); [Wolfgang, Steven](#); [Gasper, John](#); [Lewis, Kathleen](#); [Smegal, Deborah](#); [Sadrieh, Nakissa](#)
Subject: FW: Johnson Baby Powder lot #22318RB - (b) (5)
Date: Saturday, October 19, 2019 7:59:35 AM
Importance: High

Carie,

(b) (5)

FYI - John Gasper is the COR for the AMA contract under which the talc-containing cosmetics are being tested for asbestos.

Thank you,
Kapal

-----Original Message-----

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Friday, October 18, 2019 8:27 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>
Subject: Re: Johnson Baby Powder lot #22318RB

John, for clarity, what sample material is being made available. Powder from the original container or powder from the blinded samples? Or both? Thanks for the clarification.

Best regards, Paul

> On Oct 18, 2019, at 8:14 PM, Edson, Paul [JJCUS] <PEDSON@its.jnj.com> wrote:
>

From: [Dewan, Kapal](#)
To: [Katz, Linda](#); [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Wolfgang, Steven](#); [Smegal, Deborah](#); [Roosevelt, Michael](#); [Scarborough, Kim](#)
Cc: [Gasper, John](#)
Subject: FW: Johnson Baby Powder lot #22318RB
Date: Friday, October 18, 2019 6:57:29 PM

FYI—As per email below, J&J plans to be onsite on Monday late morning.

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Friday, October 18, 2019 6:15 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>
Subject: Re: Johnson Baby Powder lot #22318RB

We plan to be onsite to pick up the sample late morning. I do not yet have the name of the individual. We will notify you of the individuals ASAP. Thank you!

Paul

On Oct 18, 2019, at 5:16 PM, Gasper, John <John.Gasper@fda.hhs.gov> wrote:

Mr. Edson,

Please bring your own container to use for sample collection. Thank you.

Regards,

John Gasper

CFSAN
Office of Cosmetics and Colors
U.S. Food and Drug Administration
Tel: 240-402-1133

john.gasper@fda.hhs.gov

[<image007.png>](#)

[<image008.jpg>](#)

[<image009.jpg>](#)

[<image010.jpg>](#)

[<image011.jpg>](#)

[<image012.jpg>](#)

From: [Dewan, Kapal](#)
To: [Wolfgang, Steven](#)
Cc: [Gasper, John](#)
Subject: FW: RE: J&J Has Contacted Me About Logistics of Providing Sample
Date: Friday, October 18, 2019 2:28:35 PM

Steve,

(b) (5)

I will ask John and walk him through so we get the aliquot for J&J ready.

Thank you for your understanding!
Kapal

From: Katz, Linda
Sent: Friday, October 18, 2019 2:19 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

There was supposed to (b) (5)

This needs to be done today.

From: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Sent: Friday, October 18, 2019 2:10 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

Hi John,

I thought we (b) (5)

- (b) (5)
-
-

Did I miss anything?

Kay Lewis
Senior Advisor
OCAC/CFSAN/FDA
240-402-1129 office
240-825-9944 bb

NOTE: This e-mail message is intended for the exclusive use of the recipient's named above. It may contain information that is protected, privileged, or confidential, and it must not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately.

From: Gasper, John <John.Gasper@fda.hhs.gov>
Sent: Friday, October 18, 2019 2:05 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: J&J Has Contacted Me About Logistics of Providing Sample

To All:

Please note that a (b) (5) should discuss (b) (5). Thank you.

Regards,
John G

From: [Kuntz, Thomas](#)
To: [Katz, Linda](#); [Dewan, Kapal](#); [Sadrieh, Nakissa](#); [Wolfgang, Steven](#); [Jabs, Alexandra](#); [Jasperse, Carie](#); [Roosevelt, Michael](#); [Dooren, Jennifer](#); [Lanham, Ruark](#); [Pack, Randy](#); [Darlington, Leonora](#); [Barringer, Amy](#)
Cc: [Correll, William A](#); [Mayne, Susan](#); [Musser, Steven M](#); [Stearn, Douglas](#); [Beckerman, Peter](#); [Stone, Dyana](#)
Subject: Listening session with J&J on preliminary results from their investigation
Attachments: [RE Update Results from JJ investigation related to Recalled Lot 22318RB](#) (b) (4)

Background email added.

J&J would like to update FDA on their investigation into the asbestos finding in their baby powder product and plans for a press release.

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

Meeting number (access code) (b) (6)

Meeting password: (b) (6)

Join meeting <<https://fda1.webex.com/fda1/j.php?MTID=mbbe4293811c8acf64c2241a39d59d11c>>

Join by phone

(b) (6) a mobile device (attendees only)
S Toll
S Toll Free
bers <<https://fda1.webex.com/fda1/globalcallin.php?MTID=m25db59a4eefdf274737e07994aae874c>> | Toll-free calling
restrictions <https://e-meetings.verizonbusiness.com/global/pdf/Verizon_Audio_Conferencing_Global_Access_Information_August2017.pdf>

If you are a host, go here <<https://fda1.webex.com/fda1/j.php?MTID=mb3ededc6bd5ca4d957d99bfc38d12341>> to view host information.

Need help? Go to <http://help.webex.com> <<http://help.webex.com>>

From: [Wolfgang, Steven](#)
To: [Katz, Linda](#)
Subject: mica
Date: Tuesday, October 29, 2019 12:54:00 PM

We have asked (b) (5)



The issue (b) (5)



*Steven Wolfgang, Ph.D.
Consumer Safety Officer
Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
College Park, MD
301-796-3264
240-328-9827*

From: [Wolfgang, Steven](#)
To: [Dewan, Kapal](#)
Cc: [Sadrieh, Nakissa](#); [Smegal, Deborah](#); [Katz, Linda](#)
Subject: RE: Copy of FDA Letter - IMPORTANT Guidance requested from OCAC
Date: Friday, October 25, 2019 1:12:00 PM

Will want to discuss with you first. I also think (b) (5)

(b) (5)

Steve

From: Dewan, Kapal
Sent: Friday, October 25, 2019 1:03 PM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: RE: Copy of FDA Letter - IMPORTANT Guidance requested from OCAC

Steve,

See below Linda's email. Please draft a response to the letter sent to Dr. Mayne.

Thank you,
Kapal

From: Katz, Linda
Sent: Friday, October 25, 2019 1:00 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Copy of FDA Letter - IMPORTANT Guidance requested from OCAC

For now work on the Maybe letter

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 25, 2019 at 12:42:00 PM EDT
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Copy of FDA Letter - IMPORTANT Guidance requested from OCAC

Linda,

Can you please clarify – which letter? There are 2 letters that FDA have received from the firm (1) one sent to Dr. Mayne and (2) sent to John Gasper yesterday around 5:00 pm.

Kapal

From: Katz, Linda
Sent: Friday, October 25, 2019 12:17 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Re: Copy of FDA Letter - IMPORTANT Guidance requested from OCAC

Only draft a response to the letter.

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 25, 2019 at 10:57:56 AM EDT
To: Ticker, Douglas <Douglas.Ticker@fda.hhs.gov>
Cc: Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: FW: Copy of FDA Letter - IMPORTANT Guidance requested from OCAC
Importance: High

Doug,

I tried to call you this morning but got the voice message. Please see below Linda's email to contact you regarding (b) (5) . Would you prefer to (b) (5) (b) (5) ?

Also, (b) (5) . We would like to seek guidance (b) (5) (b) (5) .

Thank you in advance!

Kapal

From: Katz, Linda
Sent: Friday, October 25, 2019 8:25 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Re: Copy of FDA Letter

Contact Doug Ticker and cc: Laura Pillsbury for clarification of some of the details needed in our response

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 25, 2019 at 8:11:17 AM EDT
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Steve,

See the attached letter. We can discuss (b) (5)

Kapal

From: Katz, Linda
Sent: Thursday, October 24, 2019 6:53 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Please assign this. We will need a (b) (5)

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Date: October 24, 2019 at 5:29:46 PM EDT
To: Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>, Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>, Correll, William A <William.Correll@fda.hhs.gov>, Musser, Steven M <Steven.Musser@fda.hhs.gov>, Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>, Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Here is the actual incoming letter (sent after the original email sent earlier today).

Susan

From: Szczepaniak, Lynne [CPCUS] <lszczepa@ITS.JNJ.com>
Sent: Thursday, October 24, 2019 5:02 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: Copy of FDA Letter

Dear Dr Mayne,

Please find attached the letter referenced in the e-mail sent to you earlier this afternoon. A hard copy of that letter has also been sent to you via Federal Express. We reiterate our interest in meeting with you as soon as it is convenient, even if that is tomorrow or over the weekend. I look

forward to hearing from you.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: **(b) (6)(b) (6)**
e-mail: lszczepa@its.jnj.com



CONSERVE OUR RESOURCES. PLEASE DO NOT PRINT THIS E-MAIL UNLESS NECESSARY.

From: [Dewan, Kapal](#)
To: [Wolfgang, Steven](#)
Cc: [Sadrieh, Nakissa](#); [Smegal, Deborah](#); [Katz, Linda](#)
Subject: RE: Copy of FDA Letter - IMPORTANT Guidance requested from OCAC
Date: Friday, October 25, 2019 1:02:55 PM

Steve,

See below Linda's email. Please (b) (5) .

Thank you,
Kapal

From: Katz, Linda
Sent: Friday, October 25, 2019 1:00 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Copy of FDA Letter - IMPORTANT Guidance requested from OCAC

For now work on (b) (5)

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 25, 2019 at 12:42:00 PM EDT
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Copy of FDA Letter - IMPORTANT Guidance requested from OCAC

Linda,

Can you please clarify – (b) (5) ? (b) (5) yesterday around 5:00 pm.

Kapal

From: Katz, Linda
Sent: Friday, October 25, 2019 12:17 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Re: Copy of FDA Letter - IMPORTANT Guidance requested from OCAC

Only draft a response to the letter.

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 25, 2019 at 10:57:56 AM EDT
To: Ticker, Douglas <Douglas.Ticker@fda.hhs.gov>
Cc: Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: FW: Copy of FDA Letter - IMPORTANT Guidance requested from OCAC
Importance: High

Doug,

I tried to call you this morning but got the voice message. Please see below Linda's email to contact you regarding some guidance on responding to the letter. Would you prefer to meet to discuss a strategy to respond to the letter?

Also, OCAC has received another email from the firm (attached) with some overlapping request that is listed in appendix of the letter that was sent to Dr. Mayne. We would like (b) (5)

(b) (5)

Thank you in advance!
Kapal

From: Katz, Linda
Sent: Friday, October 25, 2019 8:25 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Re: Copy of FDA Letter

Contact Doug Ticker and cc: Laura Pillsbury for clarification of some of the details needed in our response

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 25, 2019 at 8:11:17 AM EDT
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Steve,

See the attached letter. We can discuss once you review it.

Kapal

From: Katz, Linda
Sent: Thursday, October 24, 2019 6:53 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Please assign this. (b) (5)

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Date: October 24, 2019 at 5:29:46 PM EDT
To: Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>, Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>, Correll, William A <William.Correll@fda.hhs.gov>, Musser, Steven M <Steven.Musser@fda.hhs.gov>, Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>, Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Here is the actual incoming letter (sent after the original email sent earlier today).

Susan

From: Szczepaniak, Lynne [CPCUS] <lszczepa@ITS.JNJ.com>
Sent: Thursday, October 24, 2019 5:02 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: Copy of FDA Letter

Dear Dr Mayne,

Please find attached the letter referenced in the e-mail sent to you earlier this afternoon. A hard copy of that letter has also been sent to you via Federal Express. We reiterate our interest in meeting with you as soon as it is convenient, even if that is tomorrow or over the weekend. I look forward to hearing from you.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: (b) (6)(b) (6)
e-mail: lszczepa@its.jnj.com



.

From: [Dewan, Kapal](#)
To: [Ticker, Douglas](#)
Cc: [Pillsbury, Laura](#); [Katz, Linda](#); [Smegal, Deborah](#); [Sadrieh, Nakissa](#); [Wolfgang, Steven](#)
Subject: RE: Copy of FDA Letter - IMPORTANT Guidance requested from OCAC
Date: Monday, October 28, 2019 8:48:37 AM

Good Morning Doug,

Let us know what time works for you. We can meet to (b) (5) .
OCAC's SME is Steve Wolfgang whom I have cc'e in this email.

Thank you in advance!
Kapal

From: Ticker, Douglas
Sent: Friday, October 25, 2019 3:22 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: Copy of FDA Letter - IMPORTANT Guidance requested from OCAC

Hi Kapal,

I (b) (5) are you available to discuss? I'd also
be happy to look for a time in Outlook and sent out an invite.

Doug Ticker
Policy Analyst
Office of Executive Programs
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Phone Number: 301-796-5391

From: Ticker, Douglas
Sent: Friday, October 25, 2019 1:03 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: Copy of FDA Letter - IMPORTANT Guidance requested from OCAC

Hi Kapal,

I just got into the office. I'm taking a look at both letters right now and will get back to you soon.

Doug Ticker
Policy Analyst

From: [Sadrieh, Nakissa](#)
To: [Dewan, Kapal](#)
Cc: [Wolfgang, Steven](#); [Smegal, Deborah](#); [Gasper, John](#); [Katz, Linda](#)
Subject: Re: Copy of FDA Letter
Date: Friday, October 25, 2019 10:31:09 AM

Kapal,

I am in a meeting now. Linda asked you to reach out to Doug today, so please go ahead and do that. (b) (5)

. Thanks.

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 25, 2019 at 10:25:55 AM EDT
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Gasper, John <John.Gasper@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Nakissa,

As mentioned on Monday that all email going outside should be sent to you so doing my due diligence. Can you please check the email draft below?

(b) (5)

From: Katz, Linda
Sent: Friday, October 25, 2019 8:25 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Re: Copy of FDA Letter

Contact Doug Ticker and cc: Laura Pillsbury for clarification of some of the details needed in our response

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 25, 2019 at 8:11:17 AM EDT
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Steve,

See the attached letter. We can discuss (b) (5)

Kapal

From: Katz, Linda
Sent: Thursday, October 24, 2019 6:53 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Please assign this. We will need a (b) (5).

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Date: October 24, 2019 at 5:29:46 PM EDT
To: Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>, Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>, Correll, William A <William.Correll@fda.hhs.gov>, Musser, Steven M <Steven.Musser@fda.hhs.gov>, Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>, Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Here is the actual incoming letter (sent after the original email sent earlier today).

Susan

From: Szczepaniak, Lynne [CPCUS] <lszczepa@ITS.JNJ.com>
Sent: Thursday, October 24, 2019 5:02 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: Copy of FDA Letter

Dear Dr Mayne,

Please find attached the letter referenced in the e-mail sent to you earlier this afternoon. A hard copy of that letter has also been sent to you via Federal Express. We reiterate our interest in

meeting with you as soon as it is convenient, even if that is tomorrow or over the weekend. I look forward to hearing from you.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: **(b) (6)(b) (6)**
e-mail: lszczepa@its.jnj.com



CONSERVE OUR RESOURCES. PLEASE DO NOT PRINT THIS E-MAIL UNLESS NECESSARY.

From: [Sadrieh, Nakissa](#)
To: [Dewan, Kapal](#); [Wolfgang, Steven](#)
Cc: [Smegal, Deborah](#); [Katz, Linda](#)
Subject: Re: Copy of FDA Letter
Date: Friday, October 25, 2019 8:20:21 AM

Kapal,

Who (b) (5) ?

I also suggest (b) (5)

(b) (5)

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 25, 2019 at 8:11:17 AM EDT
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Steve,

See the attached letter. We can discuss (b) (5)

Kapal

From: Katz, Linda
Sent: Thursday, October 24, 2019 6:53 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Please assign this. We will need a (b) (5).

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Date: October 24, 2019 at 5:29:46 PM EDT
To: Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>, Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>, Correll, William A <William.Correll@fda.hhs.gov>, Musser, Steven M <Steven.Musser@fda.hhs.gov>, Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>, Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>

Subject: FW: Copy of FDA Letter

Here is the actual incoming letter (sent after the original email sent earlier today).

Susan

From: Szczepaniak, Lynne [CPCUS] <lszczepa@ITS.JNJ.com>

Sent: Thursday, October 24, 2019 5:02 PM

To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>

Subject: Copy of FDA Letter

Dear Dr Mayne,

Please find attached the letter referenced in the e-mail sent to you earlier this afternoon. A hard copy of that letter has also been sent to you via Federal Express. We reiterate our interest in meeting with you as soon as it is convenient, even if that is tomorrow or over the weekend. I look forward to hearing from you.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: **(b) (6)(b) (6)**
e-mail: lszczepa@its.jnj.com



CONSERVE OUR RESOURCES. PLEASE DO NOT PRINT THIS E-MAIL UNLESS NECESSARY.

From: [Sadrieh, Nakissa](#)
To: [Katz, Linda](#); [Dewan, Kapal](#); [Wolfgang, Steven](#)
Cc: [Smegal, Deborah](#)
Subject: Re: Copy of FDA Letter
Date: Friday, October 25, 2019 8:26:55 AM

I will ask Kapal to do this and cc us.

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Date: October 25, 2019 at 8:25:04 AM EDT
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>, Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Re: Copy of FDA Letter

Contact Doug Ticker and cc: Laura Pillsbury for clarification of some of the details needed in our response

From: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Date: October 25, 2019 at 8:20:20 AM EDT
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>, Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: Re: Copy of FDA Letter

Kapal,

Who is redacting the report from sample D38 and when will the redaction go to Linda?

I also suggest (b) (5)



From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 25, 2019 at 8:11:17 AM EDT
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Steve,

From: [Katz, Linda](#)
To: [Sadrieh, Nakissa](#); [Dewan, Kapal](#); [Wolfgang, Steven](#)
Cc: [Smegal, Deborah](#)
Subject: Re: Copy of FDA Letter
Date: Friday, October 25, 2019 8:25:05 AM

Contact Doug Ticker and cc: Laura Pillsbury for clarification of some of the details needed in our response

From: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Date: October 25, 2019 at 8:20:20 AM EDT
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>, Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: Re: Copy of FDA Letter

Kapal,

Who is redacting the report from sample D38 and when will the redaction go to Linda?

I also suggest (b) (5)



From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 25, 2019 at 8:11:17 AM EDT
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: FW: Copy of FDA Letter

Steve,

See the attached letter. We can discuss once you review it.

Kapal

From: Katz, Linda
Sent: Thursday, October 24, 2019 6:53 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Smegal, Deborah

<Deborah.Smegal@fda.hhs.gov>

Subject: FW: Copy of FDA Letter

Please assign this. We will need a (b) (5) .

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>

Date: October 24, 2019 at 5:29:46 PM EDT

To: Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>, Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>, Correll, William A <William.Correll@fda.hhs.gov>, Musser, Steven M <Steven.Musser@fda.hhs.gov>, Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>, Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>

Subject: FW: Copy of FDA Letter

Here is the actual incoming letter (sent after the original email sent earlier today).

Susan

From: Szczepaniak, Lynne [CPCUS] <lszczepa@ITS.JNJ.com>

Sent: Thursday, October 24, 2019 5:02 PM

To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>

Subject: Copy of FDA Letter

Dear Dr Mayne,

Please find attached the letter referenced in the e-mail sent to you earlier this afternoon. A hard copy of that letter has also been sent to you via Federal Express. We reiterate our interest in meeting with you as soon as it is convenient, even if that is tomorrow or over the weekend. I look forward to hearing from you.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: (b) (6)
e-mail: lszczepa@its.jnj.com



CONSERVE OUR RESOURCES. PLEASE DO NOT PRINT THIS E-MAIL UNLESS NECESSARY.

From: [Sadrieh, Nakissa](#)
To: [Spence, Susan](#); [Dewan, Kapal](#)
Cc: [Lewis, Kathleen](#); [Katz, Linda](#); [Wolfgang, Steven](#)
Subject: RE: Follow up from today's 29 October call
Date: Wednesday, October 30, 2019 11:06:16 AM

I like your proposed (b) (5)

. Thanks.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Spence, Susan <Susan.Spence@fda.hhs.gov>
Sent: Wednesday, October 30, 2019 10:57 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

Dear Kapal,

I think (b) (5)

(b) (5)

. I think (b) (5)

Best wishes,

Susan

From: Dewan, Kapal
Sent: Wednesday, October 30, 2019 8:29 AM
To: Spence, Susan <Susan.Spence@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call
Importance: High

Susan,

Can you send a (b) (5) [redacted] ?

Kapal

From: Sadrieh, Nakissa
Sent: Tuesday, October 29, 2019 6:37 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Spence, Susan <Susan.Spence@fda.hhs.gov>
Subject: Re: Follow up from today's 29 October call

I take it (b) (5) [redacted]
[redacted]
[redacted] ?

By this I mean (b) (5) [redacted]
(b) (5) [redacted]

I am adding Susan (b) (5) [redacted]
[redacted]

If (b) (5) [redacted]
[redacted].

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Date: October 29, 2019 at 5:26:35 PM EDT
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Subject: FW: Follow up from today's 29 October call

Please create a summary of the differences between AMA and J&J's methods. Due by Friday.

From: Musser, Steven M <Steven.Musser@fda.hhs.gov>

Sent: Tuesday, October 29, 2019 5:14 PM

To: Katz, Linda <Linda.Katz@fda.hhs.gov>

Subject: FW: Follow up from today's 29 October call

It looks as though (b) (5)

[REDACTED]
[REDACTED]
[REDACTED] ?

From: "Kuntz, Thomas" <Thomas.Kuntz@fda.hhs.gov>

Date: Tuesday, October 29, 2019 at 4:15 PM

To: Linda Katz <Linda.Katz@fda.hhs.gov>, "Dewan, Kapal" <Kapal.Dewan@fda.hhs.gov>, "Sadrieh, Nakissa" <Nakissa.Sadrieh@fda.hhs.gov>, "Wolfgang, Steven" <Steven.Wolfgang@fda.hhs.gov>, "Jabs, Alexandra" <Alexandra.Jabs@fda.hhs.gov>, "Jasperse, Carie" <Carie.Jasperse@fda.hhs.gov>, "Roosevelt, Michael" <Michael.Roosevelt@fda.hhs.gov>, "Dooren, Jennifer" <Jennifer.Dooren@fda.hhs.gov>, "Lanham, Ruark" <Ruark.Lanham@fda.hhs.gov>, "Pack, Randy" <Randy.Pack@fda.hhs.gov>, "Darlington, Leonora" <Leonora.Darlington@fda.hhs.gov>, "Barringer, Amy" <Amy.Barringer@fda.hhs.gov>

Cc: William Correll <William.Correll@fda.hhs.gov>, Susan Mayne <Susan.Mayne@fda.hhs.gov>, "Musser, Steven M" <Steven.Musser@fda.hhs.gov>, "Stearn, Douglas" <Douglas.Stearn@fda.hhs.gov>, "Beckerman, Peter" <Peter.Beckerman@fda.hhs.gov>, "Stone, Dyana" <Dyana.Stone@fda.hhs.gov>, "Lewis, Kathleen" <Kathleen.Lewis@fda.hhs.gov>, "Gasper, John" <John.Gasper@fda.hhs.gov>, "Ingram, Shannon" <Shannon.Ingram@fda.hhs.gov>, ORA Recall OE <orarecalloe@fda.hhs.gov>

Subject: FW: Follow up from today's 29 October call

Documents from J&J as promised during today's call.

From: Szczepaniak, Lynne [CPCUS] [<mailto:lszczepa@ITS.JNJ.com>]

Sent: Tuesday, October 29, 2019 3:02 PM

To: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>

Cc: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>; Zuyev, Natasha [CPCUS] <nzuyev@ITS.JNJ.com>; Williams, Bobette [MCCUS] <BWilli10@its.jnj.com>; Scott, Elizabeth G. [MCCUS] <EGiulian@its.jnj.com>

Subject: FW: Follow up from today's 29 October call

Mr. Kuntz

We want to thank you again for scheduling the meeting to discuss results from our investigation of Johnson's Baby Powder recalled Lot #22318RB. As we discussed on the call, attached please find

(b) (4)

(b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)

We would like to discuss these reports and findings, along with details of our full investigation. As we discussed, our investigation is on-going and we are in the process of doing additional testing. We will update you once we have additional results.

We also confirm, as we noted on today's call, that the samples tested by FDA were authentic. On the call, you asked about any discrepancies we noted in the sampling conducted by AMA based upon the AMA report. We will provide you with a detailed description of those discrepancies and information about the methods that you requested.

I have copied only you on this message per Dr Mayne's request to work with a single point of contact, however please forward this message to others who were on the call and anyone else who needs this information.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: (b) (6)(b) (6)
e-mail: lszczepa@its.jnj.com



CONSERVE OUR RESOURCES. PLEASE DO NOT PRINT THIS E-MAIL UNLESS NECESSARY.

From: [Dewan, Kapal](#)
To: [Spence, Susan](#)
Cc: [Lewis, Kathleen](#); [Sadrieh, Nakissa](#); [Katz, Linda](#); [Wolfgang, Steven](#)
Subject: RE: Follow up from today's 29 October call
Date: Wednesday, October 30, 2019 11:05:22 AM

We will see what we need. Thanks anyway.

From: Spence, Susan
Sent: Wednesday, October 30, 2019 10:57 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

Dear Kapal,

I think (b) (5)



(b) (5)



(b) (5)

I think (b) (5)

(b) (5)



Best wishes,

Susan

From: Dewan, Kapal
Sent: Wednesday, October 30, 2019 8:29 AM
To: Spence, Susan <Susan.Spence@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call
Importance: High

Susan,

Can you send a **summary table** that you have made for the working group?

Kapal

From: Sadrieh, Nakissa
Sent: Tuesday, October 29, 2019 6:37 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Spence, Susan <Susan.Spence@fda.hhs.gov>
Subject: Re: Follow up from today's 29 October call

I take it (b) (5) [redacted]
[redacted]
[redacted] ?
(b) (5) [redacted]

I am adding Susan because she has made similar summary tables for the working group and she can help Steve, Kapal and I, who will also have to work on this.

If another (b) (5) [redacted]
[redacted].

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Date: October 29, 2019 at 5:26:35 PM EDT
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Subject: FW: Follow up from today's 29 October call

Please (b) (5) [redacted]. Due by Friday.

From: Musser, Steven M <Steven.Musser@fda.hhs.gov>
Sent: Tuesday, October 29, 2019 5:14 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: FW: Follow up from today's 29 October call

It looks as though (b) (5) [redacted]
[redacted]
[redacted] ?

