DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425) 302-0340 Fax:(425) 302-0404 Industry Information: www.fda.gov/oc/industry	07/13/2015 - 07/21/2015* FEI NUMBER 3004603767

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Shawn W. Needham, RPh/President/CEO

FIRM NAME	STREET ADDRESS
JD & SN Inc., dba Moses Lake Professional Pharmacy	1555 Pilgrim St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Moses Lake, WA 98837-4623	Producer of Sterile Drug Products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. The firm has no procedure setting alert and action levels for microbial counts in the ISO 5 hood, ISO 6 clean room, and ISO 8 ante room. The following CFU's counts were recorded from the firm but no investigation was conducted per P&P No. (b) (4)[b] titled "Deviations - Out of Specification (OOS)." The firm does not identify any of these CFU's to per P&P No. 4.050 date 05/08/03 titled "Evaluation Of Compounding Surfaces for Viable Airborne Contamination" section 6.1.8 which states "At the end of the incubational period, plates will be evaluated for microbial growth. If contamination is present, the number of CFU's should be recorded, and bacteriological identification should be completed. All data must be recorded." In addition, the firm does not identify any potential trends or conduct root cause investigation and corrective action. There is no actual location/diagram to show where the firm conducted the surface sampling from.

Date	ISO 5 (b) (4)	ISO 6 (b) (4)	Anteroom (b) (4)	Anteroom (b) (4)
(b) (4)	0	7	19	60
	0	0	8	57
	0	1	2	8
	0	1	6	125
	0	0	56	11
	0	1	1	3
	3	3	1	8
	0	0	0	0
	0	0	0	0
	0	0	0	0
	0	0	0	3

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B. The following table shows failuress related to product (b) (4) potency (specification is (b) (4) % and test method done by (b) (4) by a third party lab) in which no investigations were conducted. Per P&P No. 5.060, effective date 05/01/03 titled "Assaying the Potency and Shelf Life Of an End Product" section 6.3 states "If the drug is not of acceptable potency, or does not demonstrate an acceptable shelf life, the lot should be discarded." Only two lots not meeting potency testings were recalled (Alprostadil/Procaine 20mcg/0.1%/ml injectable lot # 01242013@20 and Sermorelin lot # t06172013@26) and not the rest of the lots below not meeting potency specifications. For (b) (4) preparations, the firm did not extend its investigation or address formula adjustment/correction ((b) (4) not validated) when using (b) (4) to make final sterile drug products.

(b) (4)	LOT#	Analyte ((b) (4) (b) (4) (b) (4))	Expected Amt. (mcg/ml)	Results	% of EXP. (expected)	Date Tested
	(b) (4)	Alprostadil (b) (4) (b) (4)	(b) (4)	(b) (4)	127.4	6/18/2015
	(b) (4)	Alprostadil (b) (4) (b) (4) injectable	(b) (4)	(b) (4)	120.7	5/18/2015
		Alprostadil (b) (4) (b) (4) injectable	(b) (4)	(b) (4)	120.5	
		Alprostadil (b) (4) (b) (4) injectable	(b) (4)	(b) (4)	120.2	
	(b) (4)	Alprostadil (b) (4)	(b) (4)	(b) (4)	79.7	4/8/2015
		Alprostadil (b) (4) (b) (4)	(b) (4)	(b) (4)	79.6	
		Alprostadil (b) (4) (b) (4)	(b) (4)	(b) (4)9	79.4	
	(b) (4)	Alprostadil (b) (4) injection	(b) (4)	(b) (4)	130.4	12/16/2014
		Alprostadil (b) (4) (b) (4) injection	(b) (4)	(b) (4)	129.7	
		Alprostadil (b) (4) (b) (4) injection	(b) (4)	(b) (4)	128.6	
		Alprostadil (b) (4) (b) (4) injection	(b) (4)	(b) (4)	130.1	

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(b) (4)	(b) (4)	Alprostadil (b) (4) (b) (4) injectable	(b) (4)	(b) (4)	150.8	12/2/2014
		Alprostadil (b) (4) (b) (4) injectable	(b) (4)	(b) (4)	150.7	
		Alprostadil (b) (4), (b) (4) injectable	(b) (4)	(b) (4)	150.6	
	(b) (4)	Alprostadil (b) (4) (b) (4) injectable	(b) (4)	(b) (4)	128.9	10/17/2014
	t06172013@26 (recall letter 09/09/13)	Sermorelin Acetatate 9mg/9ml	9.0	63.884	709.8	08/28/2013
		Sermorelin Acetate Rerun	9.0	66.236	736.0	
		Sermorelin Acetate Rerun # 2	9.0	63.875	709.7	
		Sermoreline Acetate Average	9.0	64.665	718.5	
	(b) (4)	Alprostadil (b) (4) (b) (4)	(b) (4)	(b) (4)	133.9	05/31/13
	01242013@20 (recall letter 03/12/13)	Alprostadil	20	5.213	26.1	02/28/13
		Procaine	0.1	0.068	68	
	t02152013@7	Alprostadil	20	19.564	97.8	02/28/13
		Procaine HCl	0.1	0.0822	82.2	
	t02112013@21	Methylcobalamin 15mg/ml	15	12.435	82.9	02/16/13
		Methylcobalamin Average 15mg/ml	15	12.469	83.1	
		Methylcobalamin Rerun 15mg/ml	15	12.502	83.3	

(b) (4)

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OBSERVATION 2

Test procedures relative to appropriate laboratory testing for sterility and pyrogens are not written and followed.

Specifically,

A. Per the PIC, the firm does not conduct any endotoxin testing for any of the sterile products they make which is not in accordance with P&P No. 5.050, effective date 05/011/03 titled "Endotoxin Testing of An End Product" section 6.1 which states "All parenteral products compounded in the cleanroom setting should be assayed for endotoxin levels."

B. Per the PIC, sterility testing is (b) (4) (b) (4) but there is no official sterility testing procedure. The following sterile products made have not been sterility tested.

Sterile Compounded Products	Lot #	Lot Size
Glycopyrolate 0.2mg/ml solution	t04252014@9	(b) (4)
Glutathione MDV 200mg/ml injectable	t05262015@13	
Methionine/Choline/Inositol 25/50/50 mg/ml injectable	t05282015@15	
Dexpanthenol 250mg/ml injectable	t05282015@25	
Pyridoxine HCl 100mg/ml injectable	t05292015@5	
Chorionic Gonodotropin 200 unit/0.1ml injection 2000 units/ml injectable	t07102015@25	

C. P&P No. 1.070, effective date 05/01/03 titled "Quality Assurance" does not require the firm to perform 100% visual inspection of sterile injectable products produced. Per section 6.1.1 of this SOP "Visual inspection (b) (4) in prepration of products in order to determine the presence of inappropriate particulate matter or signs of deterioration."

D. On 07/13/15, we observed the following solutions with free flowing particulate matters.

a. Chorionic Gonadotropin (b) (4), lot # (b) (4) exp. 9/13/2015
   i. A needle puncture hole was observed in the septum of this (b) (4)
   ii. This (b) (4) was observed to be used to compound HCG lot # t07092015@42
   iii. The PIC stated that this (b) (4) is used/punctured multiple times until the solution is used up or expired
   iv. The PIC stated that the expiration of (b) (4) solution is not taken into consideration when assigning the BUD of the formulation produced therefore the final product can exceed the expiration date assigned to the (b) (4)

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b. Chorionic Gonadotropin (b) (4) Vial (b) (4) lot # (b) (4) exp. 9/13/2015
   i. This product is to be further unit dose per prescription received

Both of these solutions were observed not to have any protective cover on them when stored in the refrigerator or when it is stored at room temperature for use. However, there is no justification for the labeling of those two solutions' expiration dates above (see Observation # 7).

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically, per the PIC

A. The firm has no written media fill procedure and uses (b) (4) to perform media fills. This (b) (4) media fill procedure is inadequate in that it does not representative of the most challenging production conditions and procedures as it does not include any non-sterile powder similar to the non-sterile API's used. Among the procedures provided, P&P No. (b) (4) titled "Process Validation of Aseptic Compounding Personnel" from (b) (4) mentions media fills for low, medium, and high-risk products. Per the PIC, the firm only performs high-risk compounding activities (non-sterile to sterile) which is similar to (b) (4) media fill instructions. The PIC stated that the firm uses (b) (4) to similar API powder but the firm could not provide any documentation to show that the firm used (b) (4) as part of their media fill simulation.

B. Per P&P 5.010, effective date 05/01/03 titled "Evaluation of Compounding Personnel for Aseptic Technique" section 6.2 states "An initial certification consists of each compounding personnel successfully completing (b) (4) (b) (4)," and section 6.3 states "recertification will be completed once every (b) (4) days." However, the PIC stated that media fills are to be conducted every (b) (4) months after the initial certification. In actual practice,

a. (b)(6),(b)(7)(C) (b) (4) technician designated to make sterile injectable products did not go through the initial media fills qualification at the firm. The firm used the initial certification for media fills from a school (b) (6)) and (b)(6),(b)(7)(C) has been working here since (b)(6),(b)(7)(C) as a technician and performing sterile compouding activities after (b) (6) school certification per the PIC. The last media fill performed by this technician was on 11/04/14 with no positive results and there was no media fill test record prior to this. Per the PIC, media fills are to be conducted every (b) (4) months and therefore (b)(6),(b)(7)(C) s media fill would be due on (b) (4) .

b. The PIC stated that he also performs sterile compounding on an as needed basis but has not performed any sterile compounding for over 3 years. However, the PIC and other pharmacists can sign off on sterile compounding activities without having conducted any media fill tests on site.