From: "Kuntz, Thomas" <Thomas.Kuntz@fda.hhs.gov>

Date: Tuesday, October 29, 2019 at 4:15 PM

To: Linda Katz <Linda.Katz@fda.hhs.gov>, "Dewan, Kapal" <Kapal.Dewan@fda.hhs.gov>, "Sadrieh, Nakissa" <Nakissa.Sadrieh@fda.hhs.gov>, "Wolfgang, Steven" <Steven.Wolfgang@fda.hhs.gov>, "Jabs, Alexandra" <Alexandra.Jabs@fda.hhs.gov>, "Jasperse, Carie" <Carie.Jasperse@fda.hhs.gov>, "Roosevelt, Michael" <Michael.Roosevelt@fda.hhs.gov>, "Dooren, Jennifer" <Jennifer.Dooren@fda.hhs.gov>, "Lanham, Ruark" <Ruark.Lanham@fda.hhs.gov>, "Pack, Randy" <Randy.Pack@fda.hhs.gov>, "Darlington, Leonora" <Leonora.Darlington@fda.hhs.gov>, "Barringer, Amy" <Amy.Barringer@fda.hhs.gov>

Cc: William Correll <William.Correll@fda.hhs.gov>, Susan Mayne <Susan.Mayne@fda.hhs.gov>, "Musser, Steven M" <Steven.Musser@fda.hhs.gov>, "Stearn, Douglas" <Douglas.Stearn@fda.hhs.gov>, "Beckerman, Peter" <Peter.Beckerman@fda.hhs.gov>, "Stone, Dyana" <Dyana.Stone@fda.hhs.gov>, "Lewis, Kathleen" <Kathleen.Lewis@fda.hhs.gov>, "Gasper, John" <John.Gasper@fda.hhs.gov>, "Ingram, Shannon" <Shannon.Ingram@fda.hhs.gov>, ORA Recall OE <orarecalloe@fda.hhs.gov>

Subject: FW: Follow up from today's 29 October call

Documents from J&J as promised during today's call.

From: Szczepaniak, Lynne [CPCUS] [<mailto:lszczepa@ITS.JNJ.com>]

Sent: Tuesday, October 29, 2019 3:02 PM

To: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>

Cc: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>; Zuyev, Natasha [CPCUS] <nzuyev@ITS.JNJ.com>; Williams, Bobette [MCCUS] <BWilli10@its.jnj.com>; Scott, Elizabeth G. [MCCUS] <EGiulian@its.jnj.com>

Subject: FW: Follow up from today's 29 October call

Mr. Kuntz

We want to thank you again for scheduling the meeting to discuss results from our investigation of Johnson's Baby Powder recalled Lot #22318RB. As we discussed on the call, attached please find the following reports:

(b) (4)

We would like to discuss these reports and findings, along with details of our full investigation.

As we discussed, our investigation is on-going and we are in the process of doing additional testing. We will update you once we have additional results.

We also confirm, as we noted on today's call, that the samples tested by FDA were authentic. On the call, you asked about any discrepancies we noted in the sampling conducted by AMA based upon the AMA report. We will provide you with a detailed description of those discrepancies and information about the methods that you requested.

I have copied only you on this message per Dr Mayne's request to work with a single point of contact, however please forward this message to others who were on the call and anyone else who needs this information.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: **(b) (6)(b) (6)**
e-mail: lszczepa@its.jnj.com



CONSERVE OUR RESOURCES. PLEASE DO NOT PRINT THIS E-MAIL UNLESS NECESSARY.

From: [Katz, Linda](#)
To: [Sadrieh, Nakissa](#); [Spence, Susan](#); [Dewan, Kapal](#)
Cc: [Lewis, Kathleen](#); [Wolfgang, Steven](#)
Subject: RE: Follow up from today's 29 October call
Date: Wednesday, October 30, 2019 11:09:11 AM

I agree. Is it possible (b) (5)

(b) (5) ? In other words, (b) (5)

From: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Sent: Wednesday, October 30, 2019 11:06 AM
To: Spence, Susan <Susan.Spence@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

I like your proposed (b) (5)

. Thanks.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Spence, Susan <Susan.Spence@fda.hhs.gov>
Sent: Wednesday, October 30, 2019 10:57 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

Dear Kapal,

I think (b) (5)

(b) (5) That said, I don't think (b) (5)

(b) (5)
(b) (5)
(b) (5)
(b) (5). I think (b) (5)
(b) (5)
(b) (5)
(b) (5)

Best wishes,

Susan

From: Dewan, Kapal
Sent: Wednesday, October 30, 2019 8:29 AM
To: Spence, Susan <Susan.Spence@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call
Importance: High

Susan,

Can you send (b) (5) ?

Kapal

From: Sadrieh, Nakissa
Sent: Tuesday, October 29, 2019 6:37 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Spence, Susan <Susan.Spence@fda.hhs.gov>
Subject: Re: Follow up from today's 29 October call

I take it (b) (5)
(b) (5)
(b) (5) ?
By this I (b) (5)
(b) (5)

I am adding Susan because she has made similar summary tables for the working group and she can help Steve, Kapal and I, who will also have to work on this.

If another (b) (5)

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Date: October 29, 2019 at 5:26:35 PM EDT
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Subject: FW: Follow up from today's 29 October call

Please create a (b) (5) . Due by Friday.

From: Musser, Steven M <Steven.Musser@fda.hhs.gov>
Sent: Tuesday, October 29, 2019 5:14 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: FW: Follow up from today's 29 October call

It looks as though (b) (5)

?

From: "Kuntz, Thomas" <Thomas.Kuntz@fda.hhs.gov>
Date: Tuesday, October 29, 2019 at 4:15 PM
To: Linda Katz <Linda.Katz@fda.hhs.gov>, "Dewan, Kapal" <Kapal.Dewan@fda.hhs.gov>, "Sadrieh, Nakissa" <Nakissa.Sadrieh@fda.hhs.gov>, "Wolfgang, Steven" <Steven.Wolfgang@fda.hhs.gov>, "Jabs, Alexandra" <Alexandra.Jabs@fda.hhs.gov>, "Jasperse, Carie" <Carie.Jasperse@fda.hhs.gov>, "Roosevelt, Michael" <Michael.Roosevelt@fda.hhs.gov>, "Dooren, Jennifer" <Jennifer.Dooren@fda.hhs.gov>, "Lanham, Ruark" <Ruark.Lanham@fda.hhs.gov>, "Pack, Randy" <Randy.Pack@fda.hhs.gov>, "Darlington, Leonora" <Leonora.Darlington@fda.hhs.gov>, "Barringer, Amy" <Amy.Barringer@fda.hhs.gov>
Cc: William Correll <William.Correll@fda.hhs.gov>, Susan Mayne <Susan.Mayne@fda.hhs.gov>, "Musser, Steven M" <Steven.Musser@fda.hhs.gov>, "Stearn, Douglas" <Douglas.Stearn@fda.hhs.gov>, "Beckerman, Peter" <Peter.Beckerman@fda.hhs.gov>, "Stone, Dyana" <Dyana.Stone@fda.hhs.gov>, "Lewis, Kathleen" <Kathleen.Lewis@fda.hhs.gov>, "Gasper, John" <John.Gasper@fda.hhs.gov>, "Ingram, Shannon" <Shannon.Ingram@fda.hhs.gov>, ORA Recall OE <orarecalloe@fda.hhs.gov>
Subject: FW: Follow up from today's 29 October call

Documents from J&J as promised during today's call.

From: Szczepaniak, Lynne [CPCUS] [<mailto:lszczepa@ITS.JNJ.com>]
Sent: Tuesday, October 29, 2019 3:02 PM
To: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>
Cc: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>; Zuyev, Natasha [CPCUS] <nzuyev@ITS.JNJ.com>; Williams, Bobette [MCCUS] <BWilli10@its.jnj.com>; Scott, Elizabeth G. [MCCUS] <EGiulian@its.jnj.com>
Subject: FW: Follow up from today's 29 October call

Mr. Kuntz

We want to thank you again for scheduling the meeting to discuss results from our investigation of Johnson's Baby Powder recalled Lot #22318RB. As we discussed on the call, attached please find the following reports:

1. (b) (4) [redacted]
independent testing lab, RJ Lee, which tested negative for asbestos. These reports include an
(b) (4) [redacted]
(b) (4) [redacted]
(b) (4) [redacted]
2. (b) (4) [redacted]
(b) (4) [redacted]
3. (b) (4) [redacted]
asbestos.

We would like to discuss these reports and findings, along with details of our full investigation. As we discussed, our investigation is on-going and we are in the process of doing additional testing. We will update you once we have additional results.

We also confirm, as we noted on today's call, that the samples tested by FDA were authentic. On the call, you asked about any discrepancies we noted in the sampling conducted by AMA based upon the AMA report. We will provide you with a detailed description of those discrepancies and information about the methods that you requested.

I have copied only you on this message per Dr Mayne's request to work with a single point of contact, however please forward this message to others who were on the call and anyone else who needs this information.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: (b) (6) [redacted]
e-mail: lszczepa@its.jnj.com



From: [Sadrieh, Nakissa](#)
To: [Dewan, Kapal](#); [Spence, Susan](#)
Cc: [Lewis, Kathleen](#); [Katz, Linda](#); [Wolfgang, Steven](#)
Subject: RE: Follow up from today's 29 October call
Date: Wednesday, October 30, 2019 11:07:38 AM

Susan has generated a very useful template for the summary table requested by Linda. Once we have the information, I suggest (b) (5)
(b) (5)

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Wednesday, October 30, 2019 11:05 AM
To: Spence, Susan <Susan.Spence@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

We will see what we need. Thanks anyway.

From: Spence, Susan
Sent: Wednesday, October 30, 2019 10:57 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

Dear Kapal,

I think (b) (5)

That said, I don't think (b) (5)

(b) (5)
[Redacted]
[Redacted]
[Redacted]. I think (b) (5)
[Redacted]
[Redacted]
[Redacted]

Best wishes,

Susan

From: Dewan, Kapal
Sent: Wednesday, October 30, 2019 8:29 AM
To: Spence, Susan <Susan.Spence@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call
Importance: High

Susan,

Can you (b) (5) ?

Kapal

From: Sadrieh, Nakissa
Sent: Tuesday, October 29, 2019 6:37 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Spence, Susan <Susan.Spence@fda.hhs.gov>
Subject: Re: Follow up from today's 29 October call

I take it (b) (5)
[Redacted]
[Redacted] ?
By this I mean (b) (5)
[Redacted]

I am adding Susan because she has made similar summary tables for the working group and she can help Steve, Kapal and I, who will also have to work on this.

If another talc and asbestos-related assignment comes in, between now and Friday, I request that Debbie take care of that.

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Date: October 29, 2019 at 5:26:35 PM EDT
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Subject: FW: Follow up from today's 29 October call

Please create a (b) (4), (b) (5) . Due by Friday.

From: Musser, Steven M <Steven.Musser@fda.hhs.gov>
Sent: Tuesday, October 29, 2019 5:14 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: FW: Follow up from today's 29 October call

It looks as (b) (5)

From: "Kuntz, Thomas" <Thomas.Kuntz@fda.hhs.gov>
Date: Tuesday, October 29, 2019 at 4:15 PM
To: Linda Katz <Linda.Katz@fda.hhs.gov>, "Dewan, Kapal" <Kapal.Dewan@fda.hhs.gov>, "Sadrieh, Nakissa" <Nakissa.Sadrieh@fda.hhs.gov>, "Wolfgang, Steven" <Steven.Wolfgang@fda.hhs.gov>, "Jabs, Alexandra" <Alexandra.Jabs@fda.hhs.gov>, "Jasperse, Carie" <Carie.Jasperse@fda.hhs.gov>, "Roosevelt, Michael" <Michael.Roosevelt@fda.hhs.gov>, "Dooren, Jennifer" <Jennifer.Dooren@fda.hhs.gov>, "Lanham, Ruark" <Ruark.Lanham@fda.hhs.gov>, "Pack, Randy" <Randy.Pack@fda.hhs.gov>, "Darlington, Leonora" <Leonora.Darlington@fda.hhs.gov>, "Barringer, Amy" <Amy.Barringer@fda.hhs.gov>
Cc: William Correll <William.Correll@fda.hhs.gov>, Susan Mayne <Susan.Mayne@fda.hhs.gov>, "Musser, Steven M" <Steven.Musser@fda.hhs.gov>, "Stearn, Douglas" <Douglas.Stearn@fda.hhs.gov>, "Beckerman, Peter" <Peter.Beckerman@fda.hhs.gov>, "Stone, Dyana" <Dyana.Stone@fda.hhs.gov>, "Lewis, Kathleen" <Kathleen.Lewis@fda.hhs.gov>, "Gasper, John" <John.Gasper@fda.hhs.gov>, "Ingram, Shannon" <Shannon.Ingram@fda.hhs.gov>, ORA Recall OE <orarecalloe@fda.hhs.gov>
Subject: FW: Follow up from today's 29 October call

Documents from J&J as promised during today's call.

From: Szczepaniak, Lynne [CPCUS] [<mailto:lszczepa@ITS.JNJ.com>]
Sent: Tuesday, October 29, 2019 3:02 PM
To: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>
Cc: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>; Zuyev, Natasha [CPCUS] <nzuyev@ITS.JNJ.com>; Williams, Bobette [MCCUS] <BWilli10@its.jnj.com>; Scott, Elizabeth G. [MCCUS] <EGiulian@its.jnj.com>
Subject: FW: Follow up from today's 29 October call

Mr. Kuntz

We want to thank you again for scheduling the meeting to discuss results from our investigation of Johnson's Baby Powder recalled Lot #22318RB. As we discussed on the call, attached please find the following reports:

(b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)

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(b) (4)
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We also confirm, as we noted on today's call, that the samples tested by FDA were authentic. On the call, you asked about any discrepancies we noted in the sampling conducted by AMA based upon the AMA report. We will provide you with a detailed description of those discrepancies and information about the methods that you requested.

I have copied only you on this message per Dr Mayne's request to work with a single point of contact, however please forward this message to others who were on the call and anyone else who needs this information.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile (b) (6)(b) (6)
e-mail: lszczepa@its.jnj.com



From: [Katz, Linda](#)
To: [Sadrieh, Nakissa](#); [Wolfgang, Steven](#)
Cc: [Dewan, Kapal](#); [Lewis, Kathleen](#); [Spence, Susan](#)
Subject: Re: Follow up from today's 29 October call
Date: Tuesday, October 29, 2019 6:53:22 PM

(b) (5)

From: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Date: October 29, 2019 at 6:37:07 PM EDT
To: Katz, Linda <Linda.Katz@fda.hhs.gov>, Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>, Spence, Susan <Susan.Spence@fda.hhs.gov>
Subject: Re: Follow up from today's 29 October call

I take it (b) (5)

t? By this I mean (b) (5) (b) (5)
t.

I am adding Susan because she has made similar summary tables for the working group and she can help Steve, Kapal and I, who will also have to work on this.

If another (b) (5)

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Date: October 29, 2019 at 5:26:35 PM EDT
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Subject: FW: Follow up from today's 29 October call

Please create a (b) (5) . Due by Friday.

From: Musser, Steven M <Steven.Musser@fda.hhs.gov>
Sent: Tuesday, October 29, 2019 5:14 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: FW: Follow up from today's 29 October call

It looks as though (b) (5) . (b) (5)

(b) (5)

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From: "Kuntz, Thomas" <Thomas.Kuntz@fda.hhs.gov>

Date: Tuesday, October 29, 2019 at 4:15 PM

To: Linda Katz <Linda.Katz@fda.hhs.gov>, "Dewan, Kapal" <Kapal.Dewan@fda.hhs.gov>, "Sadrieh, Nakissa" <Nakissa.Sadrieh@fda.hhs.gov>, "Wolfgang, Steven" <Steven.Wolfgang@fda.hhs.gov>, "Jabs, Alexandra" <Alexandra.Jabs@fda.hhs.gov>, "Jasperse, Carie" <Carie.Jasperse@fda.hhs.gov>, "Roosevelt, Michael" <Michael.Roosevelt@fda.hhs.gov>, "Dooren, Jennifer" <Jennifer.Dooren@fda.hhs.gov>, "Lanham, Ruark" <Ruark.Lanham@fda.hhs.gov>, "Pack, Randy" <Randy.Pack@fda.hhs.gov>, "Darlington, Leonora" <Leonora.Darlington@fda.hhs.gov>, "Barringer, Amy" <Amy.Barringer@fda.hhs.gov>

Cc: William Correll <William.Correll@fda.hhs.gov>, Susan Mayne <Susan.Mayne@fda.hhs.gov>, "Musser, Steven M" <Steven.Musser@fda.hhs.gov>, "Stearn, Douglas" <Douglas.Stearn@fda.hhs.gov>, "Beckerman, Peter" <Peter.Beckerman@fda.hhs.gov>, "Stone, Dyana" <Dyana.Stone@fda.hhs.gov>, "Lewis, Kathleen" <Kathleen.Lewis@fda.hhs.gov>, "Gasper, John" <John.Gasper@fda.hhs.gov>, "Ingram, Shannon" <Shannon.Ingram@fda.hhs.gov>, ORA Recall OE <orarecalloe@fda.hhs.gov>

Subject: FW: Follow up from today's 29 October call

Documents from J&J as promised during today's call.

From: Szczepaniak, Lynne [CPCUS] [<mailto:lszczepa@ITS.JNJ.com>]

Sent: Tuesday, October 29, 2019 3:02 PM

To: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>

Cc: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>; Zuyev, Natasha [CPCUS] <nzuyev@ITS.JNJ.com>; Williams, Bobette [MCCUS] <BWilli10@its.jnj.com>; Scott, Elizabeth G. [MCCUS] <EGiulian@its.jnj.com>

Subject: FW: Follow up from today's 29 October call

Mr. Kuntz

We want to thank you again for scheduling the meeting to discuss results from our investigation of Johnson's Baby Powder recalled Lot #22318RB. As we discussed on the call, attached please find the following reports:

(b) (4)
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(b) (4)
(b) (4)
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(b) (4)

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I have copied only you on this message per Dr Mayne's request to work with a single point of contact, however please forward this message to others who were on the call and anyone else who needs this information.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: (b) (6)(b) (6)
e-mail: lszczepa@its.jnj.com



CONSERVE OUR RESOURCES. PLEASE DO NOT PRINT THIS E-MAIL UNLESS NECESSARY.

From: [Dewan, Kapal](#)
To: [Jasperse, Carie](#); [Katz, Linda](#)
Cc: [Wolfgang, Steven](#); [Gasper, John](#); [Scarborough, Kim](#); [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Date: Saturday, October 19, 2019 9:30:44 AM
Attachments: [IMG_4079.JPG](#)
[IMG_4080.JPG](#)
[IMG_4081.JPG](#)
[IMG_4082.JPG](#)
[IMG_4073.JPG](#)
[IMG_4074.JPG](#)
[IMG_4075.JPG](#)
[IMG_4076.JPG](#)
[IMG_4077.JPG](#)
[IMG_4078.JPG](#)
[FINAL OCAC Sample handling for testing by outside lab 05 21 19 10 18 19.docx..docx](#)
[analytical protocol for D58.pdf](#)
Importance: High

Carie,

Here are the attachments that are mentioned (b) (5) . (b) (5)
(b) (5) !

Thanks again,
Kapal

From: Dewan, Kapal
Sent: Saturday, October 19, 2019 7:53 AM
To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Importance: High

Carie,

(b) (5)
.

(b) (5)
.
Can you (b) (5)
(b) (5) ?

Thank you in advance!
Kapal

From: Katz, Linda
Sent: Friday, October 18, 2019 9:21 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

(b) (5) (b) (5) (b) (5)

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 18, 2019 at 7:50:39 PM EDT
To: Katz, Linda <Linda.Katz@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>, Gasper, John <John.Gasper@fda.hhs.gov>, Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Subject: FW: Johnson Baby Powder lot #22318RB - (b) (5)
Importance: High

Hello,

Please see below in blue text what we have proposed (b) (5)

We are calling a day now. Team will reconvene on Monday morning.

My sincere thanks to Steve, John, and Kim who worked way more than I can ask for to plan for next week.

Kapal

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Friday, October 18, 2019 3:42 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>
Subject: Johnson Baby Powder lot #22318RB

Hello John and Kapal,

Pursuant to FDA's agreement to help facilitate materials for our investigation of Johnson's Baby Powder lot #22318RB, we request support for the following:

- 75grams of J&J Baby Powder from the original J&J Baby Powder bottle lot #22318RB

OCAC's response: 75 grams of J&J Baby Powder in J&J provided container from the original J&J Baby Powder bottle lot #22318RB can be given to the firm.

- Access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing (to determine authenticity)

OCAC's response: FDA can provide access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing.

- A Picture of the original container sampled, prior to opening

OCAC's response: FDA has the photos of the front and back panel of original container sampled (attached)

- Picture or evidence the original tamper seals were intact prior to sampling

OCAC's response: FDA has the photo of the top seal (attached)

- A sample from any remaining J&J Baby Powder from the blinded sample containers (D58 308006-6A; D58 308006-6B) tested by AMA

OCAC's response: A sample from the remaining J&J Baby Powder from the blinded sample containers can be provided.

- AMA Labs Talc Testing SOP & Protocol

OCAC's response: Pages from AMA Lab report showing sample preparation, analysis, methods of calculations of asbestos fiber mass is attached (see file titled analytical protocol for D58).

- AMA sample preparation methods for preparation of reference control standard using Sigma-Aldrich spike with 10% chrysolite

OCAC's response: Team is not comfortable sharing the AMA QA Manual and reference control standards without AMA's permission.

- Analysis and/or TEM photos of the Sigma-Aldrich spiked with 10% chrysolite

Asked AMA - TEM was requested from AMA, and if available will provide.

Waiting for a response.

- Any asbestos environmental testing for the area used in FDA blinded sample preparation and at AMA laboratories testing labs

OCAC's response: FDA does not have any records for environmental testing for the area in which blinded samples were prepared; however, the D58 blinded sample was prepared on the same day as 14 other blinded samples were prepared with no indication that there was any contamination at the time D58 was prepared.

FDA's Standard operating procedure for preparation of samples for Blind

testing of Talc (D58 308006 series)

OCAC's response: FDA's SOP - File titled Final OCAC Sample handling for testing by outside lab (attached)

- Documentation for the chain of custody including any invoices for the purchase of the samples from the online retailer

Both documents were sent to Kay for redaction.

As the investigation is of the utmost importance, we will be available to receive any of the above material, as soon as each of them are available and at the earliest convenience.

I look forward to hearing from you soon,

Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: (b) (6)

pedson@its.jnj.com
<http://www.jnj.com>

From: [Wolfgang, Steven](#)
To: [Dewan, Kapal](#); [Gasper, John](#)
Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)
Date: Sunday, October 20, 2019 1:10:00 PM

John, Please call me to discuss or wait until I arrive before calling.

Steve

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 19, 2019 at 9:45:43 PM EDT
To: Gasper, John <John.Gasper@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: FW: Johnson Baby Powder lot #22318RB - (b) (5)
Importance: High

John,

(b) (5)

Thanks,
Kapal

From: Jasperse, Carie
Sent: Saturday, October 19, 2019 4:44 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

(b) (5)

(b) (5)

? (b) (5)

? (b) (5)

From: Dewan, Kapal
Sent: Saturday, October 19, 2019 2:04 PM
To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Importance: High

(b) (5)

Bill,

Please see below the email from J&J that includes a number of materials that they have asked. They are planning to come on Monday, 10/21/2019 at 11:00 am to collect a sample of the retail container product and blinded sample and other materials. OCAC's response is in blue font that is included in the email from J&J. (b) (5)

Thank you,
Kapal

From: Jasperse, Carie

Sent: Saturday, October 19, 2019 12:07 PM

To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

Kapal - I will look this over but please also consult with Bill Correll on this. Thanks, Carie

From: Dewan, Kapal

Sent: Saturday, October 19, 2019 7:53 AM

To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Importance: High

Carie,

You may already know that J&J baby powder product was found to be contaminated with asbestos.

We had three telecons with them and they are recalling.

J&J is planning to come on Monday, 10/21/2019 around 11:00 am to collect the product, sample tested and have requested a number of other items. They have sent us a list of items/ material that is listed below in their email to FDA from Paul Edson. We had proposed (b) (5)

[Redacted]
[Redacted] ?

Thank you in advance!

Kapal

From: Katz, Linda
Sent: Friday, October 18, 2019 9:21 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

(b) (5)

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 18, 2019 at 7:50:39 PM EDT
To: Katz, Linda <Linda.Katz@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>, Gasper, John <John.Gasper@fda.hhs.gov>, Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Subject: FW: Johnson Baby Powder lot #22318RB - (b) (5)
Importance: High

Hello,

Please see below in blue text what we have proposed (b) (5)

We are calling a day now. Team will reconvene on Monday morning.

My sincere thanks to Steve, John, and Kim who worked way more than I can ask for to plan for next week.

Kapal

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>

Sent: Friday, October 18, 2019 3:42 PM

To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>

Subject: Johnson Baby Powder lot #22318RB

Hello John and Kapal,

Pursuant to FDA's agreement to help facilitate materials for our investigation of Johnson's Baby Powder lot #22318RB, we request support for the following:

- 75grams of J&J Baby Powder from the original J&J Baby Powder bottle lot #22318RB

OCAC's response: 75 grams of J&J Baby Powder in J&J provided container from the original J&J Baby Powder bottle lot #22318RB can be given to the firm.

- Access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing (to determine authenticity)

OCAC's response: FDA can provide access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing.

- A Picture of the original container sampled, prior to opening

OCAC's response: FDA has the photos of the front and back panel of original container sampled (attached)

- Picture or evidence the original tamper seals were intact prior to sampling

OCAC's response: FDA has the photo of the top seal (attached)

- A sample from any remaining J&J Baby Powder from the blinded sample containers (D58 308006-6A; D58 308006-6B) tested by AMA

OCAC's response: A sample from the remaining J&J Baby Powder from the blinded sample containers can be provided.

- AMA Labs Talc Testing SOP & Protocol

OCAC's response: Pages from AMA Lab report showing sample preparation, analysis, methods of calculations of asbestos fiber mass is attached (see file titled analytical protocol for D58).

- AMA sample preparation methods for preparation of reference control standard using Sigma-Aldrich spike with 10% chrysolite

OCAC's response: Team is not comfortable sharing the AMA QA Manual and reference control standards without AMA's permission.

Analysis and/or TEM photos of the Sigma-Aldrich spiked with 10% chrysolite

Asked AMA - TEM was requested from AMA, and if available will provide.

Waiting for a response.

- Any asbestos environmental testing for the area used in FDA blinded sample preparation and at AMA laboratories testing labs

OCAC's response: FDA does not have any records for environmental testing for the area in which blinded samples were prepared; however, the D58 blinded sample was prepared on the same day as 14 other blinded samples were prepared with no indication that there was any contamination at the time D58 was prepared.

FDA's Standard operating procedure for preparation of samples for Blind testing of Talc (D58 308006 series)

OCAC's response: FDA's SOP - File titled Final OCAC Sample handling for testing by outside lab (attached)

- Documentation for the chain of custody including any invoices for the purchase of the samples from the online retailer

Both documents were sent to Kay for redaction.

As the investigation is of the utmost importance, we will be available to receive any of the above material, as soon as each of them are available and at the earliest convenience.

I look forward to hearing from you soon,

Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: +1 (b) (6)

pedson@its.jnj.com
<http://www.jnj.com>

From: [Katz, Linda](#)
To: [Dewan, Kapal](#); [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Wolfgang, Steven](#); [Smegal, Deborah](#); [Roosevelt, Michael](#); [Scarborough, Kim](#)
Cc: [Gasper, John](#)
Subject: Re: Johnson Baby Powder lot #22318RB
Date: Friday, October 18, 2019 7:45:01 PM

Thanks fir the heads up

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 18, 2019 at 6:57:26 PM EDT
To: Katz, Linda <Linda.Katz@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>, Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>, Roosevelt, Michael <Michael.Roosevelt@fda.hhs.gov>, Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: FW: Johnson Baby Powder lot #22318RB

FYI—As per email below, J&J plans to be onsite on Monday late morning.

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Friday, October 18, 2019 6:15 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>
Subject: Re: Johnson Baby Powder lot #22318RB

We plan to be onsite to pick up the sample late morning. I do not yet have the name of the individual. We will notify you of the individuals ASAP. Thank you!

Paul

On Oct 18, 2019, at 5:16 PM, Gasper, John <John.Gasper@fda.hhs.gov> wrote:

Mr. Edson,

Please bring your own container to use for sample collection. Thank you.

Regards,

John Gasper

CFSAN
Office of Cosmetics and Colors
U.S. Food and Drug Administration
Tel: 240-402-1133

john.gasper@fda.hhs.gov

[<image007.png>](#)

[<image008.jpg>](#)

[<image009.jpg>](#)

[<image010.jpg>](#)

[<image011.jpg>](#)

[<image012.jpg>](#)

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Friday, October 18, 2019 3:42 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
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tested by AMA

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I look forward to hearing from you soon,

Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: (b) (6)

pedson@its.jnj.com
<http://www.jnj.com>

From: [Crane, Dan - OSHA](#)
To: [Wolfgang, Steven](#)
Subject: RE: Confidential: For 2nd opinion
Date: Monday, October 07, 2019 5:02:03 PM

(b) (5) _____, assuming (b) (5) _____
(b) (5) _____

Dan

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Monday, October 7, 2019 2:43 PM
To: Crane, Dan - OSHA <Crane.Dan@dol.gov>
Subject: Confidential: For 2nd opinion

Hi Dan,

(b) (5) _____
_____ (b) (5) _____

Thanks,
Steve
Steven Wolfgang, Ph.D.
Consumer Safety Officer
Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
College Park, MD
301-796-3264
240-328-9827

From: [Wolfgang, Steven](#)
To: [Sadrieh, Nakissa](#); [Dewan, Kapal](#); [Katz, Linda](#); [Lewis, Kathleen](#); [Gasper, John](#)
Subject: RE: Follow up from today's 29 October call
Date: Wednesday, October 30, 2019 10:58:00 AM

Good morning,

(b) (5)

we need (b) (5)

etc.

Steve

From: Sadrieh, Nakissa
Sent: Wednesday, October 30, 2019 9:24 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

What I meant to ask (b) (5)

In other words, (b) (5)

(b) (5) ? That is all that I am asking.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Wednesday, October 30, 2019 9:21 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

(b) (5)

From: Sadrieh, Nakissa

Sent: Wednesday, October 30, 2019 9:17 AM

To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>

Subject: RE: Follow up from today's 29 October call

Kapal,

Does this mean (b) (5) ?

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Sent: Wednesday, October 30, 2019 9:13 AM

To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>

Subject: RE: Follow up from today's 29 October call

(b) (5)

Kapal

From: Szczepaniak, Lynne [CPCUS] [<mailto:lszczepa@ITS.JNJ.com>]

Sent: Tuesday, October 29, 2019 3:02 PM

To: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>

Cc: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>; Zuyev, Natasha [CPCUS] <nzuyev@ITS.JNJ.com>; Williams, Bobette [MCCUS] <BWilli10@its.jnj.com>; Scott, Elizabeth G. [MCCUS]

<EGiulian@its.jnj.com>

Subject: FW: Follow up from today's 29 October call

Mr. Kuntz

We want to thank you again for scheduling the meeting to discuss results from our investigation of Johnson's Baby Powder recalled Lot #22318RB. As we discussed on the call, attached please find the following reports:

(b) (4)

[Redacted content]

We would like to discuss these reports and findings, along with details of our full investigation. As we discussed, our investigation is on-going and we are in the process of doing additional testing. We will update you once we have additional results.

We also confirm, as we noted on today's call, that the samples tested by FDA were authentic. On the call, you asked about any discrepancies we noted in the sampling conducted by AMA based upon the AMA report. We will provide you with a detailed description of those discrepancies and information about the methods that you requested.

I have copied only you on this message per Dr Mayne's request to work with a single point of contact, however please forward this message to others who were on the call and anyone else who needs this information.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: (b) (6)(b) (6)
e-mail: lszczepa@its.jnj.com



CONSERVE OUR RESOURCES. PLEASE DO NOT PRINT THIS E-MAIL UNLESS NECESSARY.

From: [Wolfgang, Steven](#)
To: [Dewan, Kapal](#); [Sadrieh, Nakissa](#); [Katz, Linda](#); [Lewis, Kathleen](#); [Gasper, John](#)
Subject: RE: Follow up from today's 29 October call
Date: Wednesday, October 30, 2019 9:59:00 AM
Attachments: [J&J Method TM7024.pdf](#)

(b) (5)

(b) (5)

How this (b) (5)

Steve

From: Dewan, Kapal
Sent: Wednesday, October 30, 2019 9:13 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

(b) (5)

Kapal

From: Szczepaniak, Lynne [CPCUS] [<mailto:lszczepa@ITS.JNJ.com>]
Sent: Tuesday, October 29, 2019 3:02 PM
To: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>
Cc: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>; Zuyev, Natasha [CPCUS] <nzuyev@ITS.JNJ.com>; Williams, Bobette [MCCUS] <BWilli10@its.jnj.com>; Scott, Elizabeth G. [MCCUS] <EGiulian@its.jnj.com>
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Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: (b) (6)(b) (6)
e-mail: lszczepa@its.jnj.com



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From: [Sadrieh, Nakissa](#)
To: [Dewan, Kapal](#); [Katz, Linda](#); [Wolfgang, Steven](#); [Lewis, Kathleen](#); [Gasper, John](#)
Subject: RE: Follow up from today's 29 October call
Date: Wednesday, October 30, 2019 9:47:18 AM

Linda wants a summary table this Friday, so I leave it to you to deliver what is needed, since I must do other work. Just let me know if you need something specific from me.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Wednesday, October 30, 2019 9:35 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

Methods are **described very briefly** but would let Steve make that call as the SME.

From: Sadrieh, Nakissa
Sent: Wednesday, October 30, 2019 9:24 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

What I meant to ask is whether we have the information to make a summary table comparing the methods used by the 2 labs used by J7J, with the method used by AMA. In other words, do you see methods described in what you skimmed? That is all that I am asking.

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Tel: 240-402-2194

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Wednesday, October 30, 2019 9:21 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>;
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Subject: RE: Follow up from today's 29 October call

Kapal,

Does this mean that we can or cannot make the table that Linda has asked for?

Regards,
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Center for Food Safety and Applied Nutrition (CFSAN)
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Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>;
Gasper, John <John.Gasper@fda.hhs.gov>

Subject: RE: Follow up from today's 29 October call

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Kapal

From: Szczepaniak, Lynne [CPCUS] [<mailto:lszczepa@ITS.JNJ.com>]
Sent: Tuesday, October 29, 2019 3:02 PM
To: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>
Cc: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>; Zuyev, Natasha [CPCUS] <nzuyev@ITS.JNJ.com>; Williams, Bobette [MCCUS] <BWilli10@its.jnj.com>; Scott, Elizabeth G. [MCCUS] <EGiulian@its.jnj.com>
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Johnson & Johnson Consumer Inc.

mobile: **(b) (6)(b) (6)**

e-mail: lszczepa@its.jnj.com



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From: [Dewan, Kapal](#)
To: [Sadrieh, Nakissa](#); [Katz, Linda](#); [Wolfgang, Steven](#); [Lewis, Kathleen](#); [Gasper, John](#)
Subject: RE: Follow up from today's 29 October call
Date: Wednesday, October 30, 2019 9:34:53 AM

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From: Sadrieh, Nakissa
Sent: Wednesday, October 30, 2019 9:24 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
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5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

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Subject: RE: Follow up from today's 29 October call

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Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

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Sent: Wednesday, October 30, 2019 9:13 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>;
Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>;
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Kapal

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To: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>
Cc: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>; Zuyev, Natasha [CPCUS] <nzuyev@ITS.JNJ.com>;
Williams, Bobette [MCCUS] <BWilli10@its.jnj.com>; Scott, Elizabeth G. [MCCUS]
<EGiulian@its.jnj.com>
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To: [Dewan, Kapal](#); [Katz, Linda](#); [Wolfgang, Steven](#); [Lewis, Kathleen](#); [Gasper, John](#)
Subject: RE: Follow up from today's 29 October call
Date: Wednesday, October 30, 2019 9:23:42 AM

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Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
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5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Wednesday, October 30, 2019 9:21 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

I have ONLY skimmed through the reports so too early to state what can be included in the summary table. There are 300 pages that we have to go through before we can make a summary table.

From: Sadrieh, Nakissa
Sent: Wednesday, October 30, 2019 9:17 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

Kapal,

Does this mean that we can or cannot make the table that Linda has asked for?

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)

From: [Dewan, Kapal](#)
To: [Sadrieh, Nakissa](#); [Katz, Linda](#); [Wolfgang, Steven](#); [Lewis, Kathleen](#); [Gasper, John](#)
Subject: RE: Follow up from today's 29 October call
Date: Wednesday, October 30, 2019 9:21:14 AM

I have ONLY skimmed through the reports so too early to state what can be included in the summary table. There are 300 pages that we have to go through before we can make a summary table.

From: Sadrieh, Nakissa
Sent: Wednesday, October 30, 2019 9:17 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

Kapal,

Does this mean that we can or cannot make the table that Linda has asked for?

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Wednesday, October 30, 2019 9:13 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

I have checked the incoming documents that were forwarded last evening to prepare a summary of test methods. We have received 3 reports of the testing conducted by RJ Lee. However, ONLY a preliminary update letter to J&J (**NO testing data**) from the second independent lab was sent yesterday. Testing data from BV Laboratories has not been provided as mentioned in the 2nd bullet in the email below.

Kapal

From: Szczepaniak, Lynne [CPCUS] [<mailto:lszczepa@ITS.JNJ.com>]
Sent: Tuesday, October 29, 2019 3:02 PM

From: [Sadrieh, Nakissa](#)
To: [Dewan, Kapal](#); [Katz, Linda](#); [Wolfgang, Steven](#); [Lewis, Kathleen](#); [Gasper, John](#)
Subject: RE: Follow up from today's 29 October call
Date: Wednesday, October 30, 2019 9:16:34 AM

Kapal,

Does this mean that we can or cannot make the table that Linda has asked for?

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Wednesday, October 30, 2019 9:13 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: Follow up from today's 29 October call

I have checked the incoming documents that were forwarded last evening to prepare a summary of test methods. We have received 3 reports of the testing conducted by RJ Lee. However, ONLY a preliminary update letter to J&J (**NO testing data**) from the second independent lab was sent yesterday. Testing data from BV Laboratories has not been provided as mentioned in the 2nd bullet in the email below.

Kapal

From: Szczepaniak, Lynne [CPCUS] [<mailto:lszczepa@ITS.JNJ.com>]
Sent: Tuesday, October 29, 2019 3:02 PM
To: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>
Cc: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>; Zuyev, Natasha [CPCUS] <nzuyev@ITS.JNJ.com>; Williams, Bobette [MCCUS] <BWilli10@its.jnj.com>; Scott, Elizabeth G. [MCCUS] <EGiulian@its.jnj.com>
Subject: FW: Follow up from today's 29 October call

Mr. Kuntz

We want to thank you again for scheduling the meeting to discuss results from our investigation of Johnson's Baby Powder recalled Lot #22318RB. As we discussed on the call, attached please find

the following reports:

(b) (4)

[REDACTED]

[REDACTED]

[REDACTED]

We would like to discuss these reports and findings, along with details of our full investigation. As we discussed, our investigation is on-going and we are in the process of doing additional testing. We will update you once we have additional results.

We also confirm, as we noted on today's call, that the samples tested by FDA were authentic. On the call, you asked about any discrepancies we noted in the sampling conducted by AMA based upon the AMA report. We will provide you with a detailed description of those discrepancies and information about the methods that you requested.

I have copied only you on this message per Dr Mayne's request to work with a single point of contact, however please forward this message to others who were on the call and anyone else who needs this information.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: (b) (6)(b) (6)
e-mail: lszczepa@its.jnj.com



CONSERVE OUR RESOURCES. PLEASE DO NOT PRINT THIS E-MAIL UNLESS NECESSARY.

From: [Dewan, Kapal](#)
To: [Barrows, Julie N](#)
Cc: [Katz, Linda](#); [Bowes, Bryan](#); [Sadrieh, Nakissa](#); [Wolfgang, Steven](#); [Belai, Nebebech](#)
Subject: RE: Hood use - Monday morning 10/21
Date: Monday, October 21, 2019 10:18:00 AM

Great. Thank you so much.

From: Barrows, Julie N
Sent: Monday, October 21, 2019 10:16 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Katz, Linda <Linda.Katz@fda.hhs.gov>; Bowes, Bryan <Bryan.Bowes@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Belai, Nebebech <Nebebech.Belai@fda.hhs.gov>
Subject: RE: Hood use - Monday morning 10/21

Kapal,

We have found a hood that isn't in use this morning.

Julie

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Friday, October 18, 2019 6:48 PM
To: Belai, Nebebech <Nebebech.Belai@fda.hhs.gov>
Cc: Bowes, Bryan <Bryan.Bowes@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Barrows, Julie N <Julie.Barrows@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: Hood use - Monday morning 10/21
Importance: High

Neely,

(b) (5)



Thanks in advance!

Kapal

From: Katz, Linda
Sent: Friday, October 18, 2019 2:19 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Smegal, Deborah

From: [Barrows, Julie N](#)
To: [Dewan, Kapal](#)
Cc: [Katz, Linda](#); [Bowes, Bryan](#); [Sadrieh, Nakissa](#); [Wolfgang, Steven](#); [Belai, Nebebech](#)
Subject: RE: Hood use - Monday morning 10/21
Date: Monday, October 21, 2019 10:16:24 AM

Kapal,

We have found a hood that isn't in use this morning.

Julie

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Friday, October 18, 2019 6:48 PM
To: Belai, Nebebech <Nebebech.Belai@fda.hhs.gov>
Cc: Bowes, Bryan <Bryan.Bowes@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Barrows, Julie N <Julie.Barrows@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: Hood use - Monday morning 10/21
Importance: High

Neely,

(b) (5)
[Redacted]

Thanks in advance!
Kapal

From: Katz, Linda
Sent: Friday, October 18, 2019 2:19 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

(b) (5)
[Redacted]

From: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Sent: Friday, October 18, 2019 2:10 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

Hi John,

I thought we were good with this:

- (b) (5) [REDACTED]
- [REDACTED]
- [REDACTED]

Did I miss anything?

Kay Lewis
Senior Advisor
OCAC/CFSAN/FDA
240-402-1129 office
240-825-9944 bb

NOTE: This e-mail message is intended for the exclusive use of the recipient's named above. It may contain information that is protected, privileged, or confidential, and it must not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately.

From: Gasper, John <John.Gasper@fda.hhs.gov>
Sent: Friday, October 18, 2019 2:05 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: J&J Has Contacted Me About Logistics of Providing Sample

To All:

Please note that a Mr. Paul Edson of J&J (ph: 215-350-0653) left me a phone message earlier. He wants to discuss the logistics of how to arrange providing a sample to J&J. I have not returned his call yet. (b) (5) [REDACTED]. Thank you.

Regards,
John G

From: [Correll, William A](#)
To: [Dewan, Kapal](#); [Jasperse, Carie](#); [Katz, Linda](#); [Roosevelt, Michael](#)
Cc: [Wolfgang, Steven](#); [Gasper, John](#); [Scarborough, Kim](#); [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Date: Monday, October 21, 2019 8:38:31 AM

Kapal:

The proposed (b) (5) .

Bill

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 19, 2019 at 4:58:02 PM EDT
To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>, Correll, William A <William.Correll@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>, Gasper, John <John.Gasper@fda.hhs.gov>, Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Carie,

Much appreciated you getting back. (b) (5)

For AMA QA Manual and reference control standards – will contact AMA. (b) (5)
(b) (5) our proposed response, for which my sincere thanks.

Bill,

We wait to hear from your end asap.

Thanks,
Kapal

From: Jasperse, Carie
Sent: Saturday, October 19, 2019 4:44 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>;

Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

(b) (5)

From: Dewan, Kapal

Sent: Saturday, October 19, 2019 2:04 PM

To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Importance: High

Thanks Carie. Looking forward to your suggestions. I have added Bill to this email.

Bill,

Please see below the email from J&J that includes a number of materials that they have asked. They are planning to come on Monday, 10/21/2019 at 11:00 am to collect a sample of the retail container product and blinded sample and other materials. OCAC's response is in blue font that is included in the email from J&J. (b) (4)

Thank you,
Kapal

From: Jasperse, Carie

Sent: Saturday, October 19, 2019 12:07 PM

To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

(b) (5)

From: Dewan, Kapal

Sent: Saturday, October 19, 2019 7:53 AM

To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Importance: High

Carie,

You may already know that J&J baby powder product was found to be contaminated with asbestos. We had three telecons with them and they are recalling.

J&J is planning to come on Monday, 10/21/2019 around 11:00 am to collect the product, sample tested and have requested a number of other items. They have sent us a list of items/ material that is listed below in their email to FDA from Paul Edson. We had proposed (b) (5)

[REDACTED]

[REDACTED] ?

Thank you in advance!

Kapal

From: Katz, Linda

Sent: Friday, October 18, 2019 9:21 PM

To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>

Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

(b) (5)

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Date: October 18, 2019 at 7:50:39 PM EDT

To: Katz, Linda <Linda.Katz@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>, Gasper, John <John.Gasper@fda.hhs.gov>, Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>

Subject: FW: Johnson Baby Powder lot #22318RB - (b) (5)

Importance: High

From: [Jasperse, Carie](#)
To: [Dewan, Kapal](#); [Katz, Linda](#)
Cc: [Wolfgang, Steven](#); [Gasper, John](#); [Scarborough, Kim](#); [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)
Date: Saturday, October 19, 2019 12:06:50 PM

(b) (5)

From: Dewan, Kapal
Sent: Saturday, October 19, 2019 9:30 AM
To: Jasperse, Carie; Katz, Linda
Cc: Wolfgang, Steven; Gasper, John; Scarborough, Kim; Sadrieh, Nakissa; Lewis, Kathleen; Smegal, Deborah
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Carie,

Here are the attachments that are mentioned below in FDA's response in blue font. Looking forward for your guidance!

Thanks again,
Kapal

From: Dewan, Kapal
Sent: Saturday, October 19, 2019 7:53 AM
To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Importance: High

Carie,

You may already know that J&J baby powder product was found to be contaminated with asbestos. We had three telecons with them and they are recalling.

J&J is planning to come on Monday, 10/21/2019 around 11:00 am to collect the product, sample tested and have requested a number of other items. They have sent us a list of items/ material that is listed below in their email to FDA from Paul Edson. We had proposed (b) (5)

e?

Thank you in advance!
Kapal

From: [Correll, William A](#)
To: [Dewan, Kapal](#); [Jasperse, Carie](#); [Katz, Linda](#)
Cc: [Wolfgang, Steven](#); [Gasper, John](#); [Scarborough, Kim](#); [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Date: Monday, October 21, 2019 8:31:33 AM

+ Michael Roosevelt

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 19, 2019 at 5:01:00 PM EDT
To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>, Correll, William A <William.Correll@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>, Gasper, John <John.Gasper@fda.hhs.gov>, Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Okay. Will mention it to Kay who is going to do the redactions. Thanks for reminding.

Kay,

Please see below Carie's suggestion regarding redactions.

Thanks,
Kapal

From: Jasperse, Carie
Sent: Saturday, October 19, 2019 4:54 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

Also, please have the CFSAN FOIA office review the redactions.

From: Jasperse, Carie
Sent: Saturday, October 19, 2019 4:44 PM
To: Dewan, Kapal; Katz, Linda; Correll, William A
Cc: Wolfgang, Steven; Gasper, John; Scarborough, Kim; Sadrieh, Nakissa; Lewis, Kathleen; Smegal, Deborah
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

(b) (5)

From: Dewan, Kapal

Sent: Saturday, October 19, 2019 2:04 PM

To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Importance: High

Thanks Carie. Looking forward to your suggestions. I have added Bill to this email.

Bill,

Please see below the email from J&J that includes a number of materials that they have asked. They are planning to come on Monday, 10/21/2019 at 11:00 am to collect a sample of the retail container product and blinded sample and other materials. OCAC's response is in blue font that is included in the email from J&J. (b) (5)

Thank you,
Kapal

From: Jasperse, Carie

Sent: Saturday, October 19, 2019 12:07 PM

To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

(b) (5)

From: Dewan, Kapal

Sent: Saturday, October 19, 2019 7:53 AM

To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa

<Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Importance: High

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Thank you in advance!

Kapal

From: Katz, Linda

Sent: Friday, October 18, 2019 9:21 PM

To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>

Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

Send it to OCC - Carie Jasperse - not sure if she'll get it done before they show up but try.

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Date: October 18, 2019 at 7:50:39 PM EDT

To: Katz, Linda <Linda.Katz@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

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Importance: High

Hello,

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To: [Jasperse, Carie](#); [Katz, Linda](#); [Correll, William A](#)
Cc: [Wolfgang, Steven](#); [Gasper, John](#); [Scarborough, Kim](#); [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Date: Saturday, October 19, 2019 5:01:00 PM

Okay. Will mention it to Kay who is going to do the redactions. Thanks for reminding.

Kay,

Please see below Carie's suggestion regarding redactions.

Thanks,
Kapal

From: Jasperse, Carie
Sent: Saturday, October 19, 2019 4:54 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
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Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

Kapal - I will look this over but please also consult with Bill Correll on this. Thanks, Carie

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To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>

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Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Date: Saturday, October 19, 2019 4:58:03 PM

Carie,

Much appreciated you getting back. Regarding OCAC SOP - We can take out the watermark "draft." This SOP has been implemented for the current AMA contract after it was office cleared as indicated in the document review history.

For AMA QA Manual and reference control standards – will contact AMA. We first wanted to make sure OCC concurs with our proposed response, for which my sincere thanks.

Bill,

We wait to hear from your end asap.

Thanks,
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FDA's Standard operating procedure for preparation of samples for Blind testing of Talc (D58 308006 series)

OCAC's response: FDA's SOP - File titled Final OCAC Sample handling for testing by outside lab (attached)

- Documentation for the chain of custody including any invoices for the purchase of the samples from the online retailer

Both documents were sent to Kay for redaction.

As the investigation is of the utmost importance, we will be available to receive any of the above material, as soon as each of them are available and at the earliest convenience.

I look forward to hearing from you soon,

Paul

Paul Edson
Vice President

Johnson & Johnson

Johnson & Johnson Regulatory Compliance (JJRC)

M: +(b) (6)

pedson@its.jnj.com

<http://www.jnj.com>

From: [Wolfgang, Steven](#)
To: [Dewan, Kapal](#); [Jasperse, Carie](#); [Katz, Linda](#); [Correll, William A](#)
Cc: [Gasper, John](#); [Scarborough, Kim](#); [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Date: Saturday, October 19, 2019 4:06:00 PM

Linda, et al

To update you, Dan Crane (OSHA) and I spoke regarding environmental sampling in the vicinity where sample transfer/blinding takes place. He conveyed concern that chrysotile is an unusual finding in talc and he feels there is a possibility of ambient airborne asbestos that needs to be ruled out. He and I then discussed how to get sampling performed using a 3rd party contractor.

Does CFSAN have any experience hiring contractors to perform environmental air sampling in a lab? Perhaps you can look into this for us?

Thanks,
Steve

From: Dewan, Kapal
Sent: Saturday, October 19, 2019 2:04 PM
To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Importance: High

Thanks Carie. Looking forward to your suggestions. I have added Bill to this email.

Bill,

Please see below the email from J&J that includes a number of materials that they have asked. They are planning to come on Monday, 10/21/2019 at 11:00 am to collect a sample of the retail container product and blinded sample and other materials. OCAC's response is in blue font that is included in the email from J&J. (b) (5)

Thank you,
Kapal

From: Jasperse, Carie
Sent: Saturday, October 19, 2019 12:07 PM

To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

(b) (5)

From: Dewan, Kapal
Sent: Saturday, October 19, 2019 7:53 AM
To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Importance: High

Carie,

You may already know that J&J baby powder product was found to be contaminated with asbestos. We had three telecons with them and they are recalling.

J&J is planning to come on Monday, 10/21/2019 around 11:00 am to collect the product, sample tested and have requested a number of other items. They have sent us a list of items/ material that is listed below in their email to FDA from Paul Edson. We had proposed below FDA's response in blue font. Can you please **review and let us know if these items can be released to J&J and what is the procedure?**

Thank you in advance!
Kapal

From: Katz, Linda
Sent: Friday, October 18, 2019 9:21 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

Send it to OCC - Carie Jasperse - not sure if she'll get it done before they show up but try.

From: [Dewan, Kapal](#)
To: [Jasperse, Carie](#); [Katz, Linda](#); [Correll, William A](#)
Cc: [Wolfgang, Steven](#); [Gasper, John](#); [Scarborough, Kim](#); [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Date: Saturday, October 19, 2019 2:05:01 PM
Attachments: [IMG 4079.JPG](#)
[IMG 4080.JPG](#)
[IMG 4081.JPG](#)
[IMG 4082.JPG](#)
[IMG 4073.JPG](#)
[IMG 4074.JPG](#)
[IMG 4075.JPG](#)
[IMG 4076.JPG](#)
[IMG 4077.JPG](#)
[IMG 4078.JPG](#)
[FINAL OCAC Sample handling for testing by outside lab 05 21 19 10 18 19.docx..docx](#)
[analytical protocol for D58.pdf](#)
Importance: High

Thanks Carie. Looking forward to your suggestions. I have added Bill to this email.

Bill,

Please see below the email from J&J that includes a number of materials that they have asked. They are planning to come on Monday, 10/21/2019 at 11:00 am to collect a sample of the retail container product and blinded sample and other materials. OCAC's response is in blue font that is included in the email from J&J. (b) (5)

Thank you,
Kapal

From: Jasperse, Carie
Sent: Saturday, October 19, 2019 12:07 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

(b) (5)

From: Dewan, Kapal
Sent: Saturday, October 19, 2019 7:53 AM
To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Importance: High

Carie,

You may (b) (5)

We had three telecons with them and they are recalling.

J&J is planning to come on Monday, 10/21/2019 around 11:00 am to collect the product, sample tested and have requested a number of other items. They have sent us a list of items/ material that is listed below in their email to FDA from Paul Edson. We had proposed (b) (5)

?

Thank you in advance!

Kapal

From: Katz, Linda

Sent: Friday, October 18, 2019 9:21 PM

To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>

Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

(b) (5)

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Date: October 18, 2019 at 7:50:39 PM EDT

To: Katz, Linda <Linda.Katz@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>, Gasper, John <John.Gasper@fda.hhs.gov>, Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>

Subject: FW: Johnson Baby Powder lot #22318RB - (b) (5)

Importance: High

Hello,

Please see below in blue text what we have proposed (b) (5)

We are calling a day now. Team will reconvene on Monday morning.

My sincere thanks to Steve, John, and Kim who worked way more than I can ask for to plan for next

week.

Kapal

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Friday, October 18, 2019 3:42 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>
Subject: Johnson Baby Powder lot #22318RB

Hello John and Kapal,

Pursuant to FDA's agreement to help facilitate materials for our investigation of Johnson's Baby Powder lot #22318RB, we request support for the following:

- 75grams of J&J Baby Powder from the original J&J Baby Powder bottle lot #22318RB

OCAC's response: 75 grams of J&J Baby Powder in J&J provided container from the original J&J Baby Powder bottle lot #22318RB can be given to the firm.

- Access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing (to determine authenticity)

OCAC's response: FDA can provide access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing.

- A Picture of the original container sampled, prior to opening

OCAC's response: FDA has the photos of the front and back panel of original container sampled (attached)

- Picture or evidence the original tamper seals were intact prior to sampling

OCAC's response: FDA has the photo of the top seal (attached)

- A sample from any remaining J&J Baby Powder from the blinded sample containers (D58 308006-6A; D58 308006-6B) tested by AMA

OCAC's response: A sample from the remaining J&J Baby Powder from the blinded sample containers can be provided.

- AMA Labs Talc Testing SOP & Protocol

OCAC's response: Pages from AMA Lab report showing sample preparation, analysis, methods of calculations of asbestos fiber mass is attached (see file titled analytical protocol for D58).

- AMA sample preparation methods for preparation of reference control

standard using Sigma-Aldrich spike with 10% chrysolite

OCAC's response: Team is not comfortable sharing the AMA QA Manual and reference control standards without AMA's permission.

- Analysis and/or TEM photos of the Sigma-Aldrich spiked with 10% chrysolite

Asked AMA - TEM was requested from AMA, and if available will provide.

Waiting for a response.

- Any asbestos environmental testing for the area used in FDA blinded sample preparation and at AMA laboratories testing labs

OCAC's response: FDA does not have any records for environmental testing for the area in which blinded samples were prepared; however, the D58 blinded sample was prepared on the same day as 14 other blinded samples were prepared with no indication that there was any contamination at the time D58 was prepared.

FDA's Standard operating procedure for preparation of samples for Blind testing of Talc (D58 308006 series)

OCAC's response: FDA's SOP - File titled Final OCAC Sample handling for testing by outside lab (attached)

- Documentation for the chain of custody including any invoices for the purchase of the samples from the online retailer

Both documents were sent to Kay for redaction.

As the investigation is of the utmost importance, we will be available to receive any of the above material, as soon as each of them are available and at the earliest convenience.

I look forward to hearing from you soon,

Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: +1 (b) (6)

pedson@its.jnj.com
<http://www.jnj.com>

From: [Sadrieh, Nakissa](#)
To: [Dewan, Kapal](#); [Correll, William A](#); [Jasperse, Carie](#); [Katz, Linda](#); [Roosevelt, Michael](#)
Cc: [Wolfgang, Steven](#); [Gasper, John](#); [Scarborough, Kim](#); [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Date: Monday, October 21, 2019 9:19:12 AM

Where did we leave the Q&As last Friday?

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Monday, October 21, 2019 9:18 AM
To: Correll, William A <William.Correll@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Roosevelt, Michael <Michael.Roosevelt@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Thank you so much. Much appreciated!

Best regards,
Kapal

From: Correll, William A
Sent: Monday, October 21, 2019 8:39 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Roosevelt, Michael <Michael.Roosevelt@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Kapal:

The proposed approach and response looks fine.

Bill

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 19, 2019 at 4:58:02 PM EDT
To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>, Correll, William A <William.Correll@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>, Gasper, John <John.Gasper@fda.hhs.gov>, Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Carie,

Much appreciated you getting back. Regarding (b) (5) k "draft."
(b) (5)

For AMA QA Manual and reference control standards – will contact AMA. We first wanted to make
(b) (5) my sincere thanks.

Bill,

We wait to hear from your end asap.

Thanks,
Kapal

From: Jasperse, Carie
Sent: Saturday, October 19, 2019 4:44 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

From: [Dewan, Kapal](#)
To: [Correll, William A](#); [Jasperse, Carie](#); [Katz, Linda](#); [Roosevelt, Michael](#)
Cc: [Wolfgang, Steven](#); [Gasper, John](#); [Scarborough, Kim](#); [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Date: Monday, October 21, 2019 9:18:09 AM

Thank you so much. Much appreciated!

Best regards,
Kapal

From: Correll, William A
Sent: Monday, October 21, 2019 8:39 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Roosevelt, Michael <Michael.Roosevelt@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Kapal:

The proposed (b) (5) .

Bill

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Date: October 19, 2019 at 4:58:02 PM EDT
To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>, Katz, Linda <Linda.Katz@fda.hhs.gov>, Correll, William A <William.Correll@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>, Gasper, John <John.Gasper@fda.hhs.gov>, Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - URGENT ATTENTION NEEDED

Carie,

Much appreciated you getting back. Regarding OCAC SOP - We can take out the watermark "draft." This SOP has been implemented for the current AMA contract after it was office cleared as indicated in the document review history.

For AMA QA Manual and reference control standards – will contact AMA. We first wanted to make sure OCC concurs with our proposed response, for which my sincere thanks.

Bill,

We wait to hear from your end asap.

Thanks,
Kapal

From: Jasperse, Carie
Sent: Saturday, October 19, 2019 4:44 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)

Kapal – I defer to Bill, but I am fine with your proposal. However, why is the OCAC SOP document marked draft? With regard to AMA QA Manual and reference control standards, has FDA asked AMA for their permission to release? Thanks, Carie

From: Dewan, Kapal
Sent: Saturday, October 19, 2019 2:04 PM
To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Importance: High

Thanks Carie. Looking forward to your suggestions. I have added Bill to this email.

Bill,

Please see below the email from J&J that includes a number of materials that they have asked. They are planning to come on Monday, 10/21/2019 at 11:00 am to collect a sample of the retail container product and blinded sample and other materials. OCAC's response is in blue font that is included in the email from J&J. (b) (5)

Thank you,
Kapal

From: Jasperse, Carie
Sent: Saturday, October 19, 2019 12:07 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

Kapal - I will look this over but please also consult with Bill Correll on this. Thanks, Carie

From: Dewan, Kapal
Sent: Saturday, October 19, 2019 7:53 AM
To: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Johnson Baby Powder lot #22318RB - (b) (5)
Importance: High

Carie,

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[REDACTED]

Thank you in advance!
Kapal

From: Katz, Linda
Sent: Friday, October 18, 2019 9:21 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>

Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>

Subject: Re: Johnson Baby Powder lot #22318RB - (b) (5)

(b) (5)) (5)

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Date: October 18, 2019 at 7:50:39 PM EDT

To: Katz, Linda <Linda.Katz@fda.hhs.gov>, Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>, Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>, Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>, Gasper, John <John.Gasper@fda.hhs.gov>, Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>

Subject: FW: Johnson Baby Powder lot #22318RB - (b) (5)

Importance: High

Hello,

Please see below in blue text what we have proposed (b) (5)

We are calling a day now. Team will reconvene on Monday morning.

My sincere thanks to Steve, John, and Kim who worked way more than I can ask for to plan for next week.

Kapal

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>

Sent: Friday, October 18, 2019 3:42 PM

To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>

Subject: Johnson Baby Powder lot #22318RB

Hello John and Kapal,

Pursuant to FDA's agreement to help facilitate materials for our investigation of Johnson's Baby Powder lot #22318RB, we request support for the following:

- 75grams of J&J Baby Powder from the original J&J Baby Powder bottle lot #22318RB

OCAC's response: 75 grams of J&J Baby Powder in J&J provided container from the original J&J Baby Powder bottle lot #22318RB can be given to the firm.

- Access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing (to determine authenticity)

OCAC's response: FDA can provide access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing.

- A Picture of the original container sampled, prior to opening

OCAC's response: FDA has the photos of the front and back panel of original container sampled (attached)

- Picture or evidence the original tamper seals were intact prior to sampling

OCAC's response: FDA has the photo of the top seal (attached)

- A sample from any remaining J&J Baby Powder from the blinded sample containers (D58 308006-6A; D58 308006-6B) tested by AMA

OCAC's response: A sample from the remaining J&J Baby Powder from the blinded sample containers can be provided.

- AMA Labs Talc Testing SOP & Protocol

OCAC's response: Pages from AMA Lab report showing sample preparation, analysis, methods of calculations of asbestos fiber mass is attached (see file titled analytical protocol for D58).

- AMA sample preparation methods for preparation of reference control standard using Sigma-Aldrich spike with 10% chrysolite

OCAC's response: Team in not comfortable sharing the AMA QA Manual and reference control standards without AMA's permission.

- Analysis and/or TEM photos of the Sigma-Aldrich spiked with 10% chrysolite

Asked AMA - TEM was requested from AMA, and if available will provide.

Waiting for a response.

- Any asbestos environmental testing for the area used in FDA blinded sample preparation and at AMA laboratories testing labs

OCAC's response: FDA does not have any records for environmental testing for the area in which blinded samples were prepared; however, the D58 blinded sample was prepared on the same day as 14 other blinded samples were prepared with no indication that there was any contamination at the time D58 was prepared.

FDA's Standard operating procedure for preparation of samples for Blind testing of Talc (D58 308006 series)

OCAC's response: FDA's SOP - File titled Final OCAC Sample handling for testing by outside lab (attached)

- Documentation for the chain of custody including any invoices for the

purchase of the samples from the online retailer

Both documents were sent to Kay for redaction.

As the investigation is of the utmost importance, we will be available to receive any of the above material, as soon as each of them are available and at the earliest convenience.

I look forward to hearing from you soon,

Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: +(b) (6)

pedson@its.jnj.com
<http://www.jnj.com>

From: [Sadrieh, Nakissa](#)
To: [Dewan, Kapal](#); [Katz, Linda](#); [Lewis, Kathleen](#); [Roosevelt, Michael](#); [Kuntz, Thomas](#); [Wolfgang, Steven](#); [Smegal, Deborah](#)
Cc: [Gasper, John](#); [Lanham, Ruark](#)
Subject: RE: Johnson Baby Powder lot #22318RB
Date: Friday, October 18, 2019 3:57:02 PM

Please propose the logistics of how the transfer will happen and where. We need all the materials identified for ease of access and we need to make sure that the copy room and conference room are reserved and nobody comes there while this is happening. If the labs are to be use for taking aliquots, as they will be, we need to inform colors and vacate the space. We need to determine procedures for letting outsiders into our labs.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Friday, October 18, 2019 3:53 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Roosevelt, Michael <Michael.Roosevelt@fda.hhs.gov>; Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>; Lanham, Ruark <Ruark.Lanham@fda.hhs.gov>
Subject: FW: Johnson Baby Powder lot #22318RB

FYI--

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Friday, October 18, 2019 3:42 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>
Subject: Johnson Baby Powder lot #22318RB

Hello John and Kapal,

Pursuant to FDA's agreement to help facilitate materials for our investigation of

Johnson's Baby Powder lot #22318RB, we request support for the following:

- 75grams of J&J Baby Powder from the original J&J Baby Powder bottle lot #22318RB
- Access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing (to determine authenticity)
- A Picture of the original container sampled, prior to opening
- Picture or evidence the original tamper seals were intact prior to sampling
- A sample from any remaining J&J Baby Powder from the blinded sample containers (D58 308006-6A; D58 308006-6B) tested by AMA
- AMA Labs Talc Testing SOP & Protocol
- AMA sample preparation methods for preparation of reference control standard using Sigma-Aldrich spike with 10% chrysolite
- Analysis and/or TEM photos of the Sigma-Aldrich spiked with 10% chrysolite
- Any asbestos environmental testing for the area used in FDA blinded sample preparation and at AMA laboratories testing labs
- FDA's Standard operating procedure for preparation of samples for Blind testing of Talc (D58 308006 series)
- Documentation for the chain of custody including any invoices for the purchase of the samples from the online retailer

As the investigation is of the utmost importance, we will be available to receive any of the above material, as soon as each of them are available and at the earliest convenience.

I look forward to hearing from you soon,

Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: +1 (b) (6)

From: [Lewis, Kathleen](#)
To: [Gasper, John](#); [Katz, Linda](#); [Sadrieh, Nakissa](#); [Smegal, Deborah](#); [Wolfgang, Steven](#)
Subject: RE: Johnson Baby Powder lot #22318RB
Date: Friday, October 25, 2019 9:37:35 AM
Attachments: [image001.png](#)

I'm checking (b) (5) .

Kay Lewis
Senior Advisor
OCAC/CFSAN/FDA
240-402-1129 office
240-825-9944 bb

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From: Gasper, John <John.Gasper@fda.hhs.gov>
Sent: Friday, October 25, 2019 9:31 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: FW: Johnson Baby Powder lot #22318RB

To All:

FYI, please see the attached letter from J&J asking for more information from us. Should (b) (5) (b) (5) ? Thank you.

Regards,
John G

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Thursday, October 24, 2019 5:00 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Williams, Bobette [MCCUS] <BWilli10@its.jnj.com>
Subject: Re: Johnson Baby Powder lot #22318RB

Hi John,

As discussed earlier, attached is a similar request for support in our investigation. Help in retrieving these documents would be most helpful. The request is on official letterhead as suggested.

Regards, Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: +1 (b) (6)

pedson@its.jnj.com
<http://www.jnj.com>

From: "Gasper, John" <John.Gasper@fda.hhs.gov>
Date: Friday, October 18, 2019 at 4:27 PM
To: Paul Edson <PEDSON@its.jnj.com>, "Dewan, Kapal" <Kapal.Dewan@fda.hhs.gov>
Cc: Venessa Piper-Givler <VPiperG@its.jnj.com>
Subject: RE: Johnson Baby Powder lot #22318RB

Hello Mr. Edson,

We have received your information mentioned below. Please let us know which date and time you plan to collect the sample and related information. Also, please provide the name and details of the personnel coming to collect the sample. The person should be a U.S. citizen and should have valid identification to be allowed entry. Please provide this information as soon as possible so that we may inform our security. Thank you.

Regards,

John Gasper

CFSAN
Office of Cosmetics and Colors
U.S. Food and Drug Administration
Tel: 240-402-1133

john.gasper@fda.hhs.gov



From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>

Sent: Friday, October 18, 2019 3:42 PM

To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>

Subject: Johnson Baby Powder lot #22318RB

Hello John and Kapal,

Pursuant to FDA's agreement to help facilitate materials for our investigation of Johnson's Baby Powder lot #22318RB, we request support for the following:

- 75grams of J&J Baby Powder from the original J&J Baby Powder bottle lot #22318RB
- Access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing (to determine authenticity)
- A Picture of the original container sampled, prior to opening
- Picture or evidence the original tamper seals were intact prior to sampling
- A sample from any remaining J&J Baby Powder from the blinded sample containers (D58 308006-6A; D58 308006-6B) tested by AMA
- AMA Labs Talc Testing SOP & Protocol
- AMA sample preparation methods for preparation of reference control standard using Sigma-Aldrich spike with 10% chrysolite
- Analysis and/or TEM photos of the Sigma-Aldrich spiked with 10% chrysolite
- Any asbestos environmental testing for the area used in FDA blinded sample preparation and at AMA laboratories testing labs
- FDA's Standard operating procedure for preparation of samples for Blind testing of Talc (D58 308006 series)
- Documentation for the chain of custody including any invoices for the purchase of the samples from the online retailer

As the investigation is of the utmost importance, we will be available to receive any of the above material, as soon as each of them are available and at the earliest convenience.

I look forward to hearing from you soon,

From: [Wolfgang, Steven](#)
To: [Dewan, Kapal](#)
Cc: [Gasper, John](#)
Subject: RE: Johnson Baby Powder lot #22318RB
Date: Friday, October 18, 2019 7:29:00 PM
Attachments: [blanks and controls for D58.pdf](#)
[QA Manual Sections 9-14 TEM Analysis.pdf](#)

Response to

- AMA sample preparation methods for preparation of reference control standard using Sigma-Aldrich spike with 10% chrysolite

(b) (5)

(b) (5)

- Analysis and/or TEM photos of the Sigma-Aldrich spiked with 10% chrysolite

(b) (5)

(b) (5)

- Any asbestos environmental testing for the area used in FDA blinded sample preparation and at AMA laboratories testing labs

(b) (5)

John sent AMA an email to determine if they have any other information that would be helpful.

Steve

From: Dewan, Kapal
Sent: Friday, October 18, 2019 7:04 PM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: FW: Johnson Baby Powder lot #22318RB

Hello,

See below in blue text what we have

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Friday, October 18, 2019 3:42 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>
Subject: Johnson Baby Powder lot #22318RB

Hello John and Kapal,

Pursuant to FDA's agreement to help facilitate materials for our investigation of Johnson's Baby Powder lot #22318RB, we request support for the following:

- 75grams of J&J Baby Powder from the original J&J Baby Powder bottle lot #22318RB

OCAC's response: 75 grams of J&J Baby Powder in J&J provided container from the original J&J Baby Powder bottle lot #22318RB can be given to the firm.

- Access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing (to determine authenticity)

OCAC's response: FDA can provide access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing.

- A Picture of the original container sampled, prior to opening

OCAC's response: FDA has the photos of the front and back panel of original container sampled (attached)

- Picture or evidence the original tamper seals were intact prior to sampling

OCAC's response: FDA has the photo of the top seal (attached)

- A sample from any remaining J&J Baby Powder from the blinded sample containers (D58 308006-6A; D58 308006-6B) tested by AMA

OCAC's response: A sample from the remaining J&J Baby Powder from the blinded sample containers can be provided.

- AMA Labs Talc Testing SOP & Protocol

OCAC's response: AMA Labs sample preparation attached (see file titled analytical protocol for D58)

- AMA sample preparation methods for preparation of reference control standard using Sigma-Aldrich spike with 10% chrysolite
- Analysis and/or TEM photos of the Sigma-Aldrich spiked with 10% chrysolite
- Any asbestos environmental testing for the area used in FDA blinded sample preparation and at AMA laboratories testing labs

OCAC's response: Refer AMA's QA Manual section 9.5.

- FDA's Standard operating procedure for preparation of samples for Blind testing of Talc (D58 308006 series)

OCAC's response: FDA's SOP - File titled Final OCAC Sample handling for testing

by outside lab (attached)

- Documentation for the chain of custody including any invoices for the purchase of the samples from the online retailer

As the investigation is of the utmost importance, we will be available to receive any of the above material, as soon as each of them are available and at the earliest convenience.

I look forward to hearing from you soon,

Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: +1 (b) (6)

pedson@its.jnj.com
<http://www.jnj.com>

From: [Kuntz, Thomas](#)
To: [Lanham, Ruark](#); [Pack, Randy](#); [Correll, William A](#); [Roosevelt, Michael](#)
Cc: [Jasperse, Carie](#); [Wolfgang, Steven](#); [Muszynski, William](#); [Darlington, Leonora](#); [Bonnin, Evelyn](#); [Dewan, Kapal](#); [ORA HAF EAST2 RECALLS](#); [Rivers, Robin M](#); [Barringer, Amy](#); [Sadrieh, Nakissa](#); [Tirio, Beth](#); [Beckerman, Peter](#); [Lewis, Kathleen](#); [Jabs, Alexandra](#)
Subject: RE: Johnson's Baby Powder, Batch #22318RB / Positive Sample found for chrysotile, a type of asbestos.
Date: Thursday, October 17, 2019 12:59:07 PM

Hi Ruark,

As you schedule the follow up call with J&J on the invite please include Bill Correll and Michael Roosevelt, director and deputy director of Office of Compliance. They can be available after 3pm this afternoon. 3:30 would probably work best.

Thanks

Tom

-----Original Appointment-----

From: Lanham, Ruark

Sent: Wednesday, October 16, 2019 6:20 PM

To: Lanham, Ruark; Szczepaniak, Lynne [CPCUS; BWilli10@its.jnj.com]; Pack, Randy; Muszynski, William; Darlington, Leonora; Bonnin, Evelyn; Kuntz, Thomas; Dewan, Kapal; ORA HAF EAST2 RECALLS; Rivers, Robin M; Barringer, Amy; Sadrieh, Nakissa; Tirio, Beth; Beckerman, Peter; Lewis, Kathleen; Jabs, Alexandra

Cc: Jasperse, Carie; Wolfgang, Steven; White, Andrew [JJCUS]; Edson, Paul [JJCUS]

Subject: Johnson's Baby Powder, Batch #22318RB / Positive Sample found for chrysotile, a type of asbestos.

When: Thursday, October 17, 2019 10:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Via WebEx

Importance: High

Good Evening All:

This conference call is for the purpose of discussing analytical results of asbestos testing for **Johnson's Baby Powder Batch #22318RB**. The results of the testing concludes that the product contains chrysotile, a type of asbestos. Asbestos is a poisonous and/or deleterious substance, and, therefore, Johnson's Baby Powder Batch #22318RB is adulterated within the meaning of Section 601(a) of the Federal Food, Drug, and Cosmetics Act.

The agency would like to discuss with the firm the results of the testing and if any plans the firm has in doing a recall of the product. Thank you all for making time to discuss this very important issue.

Respectfully

Ruark Lanham, MSODL
Divisional Recall Coordinator
US Food & Drug Administration

Division of Human and Animal Food Operations East II
(DC, DE, MD, PA, NJ, VA, WVA)
900 US Customhouse, Suite 904
200 Chestnut Street
Philadelphia, PA 19106
Phone: 215-717-3738
Gov Cell: 410-387-3851
Fax: 215-517-6649
orahafeast2recalls@fda.hhs.gov

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From: [Sadrieh, Nakissa](#)
To: [Kuntz, Thomas](#); [Darlington, Leonora](#); [Dewan, Kapal](#); [Tirio, Beth](#); [Lewis, Kathleen](#)
Cc: [Wolfgang, Steven](#)
Subject: RE: Johnson's Baby Powder, Batch #22318RB / Positive Sample found for chrysotile, a type of asbestos.
Date: Thursday, October 17, 2019 9:37:46 AM

Steve Wolfgang needs to be in the meeting.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>
Sent: Thursday, October 17, 2019 9:26 AM
To: Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Tirio, Beth <Beth.Tirio@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Subject: RE: Johnson's Baby Powder, Batch #22318RB / Positive Sample found for chrysotile, a type of asbestos.

Hello OCAC,

For this morning's meeting with J&J please ensure and forward the meeting invite to the people who are able to talk about the testing program at AMA and the particular findings. We will be looking to you to provide those details similar to what we have done in the past.

Thank you

Tom

-----Original Appointment-----

From: Lanham, Ruark
Sent: Wednesday, October 16, 2019 6:20 PM
To: Lanham, Ruark; Szczepaniak, Lynne [CPCUS]; BWilli10@its.inj.com; Pack, Randy; Muszynski, William; Darlington, Leonora; Bonnin, Evelyn; Kuntz, Thomas; Dewan, Kapal; ORA HAF EAST2 RECALLS; Rivers, Robin M; Barringer, Amy; Sadrieh, Nakissa; Tirio, Beth; Beckerman, Peter; Lewis, Kathleen; Jabs, Alexandra
Cc: Jasperse, Carie; Edson, Paul [JJCUS]; White, Andrew [JJCUS]
Subject: Johnson's Baby Powder, Batch #22318RB / Positive Sample found for chrysotile, a type of asbestos.

When: Thursday, October 17, 2019 10:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Via WebEx

Importance: High

Good Evening All:

This conference call is for the purpose of discussing analytical results of asbestos testing for **Johnson's Baby Powder Batch #22318RB**, . The results of the testing concludes that the product contains chrysotile, a type of asbestos. . Asbestos is a poisonous and/or deleterious substance, and, therefore, Johnson's Baby Powder Batch #22318RB is adulterated within the meaning of Section 601(a) of the Federal Food, Drug, and Cosmetics Act.

The agency would like to discuss with the firm the results of the testing and if any plans the firm has in doing a recall of the product. Thank you all for making time to discuss this very important issue.

Respectfully

Ruark Lanham, MSODL
Divisional Recall Coordinator
US Food & Drug Administration
Division of Human and Animal Food Operations East II
(DC, DE, MD, PA, NJ, VA, WVA)
900 US Customhouse, Suite 904
200 Chestnut Street
Philadelphia, PA 19106
Phone: 215-717-3738
Gov Cell: 410-387-3851
Fax: 215-517-6649
orahafeast2recalls@fda.hhs.gov

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From: [ORA HAF EAST2 RECALLS](#)
To: [Kuntz, Thomas](#); [Pack, Randy](#); [Correll, William A](#); [Roosevelt, Michael](#)
Cc: [Jasperse, Carie](#); [Wolfgang, Steven](#); [Muszynski, William](#); [Darlington, Leonora](#); [Bonnin, Evelyn](#); [Dewan, Kapal](#); [ORA HAF EAST2 RECALLS](#); [Rivers, Robin M](#); [Barringer, Amy](#); [Sadrieh, Nakissa](#); [Tirio, Beth](#); [Beckerman, Peter](#); [Lewis, Kathleen](#); [Jabs, Alexandra](#); [Pack, Randy](#)
Subject: RE: Johnson's Baby Powder, Batch #22318RB / Positive Sample found for chrysotile, a type of asbestos.
Date: Thursday, October 17, 2019 1:10:57 PM

Good Afternoon Thomas:

I will schedule the call for 3:30 PM today. I will make sure I have added the other individuals you have requested be on the conference call. Please let me know if I can be of further assistance to you in this matter.

Respectfully

*Ruark Lanham, MSODL
Divisional Recall Coordinator
US Food & Drug Administration
Division of Human and Animal Food Operations East II
(DC, DE, MD, PA, NJ, VA, WVA)
900 US Customhouse, Suite 904
200 Chestnut Street
Philadelphia, PA 19106
Phone: 215-717-3738
Gov Cell: 410-387-3851
Fax: 215-517-6649
orahafeast2recalls@fda.hhs.gov*

From: Kuntz, Thomas
Sent: Thursday, October 17, 2019 12:59 PM
To: Lanham, Ruark <Ruark.Lanham@fda.hhs.gov>; Pack, Randy <Randy.Pack@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>; Roosevelt, Michael <Michael.Roosevelt@fda.hhs.gov>
Cc: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Muszynski, William <William.Muszynski@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Bonnin, Evelyn <Evelyn.Bonnin@FDA.HHS.GOV>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; ORA HAF EAST2 RECALLS <orahafeast2recalls@fda.hhs.gov>; Rivers, Robin M <Robin.Rivers@fda.hhs.gov>; Barringer, Amy <Amy.Barringer@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Tirio, Beth <Beth.Tirio@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Jabs, Alexandra <Alexandra.Jabs@fda.hhs.gov>
Subject: RE: Johnson's Baby Powder, Batch #22318RB / Positive Sample found for chrysotile, a type of asbestos.

Hi Ruark,

As you schedule the follow up call with J&J on the invite please include Bill Correll and Michael Roosevelt, director and deputy director of Office of Compliance. They can be available after 3pm this afternoon. 3:30 would probably work best.

Thanks

Tom

-----Original Appointment-----

From: Lanham, Ruark

Sent: Wednesday, October 16, 2019 6:20 PM

To: Lanham, Ruark; Szczepaniak, Lynne [CPCUS; BWilli10@its.inj.com]; Pack, Randy; Muszynski, William; Darlington, Leonora; Bonnin, Evelyn; Kuntz, Thomas; Dewan, Kapal; ORA HAF EAST2 RECALLS; Rivers, Robin M; Barringer, Amy; Sadrieh, Nakissa; Tirio, Beth; Beckerman, Peter; Lewis, Kathleen; Jabs, Alexandra

Cc: Jasperse, Carie; Wolfgang, Steven; White, Andrew [JJCUS]; Edson, Paul [JJCUS]

Subject: Johnson's Baby Powder, Batch #22318RB / Positive Sample found for chrysotile, a type of asbestos.

When: Thursday, October 17, 2019 10:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Via WebEx

Importance: High

Good Evening All:

This conference call is for the purpose of discussing analytical results of asbestos testing for **Johnson's Baby Powder Batch #22318RB**, . The results of the testing concludes that the product contains chrysotile, a type of asbestos. . Asbestos is a poisonous and/or deleterious substance, and, therefore, Johnson's Baby Powder Batch #22318RB is adulterated within the meaning of Section 601(a) of the Federal Food, Drug, and Cosmetics Act.

The agency would like to discuss with the firm the results of the testing and if any plans the firm has in doing a recall of the product. Thank you all for making time to discuss this very important issue.

Respectfully

Ruark Lanham, MSODL
Divisional Recall Coordinator
US Food & Drug Administration
Division of Human and Animal Food Operations East II
(DC, DE, MD, PA, NJ, VA, WVA)
900 US Customhouse, Suite 904
200 Chestnut Street
Philadelphia, PA 19106
Phone: 215-717-3738
Gov Cell: 410-387-3851
Fax: 215-517-6649
orahafeast2recalls@fda.hhs.gov

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From: [Sadrieh, Nakissa](#)
To: [Kuntz, Thomas](#); [Lanham, Ruark](#); [Pack, Randy](#); [Correll, William A](#); [Roosevelt, Michael](#)
Cc: [Jasperse, Carie](#); [Wolfgang, Steven](#); [Muszynski, William](#); [Darlington, Leonora](#); [Bonnin, Evelyn](#); [Dewan, Kapal](#); [ORA HAF EAST2 RECALLS](#); [Rivers, Robin M](#); [Barringer, Amy](#); [Tirio, Beth](#); [Beckerman, Peter](#); [Lewis, Kathleen](#); [Jabs, Alexandra](#)
Subject: RE: Johnson's Baby Powder, Batch #22318RB / Positive Sample found for chrysotile, a type of asbestos.
Date: Thursday, October 17, 2019 1:04:21 PM

I am adding Dr. Linda Katz who is the OCAC director to this email. Thank you.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>
Sent: Thursday, October 17, 2019 12:59 PM
To: Lanham, Ruark <Ruark.Lanham@fda.hhs.gov>; Pack, Randy <Randy.Pack@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>; Roosevelt, Michael <Michael.Roosevelt@fda.hhs.gov>
Cc: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Muszynski, William <William.Muszynski@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Bonnin, Evelyn <Evelyn.Bonnin@FDA.HHS.GOV>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; ORA HAF EAST2 RECALLS <orahafeast2recalls@fda.hhs.gov>; Rivers, Robin M <Robin.Rivers@fda.hhs.gov>; Barringer, Amy <Amy.Barringer@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Tirio, Beth <Beth.Tirio@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Jabs, Alexandra <Alexandra.Jabs@fda.hhs.gov>
Subject: RE: Johnson's Baby Powder, Batch #22318RB / Positive Sample found for chrysotile, a type of asbestos.

Hi Ruark,

As you schedule the follow up call with J&J on the invite please include Bill Correll and Michael Roosevelt, director and deputy director of Office of Compliance. They can be available after 3pm this afternoon. 3:30 would probably work best.

Thanks

Tom

-----Original Appointment-----

From: Lanham, Ruark

Sent: Wednesday, October 16, 2019 6:20 PM

To: Lanham, Ruark; Szczepaniak, Lynne [CPCUS]; BWilli10@its.jnj.com; Pack, Randy; Muszynski, William; Darlington, Leonora; Bonnin, Evelyn; Kuntz, Thomas; Dewan, Kapal; ORA HAF EAST2 RECALLS; Rivers, Robin M; Barringer, Amy; Sadrieh, Nakissa; Tirio, Beth; Beckerman, Peter; Lewis, Kathleen; Jabs, Alexandra

Cc: Jasperse, Carie; Wolfgang, Steven; White, Andrew [JJCUS]; Edson, Paul [JJCUS]

Subject: Johnson's Baby Powder, Batch #22318RB / Positive Sample found for chrysotile, a type of asbestos.

When: Thursday, October 17, 2019 10:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Via WebEx

Importance: High

Good Evening All:

This conference call is for the purpose of discussing analytical results of asbestos testing for **Johnson's Baby Powder Batch #22318RB**, . The results of the testing concludes that the product contains chrysotile, a type of asbestos. . Asbestos is a poisonous and/or deleterious substance, and, therefore, Johnson's Baby Powder Batch #22318RB is adulterated within the meaning of Section 601(a) of the Federal Food, Drug, and Cosmetics Act.

The agency would like to discuss with the firm the results of the testing and if any plans the firm has in doing a recall of the product. Thank you all for making time to discuss this very important issue.

Respectfully

Ruark Lanham, MSODL
Divisional Recall Coordinator
US Food & Drug Administration
Division of Human and Animal Food Operations East II
(DC, DE, MD, PA, NJ, VA, WVA)
900 US Customhouse, Suite 904
200 Chestnut Street
Philadelphia, PA 19106
Phone: 215-717-3738
Gov Cell: 410-387-3851
Fax: 215-517-6649
orahafeast2recalls@fda.hhs.gov

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

Meeting number (access code): **(b) (6)**

Meeting password (b) (6)



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(b) (6) JS Toll
(b) (6) JS Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

Need help? Go to <http://help.webex.com>

From: [Wolfgang, Steven](#)
To: [Sadrieh, Nakissa](#)
Cc: [Scarborough, Kim](#)
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample
Date: Friday, October 18, 2019 3:51:00 PM

(b) (5)



Steve

From: Sadrieh, Nakissa
Sent: Friday, October 18, 2019 3:48 PM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

Thank you. we also needed (b) (5)



  (b) (5) 
  
   ?

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 3:44 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Cc: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

I helped Kim answer that question a few minutes ago.

Steve

From: Sadrieh, Nakissa
Sent: Friday, October 18, 2019 2:52 PM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

Do you know when sample 38 was tested?

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 2:45 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

You are going to have to go to Donnie for that information. She keeps excellent records of all samples that she orders and receives.

From: Sadrieh, Nakissa
Sent: Friday, October 18, 2019 2:43 PM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

Can (b) (5)

(b) (5)

(b) (5)

I am answering the latest inquiry from Gloria. Can I get this information asap? Thanks.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)

From: [Wolfgang, Steven](#)
To: [Dewan, Kapal](#)
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample
Date: Friday, October 18, 2019 3:43:00 PM

How early?

From: Dewan, Kapal
Sent: Friday, October 18, 2019 3:04 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

Hello,

Linda asked me to call Paul. I talked to him. He wanted to know where we are located and misunderstood that we are in Philadelphia. I told him that we are in Maryland. He will send his questions via email to John and Ruark as they relate to sample/ aliquot collection. J&J will come over for sample collection on Monday. Details of when, where, and what time will be indicated in the email that J&J will send us. NO rush for sample to aliquot for J&J today.

Steve,

Linda has asked that you come in early on Monday morning.

This is for now!
Kapal

From: Gasper, John
Sent: Friday, October 18, 2019 2:05 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: J&J Has Contacted Me About Logistics of Providing Sample

To All:

Please note that a Mr. Paul Edson of J&J (ph: 215-350-0653) left me a phone message earlier. He wants to discuss the logistics of how to arrange providing a sample to J&J. I have not returned his call yet. (b) (5) . Thank you.

Regards,
John G

From: [Sadrieh, Nakissa](mailto:Sadrieh.Nakissa)
To: [Wolfgang, Steven](mailto:Wolfgang.Steven)
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample
Date: Friday, October 18, 2019 2:51:44 PM

Do you know when sample 38 was tested?

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 2:45 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

You are going to have to go to Donnie for that information. She keeps excellent records of all samples that she orders and receives.

From: Sadrieh, Nakissa
Sent: Friday, October 18, 2019 2:43 PM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

Can (b) (5)

(b) (5)

(b) (5)

I am answering the latest inquiry from Gloria. Can I get this information asap? Thanks.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)

From: [Wolfgang, Steven](#)
To: [Gasper, John](#); [Sadrieh, Nakissa](#); [Dewan, Kapal](#); [Katz, Linda](#); [Smegal, Deborah](#); [Lewis, Kathleen](#)
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample
Date: Friday, October 18, 2019 2:46:00 PM

Let's discuss how to make the transfer. My understanding now is that the sample is enroute with John back to home base.

From: Gasper, John
Sent: Friday, October 18, 2019 2:05 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: J&J Has Contacted Me About Logistics of Providing Sample

To All:

Please note that a Mr. Paul Edson of J&J (ph: 215-350-0653) left me a phone message earlier. He wants to discuss the logistics of how to arrange providing a sample to J&J. I have not returned his call yet. We should discuss this before I contact him back. Thank you.

Regards,
John G

From: [Wolfgang, Steven](#)
To: [Katz, Linda](#)
Cc: [Lewis, Kathleen](#); [Sadrieh, Nakissa](#); [Dewan, Kapal](#); [Smegal, Deborah](#); [Gasper, John](#)
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample
Date: Friday, October 18, 2019 2:37:00 PM

Linda,

John and I spoke with Dana at AMA about 45 minutes ago and right this minute I think John is tied up collecting the sample from AMA and making sure we have all the documentation to go along with the change in possession. We have a plan and John and I will be communicating throughout the remainder of the day. Will give you an update later.

Steve

From: Katz, Linda
Sent: Friday, October 18, 2019 2:19 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

There was supposed to be a paragraph regarding chain of custody in which AMA was to describe what they have done with the sample after testing was completed and before delivery back to FDA. You also need to contact AMA to find out FDA can pick up the sample. When the sample is retrieved please make sure that you have the paragraph and chain of custody documents signed appropriately by AMA and the person picking up the sample. Once the samples are here we need to document our storage and preparation of the aliquot for J&J. This needs to be done today.

From: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Sent: Friday, October 18, 2019 2:10 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

Hi John,

I thought we were good with this:

- (b) (5)
- 

From: [Wolfgang, Steven](#)
To: [Dewan, Kapal](#)
Cc: [Gasper, John](#)
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample
Date: Friday, October 18, 2019 2:29:00 PM

I think we have everything under control as far as bringing the sample home.
Remain calm.

Call me if you need assistance.

Steve

From: Dewan, Kapal
Sent: Friday, October 18, 2019 2:29 PM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: FW: RE: J&J Has Contacted Me About Logistics of Providing Sample

Steve,

(b) (5)

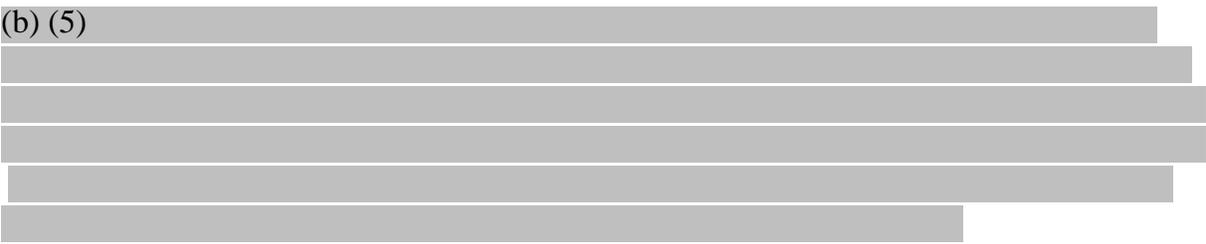


I will ask John and walk him through so we get the aliquot for J&J ready.

Thank you for your understanding!
Kapal

From: Katz, Linda
Sent: Friday, October 18, 2019 2:19 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

(b) (5)



From: [Lewis, Kathleen](#)
To: [Gasper, John](#); [Sadrieh, Nakissa](#); [Dewan, Kapal](#); [Katz, Linda](#); [Smegal, Deborah](#); [Wolfgang, Steven](#)
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample
Date: Friday, October 18, 2019 2:09:38 PM

Hi John,

I thought we were good with this:

- **(b) (5)** [REDACTED]
- [REDACTED]
- [REDACTED]

Did I miss anything?

Kay Lewis
Senior Advisor
OCAC/CFSAN/FDA
240-402-1129 office
240-825-9944 bb

NOTE: This e-mail message is intended for the exclusive use of the recipient's named above. It may contain information that is protected, privileged, or confidential, and it must not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately.

From: Gasper, John <John.Gasper@fda.hhs.gov>
Sent: Friday, October 18, 2019 2:05 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: J&J Has Contacted Me About Logistics of Providing Sample

To All:

Please note that a Mr. Paul Edson of J&J (ph: 215-350-0653) left me a phone message earlier. He wants to discuss the logistics of how to arrange providing a sample to J&J. I have not returned his call yet. **(b) (5)** [REDACTED]. Thank you.

Regards,
John G

From: [Dewan, Kapal](#)
To: [Wolfgang, Steven](#)
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample
Date: Friday, October 18, 2019 4:13:47 PM

Steve,

Try to be in around 7:00 – 7:30 am.

Kapal

From: Wolfgang, Steven
Sent: Friday, October 18, 2019 3:43 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

How early?

From: Dewan, Kapal
Sent: Friday, October 18, 2019 3:04 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

Hello,

Linda asked me to call Paul. I talked to him. He wanted to know where we are located and misunderstood that we are in Philadelphia. I told him that we are in Maryland. He will send his questions via email to John and Ruark as they relate to sample/ aliquot collection. J&J will come over for sample collection on Monday. Details of when, where, and what time will be indicated in the email that J&J will send us. NO rush for sample to aliquot for J&J today.

Steve,

Linda has asked that you come in early on Monday morning.

This is for now!

Kapal

From: Gasper, John
Sent: Friday, October 18, 2019 2:05 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>

Subject: RE: J&J Has Contacted Me About Logistics of Providing Sample

To All:

Please note that a Mr. Paul Edson of J&J (ph: 215-350-0653) left me a phone message earlier. He wants to discuss the logistics of how to arrange providing a sample to J&J. I have not returned his call yet. (b) (5) Thank you.

Regards,
John G

From: [Sadrieh, Nakissa](#)
To: [Wolfgang, Steven](#)
Cc: [Scarborough, Kim](#)
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample
Date: Friday, October 18, 2019 3:54:28 PM

[Redacted] (b) (5) [Redacted]
[Redacted] [Redacted] [Redacted] [Redacted]

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 3:51 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Cc: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

I do not (b) (5) [Redacted]
[Redacted]

Steve

From: Sadrieh, Nakissa
Sent: Friday, October 18, 2019 3:48 PM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Subject: RE: RE: J&J Has Contacted Me About Logistics of Providing Sample

Thank you. we also needed (b) (5) [Redacted]
[Redacted] [Redacted]
[Redacted] [Redacted] [Redacted]
[Redacted] [Redacted] [Redacted] ?

From: [Lanham, Ruark](#)
To: [Szczepaniak, Lynne \[CPCUS\]](#); BWilli10@its.jnj.com; [Pack, Randy](#); [Muszynski, William](#); [Darlington, Leonora](#); [Bonnin, Evelyn](#); [Kuntz, Thomas](#); [Dewan, Kapal](#); [ORA HAF EAST2 RECALLS](#); [Rivers, Robin M](#); [Barringer, Amy](#); [Sadrieh, Nakissa](#); [Tirio, Beth](#); [Beckerman, Peter](#); [Lewis, Kathleen](#); [Jabs, Alexandra](#); [White, Andrew \[JJCUS\]](#); [Jasperse, Carrie](#); [Edson, Paul \[JJCUS\]](#); [Wolfgang, Steven](#); [Beasley-Wright, Shelia](#); [ORA Recall OE](#); [Stone, Dyana](#); [Correll, William A](#); [Roosevelt, Michael](#); [Howard King, Vinetta](#)
Subject: RE: Recall of Johnson's baby Powder Lot 22318RB
Date: Friday, October 18, 2019 8:22:24 AM
Importance: High

Good Morning Ms. Lynne M. Szczepaniak, Vice President Global Regulatory Affairs

Thank you for letting the agency know of your intentions of doing a voluntary recall of the product. I will work with you thru out the entire process as well as get your firms press release posted to the agency web site. Thank you and your firm for working with the agency on this important matter.

Respectfully

*Ruark Lanham, MSODL
Divisional Recall Coordinator
US Food & Drug Administration
Division of Human and Animal Food Operations East II
(DC, DE, MD, PA, NJ, VA, WVA)
900 US Customhouse, Suite 904
200 Chestnut Street
Philadelphia, PA 19106
Phone: 215-717-3738
Gov Cell: 410-387-3851
Fax: 215-517-6649
orahafeast2recalls@fda.hhs.gov*

From: Szczepaniak, Lynne [CPCUS] <lszczepa@ITS.JNJ.com>
Sent: Friday, October 18, 2019 8:17 AM
To: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>; Lanham, Ruark <Ruark.Lanham@fda.hhs.gov>
Subject: Recall of Johnson's baby Powder Lot 22318RB

Mr Lanham and Mr Kuntz – I am writing to you this morning to inform you that Johnson & Johnson Consumer Inc. has made the decision to voluntarily recall Lot (22318RB) of Johnson's Baby Powder out of an abundance of caution. Our Press Release will be issued shortly. We look forward to speaking with you at 10:00 and collaborating with you to plan the next steps of the investigation.

Kindest regards,
Lynne

Lynne M. Szczepaniak
Vice President Global Regulatory Affairs
Johnson & Johnson Consumer Inc.
mobile: **(b) (6)**

From: [Dwyer, Lisa](#)
To: [Katz, Linda](#)
Cc: [Bradshaw, Sheldon](#)
Subject: Quick Check-In?
Date: Monday, October 07, 2019 9:45:53 AM
Attachments: [image001.png](#)

Hi Linda – we were wondering if you have a couple minutes for a quick check-in today or tomorrow. With the expiration of the 2019 fiscal year, we were wondering if there was additional information about the remaining testing. We are flexible this afternoon, and tomorrow from 10:30 a.m. -1:00 p.m., and again from 2:00-4:00 pm.

Best,

Lisa

Lisa M. Dwyer

Partner

T: +1 202 626 2393 | E: ldwyer@kslaw.com | www.kslaw.com

[BIO](#) | [vCARD](#)

King & Spalding LLP
1700 Pennsylvania Avenue, NW
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KING & SPALDING

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From: [Musser, Steven M](#)
To: [Katz, Linda](#)
Subject: Re: Letter of Sample Testing Results
Date: Friday, September 20, 2019 5:51:56 PM

Well, it's my understanding that they are entitled to their results. So, you should start working on a complete packet that only contains their results.

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Date: September 20, 2019 at 5:33:21 PM EDT
To: Musser, Steven M <Steven.Musser@fda.hhs.gov>
Subject: Fwd: Letter of Sample Testing Results

See below. Clearly they want a copy of the results. It would take us a little time to get a redacted report together. Let me if you want me to have a redacted report made available.

From: Dwyer, Lisa <LDwyer@KSLAW.com>
Date: September 20, 2019 at 4:50:26 PM EDT
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Bradshaw, Sheldon <SBradshaw@KSLAW.com>
Subject: RE: Letter of Sample Testing Results

Linda – thank you for the letter. We want to confirm that we have received it. We are hoping to follow-up with you on Monday or Wednesday with a couple quick questions, including about how we should go about requesting the testing results. Please let us know if you have a couple minutes to discuss.

Have a great weekend.

Lisa

From: Industry.Cosmetics <Industry.Cosmetics@fda.hhs.gov>
Sent: Friday, September 20, 2019 12:10 PM
To: Iszczepa@ITS.JNJ.com; Bradshaw, Sheldon <SBradshaw@KSLAW.com>; Dwyer, Lisa <LDwyer@KSLAW.com>
Subject: Letter of Sample Testing Results

****External Sender****

Greetings,

On behalf of Dr. Linda Katz, Director, Office of Cosmetics and Colors, please see the attached

correspondence.

Please acknowledge receipt of this email.

Thank you very much.

The Cosmetics Staff
Office of Cosmetics and Colors
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

King & Spalding Confidentiality Notice:

This message is being sent by or on behalf of a lawyer. It is intended exclusively for the individual or entity to which it is addressed. This communication may contain information that is proprietary, privileged or confidential or otherwise legally exempt from disclosure. If you are not the named addressee, you are not authorized to read, print, retain, copy or disseminate this message or any part of it. If you have received this message in error, please notify the sender immediately by e-mail and delete all copies of the message.

From: [Lanham, Ruark](#)
To: [Katz, Linda](#); [Wolfgang, Steven](#); [Kuntz, Thomas](#)
Cc: [Darlington, Leonora](#); [Sadrieh, Nakissa](#); [Pack, Randy](#); [ORA HAF EAST2 RECALLS](#)
Subject: RE: Agenda for meeting J and J Conference Call.doc
Date: Friday, October 18, 2019 8:54:39 AM
Attachments: [image001.png](#)

Good Morning Dr. Katz, I will make sure you are added to future e-mails etc.

Respectfully

*Ruark Lanham, MSODL
Divisional Recall Coordinator
US Food & Drug Administration
Division of Human and Animal Food Operations East II
(DC, DE, MD, PA, NJ, VA, WVA)
900 US Customhouse, Suite 904
200 Chestnut Street
Philadelphia, PA 19106
Phone: 215-717-3738
Gov Cell: 410-387-3851
Fax: 215-517-6649
orahafeast2recalls@fda.hhs.gov*

From: Katz, Linda
Sent: Friday, October 18, 2019 8:50 AM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lanham, Ruark <Ruark.Lanham@fda.hhs.gov>; Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>
Cc: Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Pack, Randy <Randy.Pack@fda.hhs.gov>; [ORA HAF EAST2 RECALLS](#) <orahafeast2recalls@fda.hhs.gov>
Subject: RE: Agenda for meeting J and J Conference Call.doc

Please add me to future emails. Thanks.

Linda M. Katz, M.D., M.P.H.

Director, Office of Cosmetics and Colors

Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
U.S. Food and Drug Administration

240-402-1130 (phone)
301-436-2976 (fax)
linda.katz@fda.hhs.gov



From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Thursday, October 17, 2019 12:57 PM
To: Lanham, Ruark <Ruark.Lanham@fda.hhs.gov>; Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>
Cc: Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Pack, Randy <Randy.Pack@fda.hhs.gov>; ORA HAF EAST2 RECALLS <orahafeast2recalls@fda.hhs.gov>
Subject: RE: Agenda for meeting J and J Conference Call.doc

Ruark,

(b) (5)(b) (5)(b) (5)(b) (5)(b) (5)(b) (5)
(b) (5)(b) (5)

Thanks,
Steve

From: Lanham, Ruark
Sent: Thursday, October 17, 2019 11:46 AM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>
Cc: Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Pack, Randy <Randy.Pack@fda.hhs.gov>; ORA HAF EAST2 RECALLS <orahafeast2recalls@fda.hhs.gov>
Subject: RE: Agenda for meeting J and J Conference Call.doc

Hi Steve If I set up a meeting I will work with in your time frame. I will also let firm know they can contact you directly to discuss lab etc after 3:00 PM. Please let me know if you are in agreement with this.

Respectfully

*Ruark Lanham, MSODL
Divisional Recall Coordinator
US Food & Drug Administration
Division of Human and Animal Food Operations East II
(DC, DE, MD, PA, NJ, VA, WVA)
900 US Customhouse, Suite 904
200 Chestnut Street
Philadelphia, PA 19106
Phone: 215-717-3738
Gov Cell: 410-387-3851*

Fax: 215-517-6649

orahafeast2recalls@fda.hhs.gov

From: Wolfgang, Steven

Sent: Thursday, October 17, 2019 11:34 AM

To: Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>; Lanham, Ruark <Ruark.Lanham@fda.hhs.gov>

Cc: Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>

Subject: RE: Agenda for meeting J and J Conference Call.doc

I am unavailable until 3 pm today. Please keep that in mind.

Thanks,
Steve

From: Kuntz, Thomas

Sent: Thursday, October 17, 2019 11:31 AM

To: Lanham, Ruark <Ruark.Lanham@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>

Cc: Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>

Subject: RE: Agenda for meeting J and J Conference Call.doc

Hi Ruark,

Steve Wolfgang (cc'd) from OCAC can make himself available to discuss the lab report with J&J's experts. Please share his contact info with them so they can connect.

Thanks

Tom Kuntz
Team Lead
Recall and Product Reconditioning Team
FDA/CFSAN/OC/DE/RPRT
Desk Phone: 240-402-1725
Work Cell: 240-701-2555

From: Lanham, Ruark

Sent: Thursday, October 17, 2019 9:56 AM

To: Pack, Randy <Randy.Pack@fda.hhs.gov>; Bonnin, Evelyn <Evelyn.Bonnin@FDA.HHS.GOV>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Kuntz, Thomas <Thomas.Kuntz@fda.hhs.gov>; Muszynski, William <William.Muszynski@fda.hhs.gov>; Rivers, Robin

M <Robin.Rivers@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>

Subject: Agenda for meeting J and J Conference Call.doc

Importance: High

Good Morning All:

Please see agenda I will be using for today's call.

Respectfully

*Ruark Lanham, MSODL
Divisional Recall Coordinator
US Food & Drug Administration
Division of Human and Animal Food Operations East II
(DC, DE, MD, PA, NJ, VA, WVA)
900 US Customhouse, Suite 904
200 Chestnut Street
Philadelphia, PA 19106
Phone: 215-717-3738
Gov Cell: 410-387-3851
Fax: 215-517-6649
orahafeast2recalls@fda.hhs.gov*

From: [Wolfgang, Steven](#)
To: [Sadrieh, Nakissa](#); [Katz, Linda](#); [Smegal, Deborah](#); [Lewis, Kathleen](#); [Dewan, Kapal](#); [Gasper, John](#)
Subject: RE: AMA Results
Date: Friday, October 18, 2019 10:32:11 AM
Attachments: [J&J Method TM7024.pdf](#)

J&J method in which the LOD is stated to be 10exp-5%.

From: Sadrieh, Nakissa
Sent: Friday, October 18, 2019 10:26 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: FW: AMA Results

Fiber calculations below from Steve.

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Tuesday, October 15, 2019 4:26 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: AMA Results

I calculated the total fibers in the bottle (623 grams of powder) to be about 5 billion based on 6 fibers detected:

total weight of sample analyzed (A)	7.55866E-07
f/gm (B = 6/A)	7937911.932
fibers total (C = 632 x B)	5.02E+09

From: Sadrieh, Nakissa
Sent: Tuesday, October 15, 2019 4:06 PM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: AMA Results

Our position in the past has been that if a single (out of 3) aliquot tests positive (with 1 or 2 fibers), that we can't call that a positive. Is this correct? Thanks.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)

5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Tuesday, October 15, 2019 3:59 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: AMA Results

The Certificates of Analysis for the remaining 30 samples were received and indicate some samples tested positive in single aliquots. I think (b) (5)

Steve

From: Sadrieh, Nakissa
Sent: Tuesday, October 15, 2019 2:43 PM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: AMA Results

Steve,

(b) (5)

? Are (b) (5)

(b) (5) ?

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Tuesday, October 15, 2019 2:10 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: AMA Results

I don't have the report for the remaining samples so cannot comment as to the results.

From: Katz, Linda
Sent: Tuesday, October 15, 2019 2:05 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: AMA Results

I thought (b) (5) ? (b) (5) ?

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Tuesday, October 15, 2019 1:57 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: AMA Results

Nakissa,

(b) (5)

Kapal

From: Sadrieh, Nakissa
Sent: Tuesday, October 15, 2019 11:39 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: AMA Results

Kapal,

We also need the (b) (5)

Thanks.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Katz, Linda <Linda.Katz@fda.hhs.gov>

Sent: Tuesday, October 15, 2019 11:17 AM

To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Subject: AMA Results

Have we (b) (5) ? If (b) (5)
(b) (5) ?

Also, has (b) (5) ?

Linda

From: [Kimberly, Brad](#)
To: [Scarborough, Kim](#); [Sanchez-Contreras, Gloria](#); [Dewan, Kapal](#); [Haake, Lindsay](#); [Lehman, Kristen](#)
Cc: [Naum, Marianna](#); [Meyer, Lyndsay](#); [Matos, Carmen](#); [Sadrieh, Nakissa](#); [Katz, Linda](#)
Subject: RE: Baby Powder Social Media
Date: Friday, October 18, 2019 2:56:43 PM
Attachments: [Recall Alert_baby powder_tw_v3_10.18.19_Food_recall_tw_4_12_19_Rev.png](#)
[image001.png](#)
[image008.png](#)
[image013.png](#)

Hey, y'all. (b) (5)

, I think (b) (5)

(b) (5).

Brad Kimberly

Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: Scarborough, Kim
Sent: Friday, October 18, 2019 1:51 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Sanchez-Contreras, Gloria <Gloria.Sanchez-Contreras@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>
Cc: Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Matos, Carmen <Carmen.Matos@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: RE: Baby Powder Social Media for Tomorrow

Hello Brad,

Understood. Thanks for clarifying the other limitations associated with the image.

Warm Regards,
Kim

From: Kimberly, Brad
Sent: Friday, October 18, 2019 1:39 PM
To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sanchez-Contreras, Gloria <Gloria.Sanchez-Contreras@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>

Cc: Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Matos, Carmen <Carmen.Matos@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>

Subject: RE: Baby Powder Social Media for Tomorrow

So, I had suggested (b) (5) [redacted]
[redacted]
[redacted]
[redacted]
[redacted].

The idea (b) (5) [redacted]
[redacted]).

Brad Kimberly

Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: Scarborough, Kim
Sent: Friday, October 18, 2019 1:34 PM
To: Sanchez-Contreras, Gloria <Gloria.Sanchez-Contreras@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>
Cc: Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Matos, Carmen <Carmen.Matos@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: RE: Baby Powder Social Media for Tomorrow

Good Afternoon All,

Gloria- Please see OCAC's edits in (b) (5) [redacted]
[redacted]
[redacted]
[redacted] ?

Kristen- can you (b) (5) [redacted] ? And
assuming (b) (5) [redacted]
[redacted] ?

Thank you,
Kim

From: Sanchez-Contreras, Gloria
Sent: Friday, October 18, 2019 12:41 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>
Cc: Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Matos, Carmen <Carmen.Matos@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: RE: Baby Powder Social Media for Tomorrow

Hi all,

Please see few edits below to the social media posts and a graphic **for your approval**. We will also use the product graphic with the lot number in the post thread

1. FDA's ongoing survey of cosmetic products for asbestos, recently found one batch of Johnson's Baby Powder tested positive for chrysotile ~~fibers~~, a type of asbestos and advising consumers to stop using the affected products. [\[Link to Press Release\]](#)
2. FDA advises consumers to stop using Johnson's Baby Powder with **lot #22318RB in 22 oz (623 g) bottles** due to possible contamination with asbestos-~~fibers~~ [\[Link to Safety Alert\]](#)
3. Consumers who have Johnson's Baby Powder with **lot #22318RB in 22 oz (623 g) bottles** found on the back of the bottle or directly underneath the cap should stop using it. This product could be contaminated with asbestos ~~fibers~~. For more information visit: [\[Link to CU\]](#)
4. **For the Commissioner:** The FDA continues to test cosmetic products that contain talc for the presence of asbestos, and we are committed to protect Americans from potential health risks. Consumers are encouraged to report any adverse events associated with the use of a cosmetic to the FDA's MedWatch. [\[Link to Press Release\]](#)



RECALL ALERT:
Johnson's Baby Powder

22 oz. bottle
Batch # 22318RB



From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Friday, October 18, 2019 8:43 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Sanchez-Contreras, Gloria <Gloria.Sanchez-Contreras@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>
Cc: Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Matos, Carmen <Carmen.Matos@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: RE: Baby Powder Social Media for Tomorrow

Please make sure (b) (5) . Thanks!

From: Kimberly, Brad
Sent: Friday, October 18, 2019 8:39 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Sanchez-Contreras, Gloria <Gloria.Sanchez-Contreras@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>
Cc: Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Matos, Carmen <Carmen.Matos@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: RE: Baby Powder Social Media for Tomorrow

Good morning. So, the question Gloria posed below was this:

(b) (5)

<Kristen.Lehman@fda.hhs.gov>

Cc: Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Matos, Carmen <Carmen.Matos@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>

Subject: RE: Baby Powder Social Media for Tomorrow

Good morning. So, the question Gloria posed below was this:

Given the low-quality of the images provided, can we use these hi-resolution product images (attached) on social?

I'm all about showing images of the product, but on social, we should do our users a favor and present them with a clear image of the product that may be in their homes. Not saying you should change what you're using in the alert (nor am I saying I won't use the image with the batch imprint), but can we not provide the clearest and most professional-looking alert for folks?

Thanks, y'all.

Brad Kimberly

Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: Dewan, Kapal

Sent: Friday, October 18, 2019 7:21 AM

To: Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Sanchez-Contreras, Gloria <Gloria.Sanchez-Contreras@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Cc: Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Matos, Carmen <Carmen.Matos@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>

Subject: RE: Baby Powder Social Media for Tomorrow

Importance: High

Gloria, Lindsay,

I had sent the photos of the product to Marianna on Tuesday, 2:57 pm. You can use those for the

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Kapal

From: Scarborough, Kim
Sent: Friday, October 18, 2019 6:59 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: FW: Baby Powder Social Media for Tomorrow

FYI- the current discussion occurring about what will go out via social media today. Carmen and I are copied on the emails.

Kim

From: Haake, Lindsay
Sent: Thursday, October 17, 2019 6:40 PM
To: Sanchez-Contreras, Gloria <Gloria.Sanchez-Contreras@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Matos, Carmen <Carmen.Matos@fda.hhs.gov>
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Hi Kristen and all,

Thank you for chatting with me today. Here is the link to the [Constituent Update](#) and [Safety Alert](#) that can help you to draft additional social media posts. **Please review drafts below:**

1. FDA's ongoing survey of cosmetic products for asbestos, recently found one batch of Johnson's Baby Powder tested positive for chrysotile fibers, a type of asbestos and advising consumers to stop using the affected products. [\[Link to Press Release\]](#)

2. FDA advises consumers to stop using Johnson's Baby Powder with batch #22318RB due to possible contamination with asbestos fibers [\[Link to Safety Alert\]](#)
3. Consumers who have Johnson's Baby Powder with batch #22318RB found on the back of the bottle or directly underneath the cap should stop using it. This product could be contaminated with asbestos fibers. For more information visit: [\[Link to CU\]](#)
4. **For the Commissioner:** The FDA continues to test cosmetic products that contain talc for the presence of asbestos, and we are committed to protect Americans from potential health risks. Consumers are encouraged to report any adverse events associated with the use of a cosmetic to the FDA's MedWatch. [\[Link to Press Release\]](#)

PHOTO QUESTION

The photos featured in the Safety Alert attached (Johnson Baby Powder 1, 2, and 3) were provided by CFSAN compliance, but have poor quality. I have brightened them a bit in case you want to switch them. Brad, found the other two photos attached (BabyPowderFront and Back) and want to check if we could use them, in the place of Baby Powder 1 and 2, we can keep Baby Powder 3, which has the batch # under the cap. What do you think?

Thank you,

Gloria Sánchez-Contreras

International Press Officer

Spanish-Language Communications Lead

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 301-796-7686 / Cell: 301-500-8888

gloria.sanchez-contreras@fda.hhs.gov



From: [Dewan, Kapal](#)
To: [Haake, Lindsay](#); [Sanchez-Contreras, Gloria](#); [Lehman, Kristen](#); [Kimberly, Brad](#)
Cc: [Naum, Marianna](#); [Meyer, Lyndsay](#); [Scarborough, Kim](#); [Matos, Carmen](#); [Sadrieh, Nakissa](#); [Katz, Linda](#)
Subject: RE: Baby Powder Social Media for Tomorrow
Date: Friday, October 18, 2019 7:21:18 AM
Attachments: [IMG_4080.JPG](#)
[IMG_4081.JPG](#)
[IMG_4082.JPG](#)
[image001.png](#)
[image006.png](#)
Importance: High

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gloria.sanchez-contreras@fda.hhs.gov



From: [Kimberly, Brad](#)
To: [Scarborough, Kim](#); [Sanchez-Contreras, Gloria](#); [Dewan, Kapal](#); [Haake, Lindsay](#); [Lehman, Kristen](#)
Cc: [Naum, Marianna](#); [Meyer, Lyndsay](#); [Matos, Carmen](#); [Sadrieh, Nakissa](#); [Katz, Linda](#)
Subject: Re: Baby Powder Social Media for Tomorrow
Date: Friday, October 18, 2019 1:52:35 PM
Attachments: [image001.png](#)
[image008.png](#)
[image013.png](#)

This is about the best I can do on the supplemental images. I hope this helps.

Brad Kimberly

Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: "Scarborough, Kim" <Kim.Scarborough@fda.hhs.gov>
Date: Friday, October 18, 2019 at 1:34 PM
To: "Sanchez-Contreras, Gloria" <Gloria.Sanchez-Contreras@fda.hhs.gov>, "Dewan, Kapal" <Kapal.Dewan@fda.hhs.gov>, Brad Kimberly <Brad.Kimberly@fda.hhs.gov>, "Haake, Lindsay" <Lindsay.Haake@fda.hhs.gov>, "Lehman, Kristen" <Kristen.Lehman@fda.hhs.gov>
Cc: "Naum, Marianna" <Marianna.Naum@fda.hhs.gov>, "Meyer, Lyndsay" <Lyndsay.Meyer@fda.hhs.gov>, "Matos, Carmen" <Carmen.Matos@fda.hhs.gov>, "Sadrieh, Nakissa" <Nakissa.Sadrieh@fda.hhs.gov>, "Katz, Linda" <Linda.Katz@fda.hhs.gov>
Subject: RE: Baby Powder Social Media for Tomorrow

Good Afternoon All,

(b) (5) [Redacted]
[Redacted]
[Redacted]
[Redacted] ?

Kristen- can (b) (5) [Redacted] ? And
assuming (b) (5) [Redacted]
[Redacted] ?

Thank you,

Kim

From: Sanchez-Contreras, Gloria

Sent: Friday, October 18, 2019 12:41 PM

To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>

Cc: Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Matos, Carmen <Carmen.Matos@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>

Subject: RE: Baby Powder Social Media for Tomorrow

Hi all,

Please see few edits below to the social media posts and a graphic **for your approval**. We will also use the product graphic with the lot number in the post thread

(b) (5)



From: [Kimberly, Brad](#)
To: [Dewan, Kapal](#); [Haake, Lindsay](#); [Sanchez-Contreras, Gloria](#); [Lehman, Kristen](#)
Cc: [Naum, Marianna](#); [Meyer, Lyndsay](#); [Scarborough, Kim](#); [Matos, Carmen](#); [Sadrieh, Nakissa](#); [Katz, Linda](#)
Subject: RE: Baby Powder Social Media for Tomorrow
Date: Friday, October 18, 2019 8:38:55 AM
Attachments: [BabyPowderBACK.jpg](#)
[BabyPowderFRONT.jpg](#)
[image007.png](#)
[image013.png](#)
[image018.png](#)

Good morning. So, the question Gloria posed below was this:

(b) (5) [Redacted]
[Redacted]

[Redacted]
[Redacted]
[Redacted]
[Redacted] ?

Thanks, y'all.

Brad Kimberly

Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



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(b) (5)

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What do you think?

Thank you,

Gloria Sánchez-Contreras

International Press Officer

Spanish-Language Communications Lead

Office of Media Affairs

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gloria.sanchez-contreras@fda.hhs.gov



*Consumer Safety Officer
Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
College Park, MD
301-796-3264
240-328-9827*

From: [Beckerman, Peter](#)
To: [Kux, Leslie](#); [Katz, Linda](#)
Subject: Re: Conversation with J&J
Date: Wednesday, September 25, 2019 9:11:29 AM

Agreed - a FOIA request is the appropriate mechanism.

-Pete

From: Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Date: September 25, 2019 at 8:14:38 AM EDT
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>
Subject: Re: Conversation with J&J

Adding Pete who has more experience with FOIA. I'm inclined to ask them to submit a FOIA request so we have a transparent record

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Date: September 25, 2019 at 8:08:53 AM EDT
To: Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Subject: Conversation with J&J

Leslie,

Steve Musser suggested that I contact you.

I am supposed to be talking to Lisa Dwyer and Sheldon Bradshaw today, regarding follow-up questions that they have related to the letter providing results on the one J&J sample that we tested. One of the issues is that they want a copy of the report. I was planning on asking them to send an official letter since we need to redact the report to send them the negative results. (All of the negative results are batched into one report. The positive results were separated out to make less work for us.) I am not sure if the request needs to be a formal FOIA request or if simply sending us a letter will suffice. Let me know.

We have not heard from anyone else who received a letter.

Linda

From: [Wolfgang, Steven](#)
To: [Katz, Linda](#); [Dewan, Kapal](#)
Cc: [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: D38 J&J sample report
Date: Thursday, October 10, 2019 4:48:12 PM

D58

From: Katz, Linda
Sent: Thursday, October 10, 2019 4:48 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: D38 J&J sample report

For (b) (5) I have (b) (5)

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Wednesday, September 25, 2019 2:31 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: RE: D38 J&J sample report

Baby powder.

From: Katz, Linda
Sent: Wednesday, September 25, 2019 1:23 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: D38 J&J sample report

Was it (b) (5)

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Yes, (b) (5)

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Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: D38 J&J sample report

Thanks. (b) (5)

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
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To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: D38 J&J sample report

Linda,

(b) (5)

Kapal Dewan
Team Lead, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
College Park, MD 20740

Phone: 240-402-2908
Fax: 301-436-2975

From: [Sadrieh, Nakissa](#)
To: [Katz, Linda](#); [Dewan, Kapal](#); [Wolfgang, Steven](#)
Cc: [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: D38 J&J sample report
Date: Thursday, October 10, 2019 4:48:20 PM

58 is the one we are working on now.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

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Sent: Thursday, October 10, 2019 4:48 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
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(b) (5) [REDACTED]
[REDACTED].

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Food and Drug Administration (FDA)
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Phone: 240-402-2908
Fax: 301-436-2975

From: [Wolfgang, Steven](#)
To: [Katz, Linda](#); [Sadrieh, Nakissa](#); [Dewan, Kapal](#)
Cc: [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: D38 J&J sample report
Date: Thursday, October 10, 2019 4:50:08 PM

I am not aware of that email. Send it over so I can see it if you wish.

From: Katz, Linda
Sent: Thursday, October 10, 2019 4:49 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
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(b) (5)

A large grey rectangular redaction box covers the majority of the text in this section. The text "(b) (5)" is visible at the top left of the redacted area.

Kapal Dewan
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To: [Katz, Linda](#); [Dewan, Kapal](#)
Cc: [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: D38 J&J sample report
Date: Thursday, October 10, 2019 4:50:28 PM

correct

From: Katz, Linda
Sent: Thursday, October 10, 2019 4:50 PM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: D38 J&J sample report

And, (b) (5) ?

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Thursday, October 10, 2019 4:49 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: D38 J&J sample report

(b) (5)

From: Katz, Linda
Sent: Thursday, October 10, 2019 4:48 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: D38 J&J sample report

For clarification is (b) (5) ? I have (b) (5)
(b) (5) .

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Wednesday, September 25, 2019 2:31 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: RE: D38 J&J sample report

(b) (5) .

From: Katz, Linda
Sent: Wednesday, September 25, 2019 1:23 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: D38 J&J sample report

Was it (b) (5) ?

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Wednesday, September 25, 2019 1:23 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: D38 J&J sample report

Yes, (b) (5)

From: Katz, Linda
Sent: Wednesday, September 25, 2019 1:22 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: D38 J&J sample report

Thanks. Have we (b) (5) ?

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Wednesday, September 25, 2019 1:19 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: D38 J&J sample report

Linda,

John has requested (b) (5)
(b) (5). Just wanted to inform you.

Kapal Dewan
Team Lead, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)

5001 Campus Drive
College Park, MD 20740

Phone: 240-402-2908

Fax: 301-436-2975

From: [Sadrieh, Nakissa](#)
To: [Katz, Linda](#)
Subject: RE: DRAFT response to JJ PR Statements
Date: Friday, October 18, 2019 3:51:37 PM
Attachments: [image001.png](#)
[image007.png](#)
[image012.png](#)

AMA will send Gasper an email indicating in which lab sample 58 was and under the supervision of whom, for the 45 minutes between 4:15 and 5 pm, and describing that the 4th aliquot taken was destroyed and not analyzed, when FDA informed AMA that a 4th aliquot was not in the terms of the contract. This information will be attached to the memo written by AMA and scanned and put in DCS and elsewhere for future reference.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Sent: Friday, October 18, 2019 3:28 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: DRAFT response to JJ PR Statements

I just saw the AMA chain of custody letter.

From: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Sent: Friday, October 18, 2019 3:22 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: RE: DRAFT response to JJ PR Statements

I just sent it to Lindsay. The sample is back here. Gasper brought it back.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division

Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Sent: Friday, October 18, 2019 3:20 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: DRAFT response to JJ PR Statements

See addition in red below:

Linda M. Katz, M.D., M.P.H.
Director, Office of Cosmetics and Colors

Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
U.S. Food and Drug Administration

240-402-1130 (phone)
301-436-2976 (fax)
linda.katz@fda.hhs.gov



From: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Sent: Friday, October 18, 2019 3:17 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: FW: DRAFT response to JJ PR Statements

Lindsay wants you to clear the following:

(b) (5)

A large, solid grey rectangular redaction box covers the majority of the page content below the text "(b) (5)".

It seems fine to me.

Regards,

Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>
Sent: Friday, October 18, 2019 3:15 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
Cc: Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Sanchez-Contreras, Gloria <Gloria.Sanchez-Contreras@fda.hhs.gov>
Subject: RE: DRAFT response to JJ PR Statements

Thanks! Is OCAC fine with the statement overall?

From: Sadrieh, Nakissa
Sent: Friday, October 18, 2019 3:14 PM
To: Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
Cc: Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Sanchez-Contreras, Gloria <Gloria.Sanchez-Contreras@fda.hhs.gov>
Subject: RE: DRAFT response to JJ PR Statements

The statement about the product being bought from Walmart and arriving via FedEx is correct.

Regards,

Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division

Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>
Sent: Friday, October 18, 2019 3:11 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
Cc: Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Sanchez-Contreras, Gloria <Gloria.Sanchez-Contreras@fda.hhs.gov>
Subject: FW: DRAFT response to JJ PR Statements
Importance: High

Hi all –

Below is an updated statement from OMA that they are requesting clearance on ASAP.
Please let me know if you have any concerns!

Thanks,
Lindsay

From: Sanchez-Contreras, Gloria
Sent: Friday, October 18, 2019 3:07 PM
To: Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Naum, Marianna <Marianna.Naum@fda.hhs.gov>
Cc: Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Subject: DRAFT response to JJ PR Statements

Hi all,

It seems that it might take few hours to get responses to all the media questions about JJ baby powder testing that I just sent few minutes ago. **Can we clear with CFSAN leadership asap the short statement below to respond to JJ PR?**

From JJ PR :

- a. Cannot confirm if cross-contamination of the sample caused a false positive.

- b. Cannot confirm whether the sample was taken from a bottle with an intact seal or whether the sample was prepared in a controlled environment.
- c. Cannot confirm whether the tested product is authentic or counterfeit.

Draft Responses Statement:

(b) (5) [Redacted]

Please confirm if we can release place of purchase.

Thank you,

Gloria Sánchez-Contreras
International Press Officer
Spanish-Language Communications Lead

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 301-796-7686 / Cell: 301-500-8888
gloria.sanchez-contreras@fda.hhs.gov



From: [Garrett, Ulysses](#)
To: [Correll, William A](#); [Sanchez-Contreras, Gloria](#); [Scarborough, Kim](#); [Katz, Linda](#); [Sadrieh, Nakissa](#); [Dewan, Kapal](#); [Spence, Susan](#); [Roosevelt, Michael](#)
Cc: [Jasperse, Carie](#); [Haake, Lindsay](#); [Naum, Marianna](#); [Meyer, Lyndsay](#); [Cardin, Megan](#); [Rogers, Michael](#); [Howard King, Vinetta](#); [Bonnin, Evelyn](#)
Subject: RE: FDA Testing - Baby Powder
Date: Friday, October 18, 2019 11:03:48 AM
Attachments: [image001.png](#)
[image011.png](#)
[image016.png](#)

Adding in ORA if any additional information is needed.

Thanks.

From: Correll, William A
Sent: Friday, October 18, 2019 10:57 AM
To: Sanchez-Contreras, Gloria <Gloria.Sanchez-Contreras@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Spence, Susan <Susan.Spence@fda.hhs.gov>; Roosevelt, Michael <Michael.Roosevelt@fda.hhs.gov>
Cc: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Garrett, Ulysses <Ulysses.Garrett@fda.hhs.gov>; Cardin, Megan <Megan.Cardin@fda.hhs.gov>
Subject: RE: FDA Testing - Baby Powder

1. FDA handling of the sample and testing followed routine laboratory standards of care and FDA sees no indication of cross-contamination.
2. OCAC will answer
3. FDA will be working with JJ to facilitate JJ's further investigation to substantiate that the product is authentic. At this time, there is no indication otherwise and FDA is not aware of any instance of counterfeit JJ baby powder on record.

Reporter Q's - OCAC has lead on most of these.

1. OCAC will answer
2. The sample was purchased from Walmart. I believe it was an on-line order (OCAC will confirm and specific whether from direct Walmart on-line or from Walmart fulfilling through another intermediary (e.g., Amazon for instance).
3. OCAC will answer (and provide product labeling photos if available)
4. OCAC will answer.

Bill

From: Sanchez-Contreras, Gloria

Sent: Friday, October 18, 2019 10:45 AM

To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Spence, Susan <Susan.Spence@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>

Cc: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Garrett, Ulysses <Ulysses.Garrett@fda.hhs.gov>; Cardin, Megan <Megan.Cardin@fda.hhs.gov>

Subject: FDA Testing - Baby Powder

Hi Bill and all,

Separate from the media statement clearance below, **we need answers for the following J&J statements about FDA [testing](#):**

(b) (5)

The content of this section is redacted with three grey bars of varying lengths.

Reporter also wants to know:

1. What was the integrity of the testing process, even just generally?
2. Consumers will want to know what online retailer sold the product -- can you please share that information?
3. What is the size of the bottle?
4. Last time that Johnson's Baby Powder was tested and confirm it was negative?

Thank you,

Gloria

From: Sanchez-Contreras, Gloria

Sent: Friday, October 18, 2019 10:37 AM

To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Spence, Susan <Susan.Spence@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>

Cc: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Garrett, Ulysses <Ulysses.Garrett@fda.hhs.gov>; Cardin, Megan <Megan.Cardin@fda.hhs.gov>

Subject: RE: EXPEDITE MEDIA STATEMENT CLEARANCE: J&J Baby Powder

Typo corrected: **The FDA stands by the quality of its testing and results and is not aware of any adverse events relating to exposure to the affected products.**

From: Sanchez-Contreras, Gloria

Sent: Friday, October 18, 2019 10:36 AM

To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>;

Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>;

Spence, Susan <Susan.Spence@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>

Cc: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>;

Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>;

Garrett, Ulysses <Ulysses.Garrett@fda.hhs.gov>; Cardin, Megan <Megan.Cardin@fda.hhs.gov>

Subject: EXPEDITE MEDIA STATEMENT CLEARANCE: J&J Baby Powder

Good morning all,

J&J has recalled the product affected and we started getting media inquiries. Here is the link to the company's press release: <https://www.jnj.com/johnson-johnson-consumer-inc-to-voluntarily-recall-a-single-lot-of-johnsons-baby-powder-in-the-united-states>

Our press release is with HHS for final clearance (latest draft attached), but in the meantime, we would like to clear the following statement to respond to media

The FDA is alerting consumers of a voluntary recall of Johnson & Johnson, Johnson's Baby Powder as FDA testing has found that a sample from one batch of the product contains chrysotile fibers, a type of asbestos. Consumers who have Johnson's Baby Powder batch #22318RB should stop using it immediately. For refund information, consumers can contact the Johnson & Johnson Consumer Care Center at www.johnsonsbaby.com or by calling +1 (866) 565-2229. **The FDA stands by the quality of its testing and results and is not aware of any adverse events relating to exposure to the affected products.**

Thank you,

Gloria Sánchez-Contreras

International Press Officer

Spanish-Language Communications Lead

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 301-796-7686 / Cell: 301-500-8888

gloria.sanchez-contreras@fda.hhs.gov



From: [Sadrieh, Nakissa](#)
To: [Sanchez-Contreras, Gloria](#); [Scarborough, Kim](#); [Katz, Linda](#); [Dewan, Kapal](#); [Spence, Susan](#); [Correll, William A](#)
Cc: [Jasperse, Carie](#); [Haake, Lindsay](#); [Naum, Marianna](#); [Meyer, Lyndsay](#); [Garrett, Ulysses](#); [Cardin, Megan](#)
Subject: RE: FDA Testing - Baby Powder
Date: Friday, October 18, 2019 10:54:31 AM
Attachments: [image001.png](#)
[image010.png](#)
[image016.png](#)

Please see my preliminary responses to the first set of questions (in red). These are not cleared and I am only sharing so that our staff can add, before we get office clearance.

From: Sanchez-Contreras, Gloria <Gloria.Sanchez-Contreras@fda.hhs.gov>
Sent: Friday, October 18, 2019 10:45 AM
To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Spence, Susan <Susan.Spence@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
Cc: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Garrett, Ulysses <Ulysses.Garrett@fda.hhs.gov>; Cardin, Megan <Megan.Cardin@fda.hhs.gov>
Subject: FDA Testing - Baby Powder

Hi Bill and all,

Separate from the media statement clearance below, **we need answers for the following J&J statements about FDA testing:**

1. Cannot confirm if cross-contamination of the sample caused a false positive. (b) (5)

2. Cannot confirm whether the sample was taken from a bottle with an intact seal or whether the sample was prepared in a controlled environment. **We have 2 exact bottles remaining which can be examined for intactness. The products were shipped from Walmart via FedEx.**
3. Cannot confirm whether the tested product is authentic or counterfeit (b) (5)


Reporter also wants to know:

1. What was the integrity of the testing process, even just generally? (b) (5)

2. Consumers will want to know what online retailer sold the product -- can you please share that information? **walmart**
3. What is the size of the bottle? **623 g**
4. Last time that Johnson's Baby Powder was tested and confirm it was negative? (b) (5)


(b) (5)

Thank you,

Gloria

From: Sanchez-Contreras, Gloria

Sent: Friday, October 18, 2019 10:37 AM

To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Spence, Susan <Susan.Spence@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>

Cc: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Garrett, Ulysses <Ulysses.Garrett@fda.hhs.gov>; Cardin, Megan <Megan.Cardin@fda.hhs.gov>

Subject: RE: EXPEDITE MEDIA STATEMENT CLEARANCE: J&J Baby Powder

Typo corrected: The FDA stands by the quality of its testing and results and is not aware of any adverse events relating to exposure to the affected products.

From: Sanchez-Contreras, Gloria

Sent: Friday, October 18, 2019 10:36 AM

To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Spence, Susan <Susan.Spence@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>

Cc: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Garrett, Ulysses <Ulysses.Garrett@fda.hhs.gov>; Cardin, Megan <Megan.Cardin@fda.hhs.gov>

Subject: EXPEDITE MEDIA STATEMENT CLEARANCE: J&J Baby Powder

Good morning all,

J&J has recalled the product affected and we started getting media inquiries. Here is the link to the company's press release: <https://www.jnj.com/johnson-johnson-consumer-inc-to-voluntarily-recall-a-single-lot-of-johnsons-baby-powder-in-the-united-states>

Our press release is with HHS for final clearance (latest draft attached), but in the meantime, we would like to clear the following statement to respond to media

The FDA is alerting consumers of a voluntary recall of Johnson & Johnson, Johnson's Baby Powder as FDA testing has found that a sample from one batch of the product contains chrysotile fibers, a type of asbestos. Consumers who have Johnson's Baby Powder batch #22318RB should stop using it immediately. For refund information, consumers can contact the Johnson & Johnson Consumer Care Center at www.johnsonsbaby.com or by calling +1 (866) 565-2229. The FDA stands by the quality of its testing and results and is not

aware of any adverse events relating to exposure to the affected products.

Thank you,

Gloria Sánchez-Contreras

*International Press Officer
Spanish-Language Communications Lead*

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 301-796-7686 / Cell: 301-500-8888

gloria.sanchez-contreras@fda.hhs.gov



Gloria Sánchez-Contreras

*International Press Officer
Spanish-Language Communications Lead*

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 301-796-7686 / Cell: 301-500-8888

gloria.sanchez-contreras@fda.hhs.gov



From: [Correll, William A](#)
To: [Sanchez-Contreras, Gloria](#); [Scarborough, Kim](#); [Katz, Linda](#); [Sadrieh, Nakissa](#); [Dewan, Kapal](#); [Spence, Susan](#); [Roosevelt, Michael](#)
Cc: [Jasperse, Carie](#); [Haake, Lindsay](#); [Naum, Marianna](#); [Meyer, Lyndsay](#); [Garrett, Ulysses](#); [Cardin, Megan](#)
Subject: RE: FDA Testing - Baby Powder
Date: Friday, October 18, 2019 10:56:55 AM
Attachments: [image001.png](#)
[image010.png](#)
[image016.png](#)

1. FDA handling of the sample and testing followed routine laboratory standards of care and FDA sees no indication of cross-contamination.
2. OCAC will answer
3. FDA will be working with JJ to facilitate JJ's further investigation to substantiate that the product is authentic. At this time, there is no indication otherwise and FDA is not aware of any instance of counterfeit JJ baby powder on record.

Reporter Q's - OCAC has lead on most of these.

1. OCAC will answer
2. The sample was purchased from Walmart. I believe it was an on-line order (OCAC will confirm and specific whether from direct Walmart on-line or from Walmart fulfilling through another intermediary (e.g., Amazon for instance).
3. OCAC will answer (and provide product labeling photos if available)
4. OCAC will answer.

Bill

From: Sanchez-Contreras, Gloria
Sent: Friday, October 18, 2019 10:45 AM
To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Spence, Susan <Susan.Spence@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>
Cc: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Garrett, Ulysses <Ulysses.Garrett@fda.hhs.gov>; Cardin, Megan <Megan.Cardin@fda.hhs.gov>
Subject: FDA Testing - Baby Powder

Hi Bill and all,

Separate from the media statement clearance below, **we need answers for the following J&J statements about FDA testing:**

1. Cannot confirm if cross-contamination of the sample caused a false positive.
2. Cannot confirm whether the sample was taken from a bottle with an intact seal or whether the sample was prepared in a controlled environment.
3. Cannot confirm whether the tested product is authentic or counterfeit.

Reporter also wants to know:

1. What was the integrity of the testing process, even just generally?
2. Consumers will want to know what online retailer sold the product -- can you please share that information?
3. What is the size of the bottle?
4. Last time that Johnson's Baby Powder was tested and confirm it was negative?

Thank you,

Gloria

From: Sanchez-Contreras, Gloria

Sent: Friday, October 18, 2019 10:37 AM

To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Spence, Susan <Susan.Spence@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>

Cc: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Garrett, Ulysses <Ulysses.Garrett@fda.hhs.gov>; Cardin, Megan <Megan.Cardin@fda.hhs.gov>

Subject: RE: EXPEDITE MEDIA STATEMENT CLEARANCE: J&J Baby Powder

Typo corrected: **The FDA stands by the quality of its testing and results and is not aware of any adverse events relating to exposure to the affected products.**

From: Sanchez-Contreras, Gloria

Sent: Friday, October 18, 2019 10:36 AM

To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Spence, Susan <Susan.Spence@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>

Cc: Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>; Naum, Marianna <Marianna.Naum@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Garrett, Ulysses <Ulysses.Garrett@fda.hhs.gov>; Cardin, Megan <Megan.Cardin@fda.hhs.gov>

Subject: EXPEDITE MEDIA STATEMENT CLEARANCE: J&J Baby Powder

Good morning all,

J&J has recalled the product affected and we started getting media inquiries. Here is the link to the company's press release: <https://www.jnj.com/johnson-johnson-consumer-inc-to-voluntarily-recall-a-single-lot-of-johnsons-baby-powder-in-the-united-states>

Our press release is with HHS for final clearance (latest draft attached), but in the meantime, we would like to clear the following statement to respond to media

The FDA is alerting consumers of a voluntary recall of Johnson & Johnson, Johnson's Baby Powder as FDA testing has found that a sample from one batch of the product contains chrysotile fibers, a type of asbestos. Consumers who have Johnson's Baby Powder batch #22318RB should stop using it immediately. For refund information, consumers can contact the Johnson & Johnson Consumer Care Center at www.johnsonsbaby.com or by calling +1 (866) 565-2229. **The FDA stands by the quality of its testing and results and is not aware of any adverse events relating to exposure to the affected products.**

Thank you,

Gloria Sánchez-Contreras

*International Press Officer
Spanish-Language Communications Lead*

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 301-796-7686 / Cell: 301-500-8888

gloria.sanchez-contreras@fda.hhs.gov



Gloria Sánchez-Contreras

*International Press Officer
Spanish-Language Communications Lead*

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 301-796-7686 / Cell: 301-500-8888
gloria.sanchez-contreras@fda.hhs.gov



From: [Katz, Linda](#)
To: [Musser, Steven M](#)
Subject: RE: Follow-up communications
Date: Wednesday, September 25, 2019 1:47:00 PM

I spoke with Lisa Dwyer and Sheldon Bradshaw today. They wanted to know about future testing of J&J samples.

If you have a minute please give me a call. 240-402-1339.

-----Original Message-----

From: Musser, Steven M <Steven.Musser@fda.hhs.gov>
Sent: Tuesday, September 24, 2019 6:19 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: Re: Follow-up communications

Can (b) (5) [REDACTED] ? It would (b) (5)
(b) (5) [REDACTED]

(b) (5) [REDACTED] . If you're uncertain, ask Leslie for clarification.

On 9/24/19, 2:41 PM, "Katz, Linda" <Linda.Katz@fda.hhs.gov> wrote:

(b) (5) [REDACTED]

Linda

-----Original Message-----

From: Musser, Steven M <Steven.Musser@fda.hhs.gov>
Sent: Friday, September 20, 2019 8:55 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: FW: Follow-up communications

See email contact info below.

On 9/16/19, 9:25 AM, "Bradshaw, Sheldon" <SBradshaw@KSLAW.com> wrote:

Dr. Musser,

Welcome back from vacation. I just wanted to follow up on the letter to Lynne Szczepaniak, Vice President and Head of Global Regulatory Affairs at J&J. When we last spoke it was going through the CFSAN clearance

process. As you can imagine, (b) (5)

(b) (5)

. Take care,

Sheldon

Sent from my iPhone

On Aug 15, 2019, at 3:05 PM, Musser, Steven M
<Steven.Musser@fda.hhs.gov<<mailto:Steven.Musser@fda.hhs.gov>>> wrote:

Thanks Lisa – we'll address any correspondence to Lynne.

From: "Dwyer, Lisa" <LDwyer@KSLAW.com<<mailto:LDwyer@KSLAW.com>>>
Date: Thursday, August 15, 2019 at 1:17 PM
To: "Musser, Steven M" <Steven.Musser@fda.hhs.gov<<mailto:Steven.Musser@fda.hhs.gov>>>
Cc: "Bradshaw, Sheldon" <SBradshaw@KSLAW.com<<mailto:SBradshaw@KSLAW.com>>>
Subject: Follow-up communications

Dr. Musser – as a follow-up, we wanted to mention that any communication related to J&J should be sent to Lynne Szczepaniak, Vice President and Head of Global Regulatory Affairs, at lszczepa@ITS.JNJ.com<<mailto:lszczepa@ITS.JNJ.com>>.

Best,

Lisa

.

Lisa M. Dwyer
Partner

T: +1 202 626 2393 | E: ldwyer@kslaw.com<<mailto:ldwyer@kslaw.com>> |
www.kslaw.com<<http://www.kslaw.com>>

BIO<<https://www.kslaw.com/people/lisa-dwyer>> | vCARD<<https://www.kslaw.com/people/lisa-dwyer.vcf>>

King & Spalding LLP
1700 Pennsylvania Avenue, NW
Suite 200
Washington, D.C. 20006

<image001.png><<https://www.kslaw.com/>>

King & Spalding Confidentiality Notice:

This message is being sent by or on behalf of a lawyer. It is intended exclusively for the individual or entity to which it is addressed. This communication may contain information that is proprietary, privileged or confidential or otherwise legally exempt from disclosure. If you are not the named addressee, you are not authorized to read, print, retain, copy or disseminate this message or any part of it. If you have received this message in error, please notify the sender immediately by e-mail and delete all copies of the message.

From: [Smegal, Deborah](#)
To: [Wolfgang, Steven](#); [Sadrieh, Nakissa](#); [Katz, Linda](#); [Gasper, John](#); [Lewis, Kathleen](#); [Dewan, Kapal](#)
Subject: RE: J&J baby power recall
Date: Friday, October 18, 2019 10:11:16 AM
Attachments: [image007.png](#)
[image008.png](#)

Steve,

Per discussion with (b) (5)
e? i (b) (5) to? Both (b) (5)

Thx

debbie

Deborah Smegal, MPH

Associate Director, Office of Cosmetics and Colors (OCAC)

Center for Food Safety and Applied Nutrition

U.S. Food and Drug Administration

Tel: 240-402-1818

Deborah.smegal@fda.hhs.gov



From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>

Sent: Friday, October 18, 2019 10:08 AM

To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Subject: RE: J&J baby power recall

Here goes

From: Sadrieh, Nakissa

Sent: Friday, October 18, 2019 10:06 AM

To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Subject: RE: J&J baby power recall

I don't think (b) (5) ? (b) (5)

(b) (5)

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Katz, Linda <Linda.Katz@fda.hhs.gov>

Sent: Friday, October 18, 2019 10:03 AM

To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Subject: RE: J&J baby power recall

I'm on the line as well.

Linda M. Katz, M.D., M.P.H.

Director, Office of Cosmetics and Colors

Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
U.S. Food and Drug Administration

240-402-1130 (phone)
301-436-2976 (fax)
linda.katz@fda.hhs.gov



From: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>

Sent: Friday, October 18, 2019 10:02 AM

To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Subject: RE: J&J baby power recall

I just called in.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 9:55 AM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

(b) (5)



Steve

From: Gasper, John
Sent: Friday, October 18, 2019 9:45 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

To All:

There is approximately (b) (5) . I'm leaving to pick it up now.
Thank you.

Regards,
John G

From: Katz, Linda
Sent: Friday, October 18, 2019 9:37 AM

To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: J&J baby power recall

I agree. The question (b) (5)

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 9:34 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: J&J baby power recall

Given we expect (b) (5)

(b) (5)

I suggest (b) (5)

(b) (5)

Steve

From: Katz, Linda
Sent: Friday, October 18, 2019 9:16 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: FW: J&J baby power recall

fyi

Linda

From: Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>

(b) (5)

[Redacted text block]

[Redacted text block]

From: [Sadrieh, Nakissa](#)
To: [Wolfgang, Steven](#); [Gasper, John](#); [Katz, Linda](#); [Lewis, Kathleen](#); [Smegal, Deborah](#); [Dewan, Kapal](#)
Subject: RE: J&J baby power recall
Date: Friday, October 18, 2019 10:13:25 AM

We will have to take out some of what Gasper collects from AMA and put in a separate vial. We need AMA to analyze some of what is left for us (sample 1), some of the stuff in the opened bottle (sample 2) and some of the talc in an unopened bottle (sample 3). AMA needs to start this analysis of the 3 samples next week if possible. Each sample will have 3 aliquots tested. Please confirm if this is OK Linda.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 9:53 AM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

AMA uses 0.5 grams/aliquot. We can probably spare up to 4 grams, but I would bargain for 3, in case we have an upset if/when we retest.

Steve

From: Gasper, John
Sent: Friday, October 18, 2019 9:45 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

To All:

There is approximately 5.6 grams of sample in the D-58 vial at AMA. I'm leaving to pick it up now. Thank you.

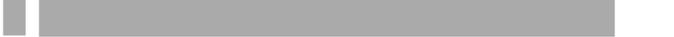
Regards,
John G

From: Katz, Linda
Sent: Friday, October 18, 2019 9:37 AM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: J&J baby power recall

I agree. The question we will be asked is how quickly we can get the sample to send to J&J.

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 9:34 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: J&J baby power recall

Given we expect (b) (5) 

- 
- 
- 

I sugges (b) (5) 



Steve

From: Katz, Linda
Sent: Friday, October 18, 2019 9:16 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: FW: J&J baby power recall

fyi

Linda

From: Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>

Sent: Friday, October 18, 2019 9:11 AM

To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Barringer, Amy <Amy.Barringer@fda.hhs.gov>

Subject: FW: J&J baby power recall

(b) (5)

From: [Wolfgang, Steven](#)
To: [Sadrieh, Nakissa](#); [Gasper, John](#); [Katz, Linda](#); [Lewis, Kathleen](#); [Smegal, Deborah](#); [Dewan, Kapal](#)
Subject: RE: J&J baby power recall
Date: Friday, October 18, 2019 10:15:05 AM

(b) (5)

From: Sadrieh, Nakissa
Sent: Friday, October 18, 2019 10:13 AM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

We will have to (b) (5)

. Please confirm if this is OK Linda.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 9:53 AM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

(b) (5)

Steve

From: Gasper, John
Sent: Friday, October 18, 2019 9:45 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>;

Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

To All:

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John G

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Sent: Friday, October 18, 2019 9:37 AM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: J&J baby power recall

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From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 9:34 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: J&J baby power recall

Given we expect (b) (5)



I suggest (b) (5)



Steve

From: Katz, Linda

Sent: Friday, October 18, 2019 9:16 AM

To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>

Subject: FW: J&J baby power recall

fyi

Linda

From: Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>

Sent: Friday, October 18, 2019 9:11 AM

To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Barringer, Amy <Amy.Barringer@fda.hhs.gov>

Subject: FW: J&J baby power recall

(b) (5)

From: [Sadrieh, Nakissa](#)
To: [Katz, Linda](#); [Dewan, Kapal](#); [Wolfgang, Steven](#); [Gasper, John](#); [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: J&J baby power recall
Date: Friday, October 18, 2019 10:16:46 AM
Attachments: [image001.png](#)

please (b) (5)

[Redacted]

[Redacted]

[Redacted]

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Sent: Friday, October 18, 2019 10:15 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: J&J baby power recall

On the line with Susan and Steve – will call back soon.

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Friday, October 18, 2019 10:14 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: J&J baby power recall

Will call you soon from the conference room.

Debbie, Nakissa, can you please come up in the conference 2013?

From: Katz, Linda

Sent: Friday, October 18, 2019 10:12 AM

To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Subject: RE: J&J baby power recall

Please call me at (b) (5), (b) (6).

Linda M. Katz, M.D., M.P.H.

Director, Office of Cosmetics and Colors

Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
U.S. Food and Drug Administration

240-402-1130 (phone)
301-436-2976 (fax)
linda.katz@fda.hhs.gov



From: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>

Sent: Friday, October 18, 2019 10:06 AM

To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Subject: RE: J&J baby power recall

I don't think that we have anything to say in this call, right? The only issue is when they can get our sample, and Gasper is getting that now from AMA.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Sent: Friday, October 18, 2019 10:03 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

I'm on the line as well.

Linda M. Katz, M.D., M.P.H.

Director, Office of Cosmetics and Colors

Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
U.S. Food and Drug Administration

240-402-1130 (phone)
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linda.katz@fda.hhs.gov



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Sent: Friday, October 18, 2019 10:02 AM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

I just called in.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: [Wolfgang, Steven](#)
To: [Smegal, Deborah](#); [Sadrieh, Nakissa](#); [Katz, Linda](#); [Gasper, John](#); [Lewis, Kathleen](#); [Dewan, Kapal](#)
Subject: RE: J&J baby power recall
Date: Friday, October 18, 2019 10:19:38 AM
Attachments: [RE AMA Results.msg](#)
[image001.png](#)
[image002.png](#)

Estimated (b) (5)

[Redacted]

From: Smegal, Deborah
Sent: Friday, October 18, 2019 10:11 AM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

Steve,

Per discussion with (b) (5)

[Redacted]

Thx

debbie

Deborah Smegal, MPH

Associate Director, Office of Cosmetics and Colors (OCAC)

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1818
Deborah.smegal@fda.hhs.gov



From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 10:08 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Subject: RE: J&J baby power recall

Here goes

From: Sadrieh, Nakissa

Sent: Friday, October 18, 2019 10:06 AM

To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Subject: RE: J&J baby power recall

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Regards,
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Tel: 240-402-2194

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Sent: Friday, October 18, 2019 10:03 AM

To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Subject: RE: J&J baby power recall

I'm on the line as well.

Linda M. Katz, M.D., M.P.H.

Director, Office of Cosmetics and Colors

Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
U.S. Food and Drug Administration

240-402-1130 (phone)

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linda.katz@fda.hhs.gov



From: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Sent: Friday, October 18, 2019 10:02 AM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

I just called in.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
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Center for Food Safety and Applied Nutrition (CFSAN)
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Tel: 240-402-2194

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 9:55 AM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

(b) (5)



Steve

From: Gasper, John
Sent: Friday, October 18, 2019 9:45 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>

Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

To All:

There is approximately 5.6 grams of sample in the D-58 vial at AMA. I'm leaving to pick it up now.
Thank you.

Regards,
John G

From: Katz, Linda
Sent: Friday, October 18, 2019 9:37 AM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: J&J baby power recall

I agree. The question we will be asked is how quickly we can get the sample to send to J&J.

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 9:34 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: J&J baby power recall

Given we expect to (b) (5)



I suggest (b) (5)



Steve

From: Katz, Linda

Sent: Friday, October 18, 2019 9:16 AM

To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>

Subject: FW: J&J baby power recall

fyi

Linda

From: Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>

Sent: Friday, October 18, 2019 9:11 AM

To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Barringer, Amy <Amy.Barringer@fda.hhs.gov>

Subject: FW: J&J baby power recall

(b) (5)

From: [Wolfgang, Steven](#)
To: [Sadrieh, Nakissa](#); [Katz, Linda](#); [Dewan, Kapal](#); [Gasper, John](#); [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: J&J baby power recall
Date: Friday, October 18, 2019 10:28:35 AM
Attachments: [image001.png](#)
[Federal Register 40 Fed. Reg. 11859 \(Mar. 14, 1975\).pdf](#)

Precisely why I don't think we want to continue to post the CoA from AMA. The units of measure in wt. percent is by convention, and as described in the methods that were submitted to FDA when AMA made the offer. We have not been using any of the wt. percent values. AMA did not propose a method to report fibers.

At issue for the person from J&J who described herself as their safety expert is what was stated by FDA in an FR notice (in which a proposed rule to impose testing by **PLM** was withdrawn is a proposed limit of 0.01% equated to 1000 fibers of chrysotile/milligram of talc. Comments to the proposed rule, as you can see, point out the difficulty in equating wt. percent to fibers/mg.

Steve

From: Sadrieh, Nakissa
Sent: Friday, October 18, 2019 10:17 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: J&J baby power recall

please remind them that we had 6 fibers in 100 ng, and this results in more than 6 billion fibers in the product. The company said 16 billion fibers yesterday. The percentage of fibers is not a good measure.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Sent: Friday, October 18, 2019 10:15 AM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>

Subject: RE: J&J baby power recall

On the line with Susan and Steve – will call back soon.

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Friday, October 18, 2019 10:14 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: J&J baby power recall

Will call you soon from the conference room.

Debbie, Nakissa, can you please come up in the conference 2013?

From: Katz, Linda
Sent: Friday, October 18, 2019 10:12 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

Please call me at (b) (6)

Linda M. Katz, M.D., M.P.H.

Director, Office of Cosmetics and Colors

Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
U.S. Food and Drug Administration

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Subject: RE: J&J baby power recall

I don't think that we have anything to say in this call, right? The only issue is when they can get our sample, and Gasper is getting that now from AMA.

Regards,
Nakissa Sadrieh, Ph.D.
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Sent: Friday, October 18, 2019 10:03 AM

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Subject: RE: J&J baby power recall

I'm on the line as well.

Linda M. Katz, M.D., M.P.H.

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linda.katz@fda.hhs.gov



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Sent: Friday, October 18, 2019 10:02 AM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

I just called in.

Regards,
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Sent: Friday, October 18, 2019 9:55 AM
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Subject: RE: J&J baby power recall

(b) (5)



Steve

From: Gasper, John
Sent: Friday, October 18, 2019 9:45 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

To All:

(b) (5)



. I'm leaving to pick it up now.

Thank you.

Regards,
John G

From: Katz, Linda
Sent: Friday, October 18, 2019 9:37 AM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: J&J baby power recall

I agree. (b) (5) J.

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 9:34 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: J&J baby power recall

Given we expect (b) (5)

(b) (5)

I suggest we c(b) (5)

(b) (5)

Steve

From: Katz, Linda
Sent: Friday, October 18, 2019 9:16 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>

Subject: FW: J&J baby power recall

fyi

Linda

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Sent: Friday, October 18, 2019 9:11 AM

To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Barringer, Amy <Amy.Barringer@fda.hhs.gov>

Subject: FW: J&J baby power recall

As you have probably already seen: – Link to J&J’s press release: <https://www.jnj.com/johnson-johnson-consumer-inc-to-voluntarily-recall-a-single-lot-of-johnsons-baby-powder-in-the-united-states>

From: [Wolfgang, Steven](#)
To: [Gasper, John](#); [Katz, Linda](#); [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Smegal, Deborah](#); [Dewan, Kapal](#)
Subject: RE: J&J baby power recall
Date: Friday, October 18, 2019 9:52:54 AM

(b) (5)

Steve

From: Gasper, John
Sent: Friday, October 18, 2019 9:45 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: J&J baby power recall

To All:

There is (b) (5) I'm leaving to pick it up now.
Thank you.

Regards,
John G

From: Katz, Linda
Sent: Friday, October 18, 2019 9:37 AM
To: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: J&J baby power recall

I agree. The question (b) (5)

From: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Sent: Friday, October 18, 2019 9:34 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>
Subject: RE: J&J baby power recall

Given we expect (b) (5)

told John Gasper to do.

(b) (5)

I suggest (b) (5)

Steve

From: Katz, Linda

Sent: Friday, October 18, 2019 9:16 AM

To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>

Subject: FW: J&J baby power recall

fyi

Linda

From: Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>

Sent: Friday, October 18, 2019 9:11 AM

To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Barringer, Amy <Amy.Barringer@fda.hhs.gov>

Subject: FW: J&J baby power recall

As you have probably already seen: – Link to J&J’s press release: <https://www.jnj.com/johnson-johnson-consumer-inc-to-voluntarily-recall-a-single-lot-of-johnsons-baby-powder-in-the-united-states>

From: [Wolfgang, Steven](#)
To: [Sadrieh, Nakissa](#); [Dewan, Kapal](#); [Scarborough, Kim](#); [Gasper, John](#)
Cc: [Lewis, Kathleen](#); [Smegal, Deborah](#); [Katz, Linda](#)
Subject: RE: JJ Testing Questions DRAFT 10-18-19
Date: Friday, October 18, 2019 3:49:00 PM

Any other questions (b) (5)



From: Sadrieh, Nakissa
Sent: Friday, October 18, 2019 3:04 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Gasper, John <John.Gasper@fda.hhs.gov>
Cc: Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: JJ Testing Questions DRAFT 10-18-19

I was working on the attached and I need (b) (5) . This is from Gloria's last request for input.

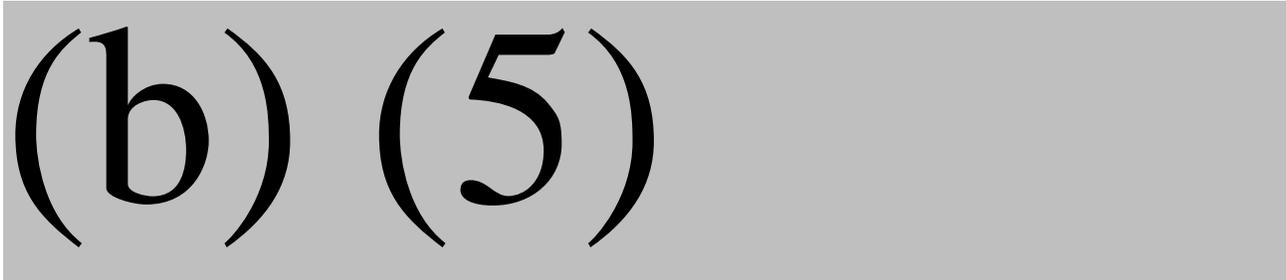
From: [Dooren, Jennifer](#)
To: [Katz, Linda](#); [Haake, Lindsay](#)
Cc: [Scarborough, Kim](#); [Sadrieh, Nakissa](#)
Subject: RE (b) (5)
Date: Friday, October 18, 2019 2:18:47 PM
Attachments: [image001.png](#)
[image007.png](#)

Thanks

From: Katz, Linda
Sent: Friday, October 18, 2019 2:13 PM
To: Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>
Cc: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE (b) (5)

Made a typo – Below is the revised paragraph.

What does the (b) (5) ?



Linda M. Katz, M.D., M.P.H.

Director, Office of Cosmetics and Colors

Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
U.S. Food and Drug Administration

240-402-1130 (phone)
301-436-2976 (fax)
linda.katz@fda.hhs.gov



From: Katz, Linda

Sent: Friday, October 18, 2019 2:07 PM

To: Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>

Cc: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>

Subject: RE: (b) (5)

Let me know i (b) (5)

What does the (b) (5) ?

(b) (5)

Linda

From: Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>

Sent: Friday, October 18, 2019 1:33 PM

To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>

Cc: Katz, Linda <Linda.Katz@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>

Subject: RE: (b) (5)

Hi Kim,

Quick question (b) (5)

What does the (b) (5) ?

(b) (5)

Can you (b) (5) ?

Thanks,
Lindsay

From: Scarborough, Kim

Sent: Friday, October 18, 2019 12:55 PM

To: Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>

Cc: Katz, Linda <Linda.Katz@fda.hhs.gov>

Subject: RE: KMQA

Importance: High

Hello Lindsay,

I (b) (5)

Please confirm that you can see all edits and new verbiage (b) (5).

Please let me know if you have any questions or concerns about the upload (I can email you the document for you to upload if need be).

Thanks,
Kim

From: Haake, Lindsay

Sent: Friday, October 18, 2019 9:55 AM

To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>

Cc: Katz, Linda <Linda.Katz@fda.hhs.gov>

Subject (b) (5)

Importance: High

Hi Kim,

Here's the link to the (b) (5).

Do you mind making your edits here?

Let me know if you can't open the link and I can send it as an attachment.

Thanks!

Lindsay Haake

Health Communication Specialist

Communications and Public Engagement Staff

Center for Food Safety and Applied Nutrition

U.S. Food and Drug Administration

5001 Campus Drive, College Park, MD 20740

Phone: 301-796-3007

Cell: 202-309-7277

Follow us on Twitter @FDAfood; @FDACosmetics; and @FDAanimalhealth



From: [Sadrieh, Nakissa](#)
To: [Scarborough, Kim](#); [Katz, Linda](#)
Cc: [Dewan, Kapal](#); [Wolfgang, Steven](#)
Subject: RE: (b) (5)
Date: Thursday, October 17, 2019 11:54:24 AM

(b) (5) . Don't worry Kim, I will (b) (5)

(b) (5) . Thanks.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Sent: Thursday, October 17, 2019 11:52 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>
Subject: RE: (b) (5)

She left different 'lead' folks in charge- (b) (5)

Kim

From: Sadrieh, Nakissa
Sent: Thursday, October 17, 2019 11:44 AM
To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Subject: RE: (b) (5)

Has Kapal left someone as acting for herself, to (b) (5)

?

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)

Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Sent: Thursday, October 17, 2019 11:43 AM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: RE: (b) (5)^{(b)(1)}

Thank you Linda. (b) (5)

Nakissa- once I'm finished, (b) (5)

Kim

From: Katz, Linda
Sent: Thursday, October 17, 2019 11:35 AM
To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
Subject: (b) (5)

Kim,

See edits and comments from Nakissa and me. A (b) (5)
if you can finish this up before 4 I'd appreciate it. Thanks.

Linda

From: [Scarborough, Kim](#)
To: [Haake, Lindsay](#)
Cc: [Katz, Linda](#)
Subject: RE: (b) (5)
Date: Friday, October 18, 2019 12:54:34 PM
Attachments: [image001.png](#)
Importance: High

Hello Lindsay,

(b) (5)

Please let me know (b) (5)

(b) (5)

Thanks,
Kim

From: Haake, Lindsay
Sent: Friday, October 18, 2019 9:55 AM
To: Scarborough, Kim <Kim.Scarborough@fda.hhs.gov>
Cc: Katz, Linda <Linda.Katz@fda.hhs.gov>
Subject: (b) (5)
Importance: High

Hi Kim,

Here's the link to (b) (5) .

Do you mind making your edits here?

Let me know if you can't open the link and I can send it as an attachment.

Thanks!

Lindsay Haake

Health Communication Specialist

**Communications and Public Engagement Staff
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration**

5001 Campus Drive, College Park, MD 20740

Phone: 301-796-3007

Cell: 202-309-7277

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From: [Dwyer, Lisa](#)
To: [Katz, Linda](#)
Cc: [Bradshaw, Sheldon](#)
Subject: RE: Letter of Sample Testing Results
Date: Friday, September 20, 2019 4:50:26 PM

Linda – thank you for the letter. We want to confirm that we have received it. We are hoping to follow-up with you on Monday or Wednesday with a couple quick questions, including about how we should go about requesting the testing results. Please let us know if you have a couple minutes to discuss.

Have a great weekend.

Lisa

From: Industry.Cosmetics <Industry.Cosmetics@fda.hhs.gov>
Sent: Friday, September 20, 2019 12:10 PM
To: Iszczepa@ITS.JNJ.com; Bradshaw, Sheldon <SBradshaw@KSLAW.com>; Dwyer, Lisa <LDwyer@KSLAW.com>
Subject: Letter of Sample Testing Results

****External Sender****

Greetings,

On behalf of Dr. Linda Katz, Director, Office of Cosmetics and Colors, please see the attached correspondence.

Please acknowledge receipt of this email.

Thank you very much.

The Cosmetics Staff
Office of Cosmetics and Colors
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

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From: [Dwyer, Lisa](#)
To: [Katz, Linda](#)
Cc: [Bradshaw, Sheldon](#)
Subject: RE: Quick Check-In?
Date: Tuesday, October 08, 2019 3:08:16 PM
Attachments: [image001.png](#)

Thanks Linda. Understood. Every day makes a very big difference on our end, and we are sure that we will get questions about whether any additional products of our client's are being tested. Is there someone on your team who can speak with us this week? I really think this will take about 5 minutes.

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Sent: Tuesday, October 8, 2019 3:00 PM
To: Dwyer, Lisa <LDwyer@KSLAW.com>
Cc: Bradshaw, Sheldon <SBradshaw@KSLAW.com>
Subject: RE: Quick Check-In?

****External Sender****

Lisa,

I'm running out of the office now and, as I mentioned yesterday, I'm out tomorrow. My calendar for this month is pretty packed with meetings and beginning of the fiscal year issues. End of the month or next month may be better for me.

Linda

Dwyer, Lisa <LDwyer@KSLAW.com>
Sent: Monday, October 7, 2019 6:09 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Bradshaw, Sheldon <SBradshaw@KSLAW.com>
Subject: RE: Quick Check-In?

No worries – is there a better time that works for you this week? I know we have the holidays.

Lisa

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Sent: Monday, October 7, 2019 5:38 PM
To: Dwyer, Lisa <LDwyer@KSLAW.com>
Cc: Bradshaw, Sheldon <SBradshaw@KSLAW.com>
Subject: Re: Quick Check-In?

****External Sender****

Lisa

Been in meetings all day. Unfortunately I don't have any time tomorrow.

Linda

From: Dwyer, Lisa <LDwyer@KSLAW.com>
Date: October 7, 2019 at 9:45:52 AM EDT
To: Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Bradshaw, Sheldon <SBradshaw@KSLAW.com>
Subject: Quick Check-In?

Hi Linda – we were wondering if you have a couple minutes for a quick check-in today or tomorrow. With the expiration of the 2019 fiscal year, we were wondering if there was additional information about the remaining testing. We are flexible this afternoon, and tomorrow from 10:30 a.m. -1:00 p.m., and again from 2:00-4:00 pm.

Best,

Lisa

Lisa M. Dwyer

Partner

T: +1 202 626 2393 | E: ldwyer@kslaw.com | www.kslaw.com

[BIO](#) | [vCARD](#)

King & Spalding LLP
1700 Pennsylvania Avenue, NW
Suite 200
Washington, D.C. 20006

KING & SPALDING

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From: [Rennie, Chalmer](#)
To: [Katz, Linda](#)
Subject: RE: Redaction Issue
Date: Thursday, October 17, 2019 8:12:25 AM
Attachments: [RE Talc Redaction.msg](#)
[image001.png](#)

Linda. I sent it back to Kathleen yesterday. Please see attached.

Thanks,

Chalmer Rennie
FOI/PRA Staff Director
Office of Regulations and Policy
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
240-402-8992

From: Katz, Linda
Sent: Wednesday, October 16, 2019 5:01 PM
To: Rennie, Chalmer <Chalmer.Rennie@fda.hhs.gov>
Subject: Redaction Issue

Chalmer,

Not sure (b) (5)

(b) (5) s this something you (b) (5) ? (b) (5)
(b) (5)

Let me know.

Linda

Linda M. Katz, M.D., M.P.H.
Director, Office of Cosmetics and Colors

Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
U.S. Food and Drug Administration

240-402-1130 (phone)
301-436-2976 (fax)
linda.katz@fda.hhs.gov



From: [Katz, Linda](#)
To: [Pillsbury, Laura](#); [Mayne, Susan](#)
Cc: [Stearn, Douglas](#); [Musser, Steven M](#); [Correll, William A](#); [Dooren, Jennifer](#)
Subject: RE: Update on talc from this morning's meeting
Date: Tuesday, October 15, 2019 2:00:00 PM
Attachments: [308006 FDA_6_6A_6B-D58_Final Data Package_Rev2.pdf](#)
[OCAC Memo D58 for OCAC clearance.docx](#)

Attached is the AMA report, revised on 10/11/19 and the OCAC Memo.

In addition, the (b) (5) [redacted]
[redacted]
[redacted]

Finally, we have (b) (5) [redacted]
(b) (5) [redacted].

Linda

From: Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Sent: Tuesday, October 15, 2019 11:19 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Cc: Katz, Linda <Linda.Katz@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Subject: Update on talc from this morning's meeting

Internal Confidential

Good morning Susan,

Knowing that (b) (5) [redacted]
[redacted] next steps we discussed just now. Our goal (b) (5) [redacted]
[redacted]
(b) (5) [redacted]. Others, please feel free to add/modify what's below, and Susan, please let us know if you have any questions.

- (b) (5) [redacted]
 - [redacted]
 - [redacted]
 - [redacted]
 - [redacted]
- [redacted]
 - [redacted]
- [redacted]
 - [redacted]

- (b) (5)

- [REDACTED]

Thanks,

Laura

From: [Wolfgang, Steven](#)
To: [Sadrieh, Nakissa](#); [Dewan, Kapal](#); [Katz, Linda](#)
Cc: [Lewis, Kathleen](#); [Smegal, Deborah](#)
Subject: RE: Update on talc from this morning's meeting
Date: Tuesday, October 15, 2019 4:05:43 PM

Here is (b) (5) . I starting (b) (5)

<https://www.barcodelookup.com/381370030140>

3 81370 03014 0

From: Sadrieh, Nakissa
Sent: Tuesday, October 15, 2019 2:24 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Update on talc from this morning's meeting

For OC they need (b) (5)

(b) (5)

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Sent: Tuesday, October 15, 2019 2:23 PM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Update on talc from this morning's meeting

OC needs a (b) (5) . I will send all the information to Kay. Allow

me some time. Thanks.

From: Sadrieh, Nakissa
Sent: Tuesday, October 15, 2019 2:20 PM
To: Katz, Linda <Linda.Katz@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: RE: Update on talc from this morning's meeting

We may need (b) (5) .

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Katz, Linda <Linda.Katz@fda.hhs.gov>
Sent: Tuesday, October 15, 2019 2:03 PM
To: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>; Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Smegal, Deborah <Deborah.Smegal@fda.hhs.gov>
Subject: FW: Update on talc from this morning's meeting

Please forward to OC (b) (5) .

Linda

Kapal,

This list looks [redacted] (b) (5) [redacted]
[redacted] ? Otherwise we can (b) (5) [redacted]
[redacted]. Thanks.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
5001 Campus Drive
Room 1042 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194

From: Dewan, Kapal
Sent: Tuesday, May 14, 2019 11:48 AM
To: Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>; Katz, Linda <Linda.Katz@fda.hhs.gov>; Lewis, Kathleen <Kathleen.Lewis@fda.hhs.gov>
Cc: Gasper, John <John.Gasper@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Periz, Goran <Goran.Periz@fda.hhs.gov>
Subject: Updated Proposed (b) (5) [redacted]
ATTENTION
Importance: High

Nakissa, Linda, Kay,

[redacted] (b) (5) [redacted]
[redacted]
[redacted]
[redacted]
[redacted]

Your speedy approval would be very much appreciated!

Thank you in advance!
Kapal

From: [Katz, Linda](#)
To: [Sadrieh, Nakissa](#); [Wolfgang, Steven](#)
Cc: [Smegal, Deborah](#)
Subject: redacted report
Date: Thursday, October 17, 2019 10:05:00 AM
Attachments: [AMA Final Report for Sample D 58 \(JJ redaction\). Redacted.pdf](#)

From: [Gasper, John](#)
To: [Edson, Paul \[JJCUS\]](#); [Dewan, Kapal](#)
Cc: [Piper-Givler, Venessa \[MCCUS\]](#)
Subject: RE: Johnson Baby Powder lot #22318RB
Date: Friday, October 18, 2019 4:27:00 PM
Attachments: [image007.png](#)

Hello Mr. Edson,

We have received your information mentioned below. Please let us know which date and time you plan to collect the sample and related information. Also, please provide the name and details of the personnel coming to collect the sample. The person should be a U.S. citizen and should have valid identification to be allowed entry. Please provide this information as soon as possible so that we may inform our security. Thank you.

Regards,

John Gasper

CFSAN
Office of Cosmetics and Colors
U.S. Food and Drug Administration
Tel: 240-402-1133

john.gasper@fda.hhs.gov



From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Friday, October 18, 2019 3:42 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>
Subject: Johnson Baby Powder lot #22318RB

Hello John and Kapal,

Pursuant to FDA's agreement to help facilitate materials for our investigation of Johnson's Baby Powder lot #22318RB, we request support for the following:

- 75grams of J&J Baby Powder from the original J&J Baby Powder bottle lot #22318RB

Access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing (to determine authenticity)

- A Picture of the original container sampled, prior to opening
- Picture or evidence the original tamper seals were intact prior to sampling
- A sample from any remaining J&J Baby Powder from the blinded sample containers (D58 308006-6A; D58 308006-6B) tested by AMA
- AMA Labs Talc Testing SOP & Protocol
- AMA sample preparation methods for preparation of reference control standard using Sigma-Aldrich spike with 10% chrysolite
- Analysis and/or TEM photos of the Sigma-Aldrich spiked with 10% chrysolite
- Any asbestos environmental testing for the area used in FDA blinded sample preparation and at AMA laboratories testing labs
- FDA's Standard operating procedure for preparation of samples for Blind testing of Talc (D58 308006 series)
- Documentation for the chain of custody including any invoices for the purchase of the samples from the online retailer

As the investigation is of the utmost importance, we will be available to receive any of the above material, as soon as each of them are available and at the earliest convenience.

I look forward to hearing from you soon,

Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: +1 (b) (6)

pedson@its.jnj.com
<http://www.jnj.com>

From: [Edson, Paul \[JJCUS\]](#)
To: [Gasper, John](#)
Cc: [Dewan, Kapal](#); [Piper-Givler, Venessa \[MCCUS\]](#)
Subject: Re: Johnson Baby Powder lot #22318RB
Date: Friday, October 18, 2019 8:14:49 PM

Hello John,

Derek Smith and Jeff Jenner are planning to be at your facility at 11:00am. Should they go to:

Center for Food Safety and Applied Nutrition
5001 Campus Dr
College Park, MD 20740
(888) 723-3366

Please let me know if this is the correct location or if there is a special entry to meet you. They will have ID and sample collection tools/containers.

Thank you, Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: **(b) (6)**

pedson@its.jnj.com
<http://www.jnj.com>

From: Paul Edson <PEDSON@its.jnj.com>
Date: Friday, October 18, 2019 at 6:14 PM
To: "Gasper, John" <John.Gasper@fda.hhs.gov>
Cc: "Dewan, Kapal" <Kapal.Dewan@fda.hhs.gov>, Venessa Piper-Givler <VPiperG@its.jnj.com>
Subject: Re: Johnson Baby Powder lot #22318RB

We plan to be onsite to pick up the sample late morning. I do not yet have the name of the individual. We will notify you of the individuals ASAP. Thank you!

Paul

On Oct 18, 2019, at 5:16 PM, Gasper, John <John.Gasper@fda.hhs.gov> wrote:

Mr. Edson,

Please bring your own container to use for sample collection. Thank you.

Regards,

John Gasper

CFSAN
Office of Cosmetics and Colors
U.S. Food and Drug Administration
Tel: 240-402-1133

john.gasper@fda.hhs.gov

[<image007.png>](#)

[<image008.jpg>](#)

[<image009.jpg>](#)

[<image010.jpg>](#)

[<image011.jpg>](#)

[<image012.jpg>](#)

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Friday, October 18, 2019 3:42 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal
<Kapal.Dewan@fda.hhs.gov>
Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>
Subject: Johnson Baby Powder lot #22318RB

Hello John and Kapal,

Pursuant to FDA's agreement to help facilitate materials for our investigation of Johnson's Baby Powder lot #22318RB, we request support for the following:

- 75grams of J&J Baby Powder from the original J&J Baby Powder bottle lot #22318RB
- Access to the original J&J Baby Powder bottle lot #22318RB that was sampled from for blind testing (to determine

authenticity)

- A Picture of the original container sampled, prior to opening
- Picture or evidence the original tamper seals were intact prior to sampling
- A sample from any remaining J&J Baby Powder from the blinded sample containers (D58 308006-6A; D58 308006-6B) tested by AMA
- AMA Labs Talc Testing SOP & Protocol
- AMA sample preparation methods for preparation of reference control standard using Sigma-Aldrich spike with 10% chrysolite
- Analysis and/or TEM photos of the Sigma-Aldrich spiked with 10% chrysolite
- Any asbestos environmental testing for the area used in FDA blinded sample preparation and at AMA laboratories testing labs
- FDA's Standard operating procedure for preparation of samples for Blind testing of Talc (D58 308006 series)
- Documentation for the chain of custody including any invoices for the purchase of the samples from the online retailer

As the investigation is of the utmost importance, we will be available to receive any of the above material, as soon as each of them are available and at the earliest convenience.

I look forward to hearing from you soon,

Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: +(b) (6)

pedson@its.jnj.com
<http://www.jnj.com>

From: [Edson, Paul \[JJCUS\]](#)
To: [Gasper, John](#)
Cc: [Dewan, Kapal](#); [Piper-Givler, Venessa \[MCCUS\]](#)
Subject: Re: Johnson Baby Powder lot #22318RB
Date: Friday, October 18, 2019 6:14:51 PM

We plan to be onsite to pick up the sample late morning. I do not yet have the name of the individual. We will notify you of the individuals ASAP. Thank you!

Paul

On Oct 18, 2019, at 5:16 PM, Gasper, John <John.Gasper@fda.hhs.gov> wrote:

Mr. Edson,

Please bring your own container to use for sample collection. Thank you.

Regards,

John Gasper

CFSAN
Office of Cosmetics and Colors
U.S. Food and Drug Administration
Tel: 240-402-1133

john.gasper@fda.hhs.gov

[<image007.png>](#)

[<image008.jpg>](#)

[<image009.jpg>](#)

[<image010.jpg>](#)

[<image011.jpg>](#)

[<image012.jpg>](#)

From: Edson, Paul [JJCUS] <PEDSON@its.jnj.com>
Sent: Friday, October 18, 2019 3:42 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>

Subject: Johnson Baby Powder lot #22318RB

Hello John and Kapal,

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- Analysis and/or TEM photos of the Sigma-Aldrich spiked with 10% chrysolite
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- FDA's Standard operating procedure for preparation of samples for Blind testing of Talc (D58 308006 series)
- Documentation for the chain of custody including any invoices for the purchase of the samples from the online retailer

As the investigation is of the utmost importance, we will be available to receive any of the above material, as soon as each of them are available and at the earliest convenience.

I look forward to hearing from you soon,

Paul

Paul Edson
Vice President

Johnson & Johnson
Johnson & Johnson Regulatory Compliance (JJRC)

M: +**(b) (6)**

pedson@its.jnj.com
<http://www.jnj.com>

From: [Gasper, John](#)
To: [Edson, Paul \[JJCUS\]](#)
Cc: [Dewan, Kapal](#); [Piper-Givler, Venessa \[MCCUS\]](#)
Subject: RE: Johnson Baby Powder lot #22318RB
Date: Friday, October 18, 2019 8:34:00 PM
Attachments: [image007.png](#)

Mr. Edson,

They should go to University Station, room 1044. We are located in the University Station building, which is the building across the parking lot from 5001 Campus Drive. 5001 Campus Drive is the main building for the Center for Food Safety and Applied Nutrition. I will notify our security that Derek Smith and Jeff Jenner are coming to meet with us. Thank you.

Regards,

John Gasper

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Tel: 240-402-1133

john.gasper@fda.hhs.gov



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Sent: Friday, October 18, 2019 8:15 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>
Cc: Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>; Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>
Subject: Re: Johnson Baby Powder lot #22318RB

Hello John,

Derek Smith and Jeff Jenner are planning to be at your facility at 11:00am. Should they go to:

Center for Food Safety and Applied Nutrition
5001 Campus Dr
College Park, MD 20740
(888) 723-3366

Please let me know if this is the correct location or if there is a special entry to meet you. They will

have ID and sample collection tools/containers.

Thank you, Paul

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pedson@its.jnj.com
<http://www.jnj.com>

From: Paul Edson <PEDSON@its.jnj.com>
Date: Friday, October 18, 2019 at 6:14 PM
To: "Gasper, John" <John.Gasper@fda.hhs.gov>
Cc: "Dewan, Kapal" <Kapal.Dewan@fda.hhs.gov>, Venessa Piper-Givler <VPiperG@its.jnj.com>
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Sent: Friday, October 18, 2019 3:42 PM

To: Gasper, John <John.Gasper@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>

Cc: Piper-Givler, Venessa [MCCUS] <VPiperG@its.jnj.com>

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To: [Gasper, John](#)
Cc: [Dewan, Kapal](#); [Piper-Givler, Venessa \[MCCUS\]](#)
Subject: Re: Johnson Baby Powder lot #22318RB
Date: Friday, October 18, 2019 9:36:47 PM

Thank you John!

Paul

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Paul

From: [Gasper, John](#)
To: [Wolfgang, Steven](#); [Dewan, Kapal](#); [Dana Hudson Nicodemus](#); [Andreas Saldivar](#)
Subject: RE: Preliminary Results for COC 308006 - Samples Received at AMA on 7/24/2019
Start: Monday, September 30, 2019 3:30:00 PM
End: Monday, September 30, 2019 4:30:00 PM
Location: WebEx Call In Telecon

To All:

Here's FDA's questions:

(b) (5)

This conference call is to discuss the preliminary data reported for COC 308006 in more detail. A WebEx call in number is provided below. Thank you.

Regards,

John G

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

Meeting number (access **(b) (6)(b) (6)**)

Meeting password: **(b) (6)**

Join <<https://fda1.webex.com/fda1/j.php?MTID=m42b2a9516b0dd27c15524f73bb3c805f>>

Join by phone

Tap to call in from a mobile device (attendees only)

(b) (6)

oll
oll Free

<<https://fda1.webex.com/fda1/globalcallin.php?MTID=me0f0a13b1759c0e23c2bb5d70e911282>> | Toll-free calling restrictions <https://e-meetings.verizonbusiness.com/global/pdf/Verizon_Audio_Conferencing_Global_Access_Information_August2017.pdf>

Need help? Go to <http://help.webex.com> <<http://help.webex.com>>

From: [Gasper, John](#)
To: [Katz, Linda](#)
Cc: [Sadrieh, Nakissa](#); [Lewis, Kathleen](#); [Smegal, Deborah](#); [Dewan, Kapal](#); [Wolfgang, Steven](#)
Subject: FW: 300396-7, 7A, 7B/D-38
Date: Friday, October 25, 2019 4:52:08 PM
Attachments: [image003.jpg](#)
[300396 FDA-7, 7A, 7B-D38 Final Data Package.pdf](#)

Linda,

Please note that we just received the separate report for FDA sample D-38 which corresponds to the J&J Baby Powder lot 00918RA. Thank you.

Regards,
John G

From: Dana Hudson Nicodemus <dHUDSON@amalab.com>
Sent: Friday, October 25, 2019 4:41 PM
To: Gasper, John <John.Gasper@fda.hhs.gov>; Wolfgang, Steven <Steven.Wolfgang@fda.hhs.gov>; Dewan, Kapal <Kapal.Dewan@fda.hhs.gov>
Cc: Andreas Saldivar <andreas@amalab.com>
Subject: 300396-7, 7A, 7B/D-38

John

Per your request, we've split sample 300396-7, 7A, 7B/D-38 into a separate report package.

Please do not hesitate to contact me with any questions or concerns that you may have.

Thank you,

Dana Nicodemus Hudson
Client Services Director



4475 Forbes Boulevard
Lanham, MD 20706
(301) 459-2640 / (800) 346-0961
(b) (6) Cell
dHUDSON@amalab.com
www.amalab.com