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C. The firm has no written (b) (4) test procedure but per the PIC, the firm does perform (b) (4) test on every batch produced. However, he stated that (b) (4) tests are not recorded anywhere after (b) (4) are tested. On 07/13/15, we did not see (b)(6),(b)(7)(C) perform any (b) (4) test after making HCG lot # t07092015@42. (b) (4) types of (b) (4) (b) (4) are used for (b) (4). The PIC stated that there are markings on the (b) (4) for the technician to know whether (b) (4) passes (b) (4) test or not. If (b) (4) below (b) (4) specifications, then the test is considered failed.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A. The firm has an ISO 5 (b) (4) laminar flow hood which has been in used for about 5 years per the PIC but the firm has not conducted static or dynamic smoke studies. The firm does not have any SOP requiring smoke studies to be conducted. In addition, there is no certification of ISO 5 hood. We did not see any certification sticker or record for the ISO 5 hood certification or smoke studies. Per P&P No. 4.020, effective date 05/01/03 titled "Measuring Particulate Matter Levels Within the Cleanroom Area" section 6.6 states "the certification sticker provided by the contractor should (b) (4) (b) (4)

B. There is a HEPA filter locating above the ISO 5 hood directly outside the entrance of the hood. The firm has not conducted smoke studies to determine if there's any air turbulence created due to the positioning of the hood and ceiling HEPA filters. (b) (4) air coming from the hood and vertical air coming from the ceiling HEPA filter may meet at the hood entry point potentially creating air turbulence.

C. There are (b) (4) pressure differential monitors: (b) (4) (b) (4) (b) (4) (b) (4) (b) (4). Per the PIC, the firm has not logged any reading from these (b) (4) devices when the clean room was set up approximately 5 years ago. P&P (b) (4) titled "Aseptic Compounding Area Requirements" does not require the firm to monitor for pressure differential. On 07/13/15, we observed the Magnehelic gauge (b) (4) reading at about zero. The PIC stated that the pressure differential was not working. The (b) (4) Magnehelic gauge was reading at about 0.03 or less. The firm has no specifications for their pressure differential reading requirements. In addition, the firm has no record of calibration for the (b) (4) Magnehelic gauges.

D. The firm fails to follow P&P No. (b) (4) titled "Environmental Monitoring of the Clean Room Facility" from (b) (4).

a. Section (b) (4) (b) (4)" In actual practice, the firm does not use touch plate for monitoring (b) (4) sterile compounding normally on

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(b) (4) but use (b) (4) for personnel monitoring. (b)(6),(b)(7)(C)'s records of fingertips testings were performed on (b) (4) without any growth.

b. Section (b) (4) (b) (4)." In actual practice, surface sampling in ISO 5 was performed on (b) (4)

c. Section (b) (4)." On 07/13/15, we observed non-sterile (b) (4) used in the cleaning of sterile gloves worn by technician and ISO 5 surface.

d. Section (b) (4)." In actual practice, viable monitoring is not performed and non-viable monitoring is performed during (b) (4) (cleanroom ISO 6 and ante room ISO 8).

OBSERVATION 5

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, the P&P No. 5.020, effecitve date 05/01/03 titled "Evaluation of the Cleanroom Personnel for Scrubbing, Gowning, and Gloving Procedures" and P&P No. (b) (4) titled "Required Garb for Buffer or Clean Area Access" are deficient in that gowning appears not to be suitable for production of sterile injectable drug products as it does not require proper sterile gowning. On 07/13/15, we observed that a technician (b)(6),(b)(7)(C) produced Chorionic Gonadotropin (HCG) 200 units/0.1ml injection 2000 units/ml injectable lot # t07092015@42 with the following apparel.

A. Non-sterile shoe cover, hair net, and face mask were worn from a non-classified area into the ante-room (ISO 8), clean room (ISO 6), and laminar flow (ISO 5). Some facial skin areas such as forehead and cheeks were exposed in ISO 5 area.

B. Non-sterile goggles and sterile gloves were worn in ISO 8 ante-room and gloves were sprayed with non-sterile (b) (4) before producing sterile products.

C. Technician was observed to wear white lab coat from a non-classified area into ISO 6 and ISO 5 areas with hands, shoulders, and lab coat touching the plastic dividing curtain (between ISO 6 and ISO 8 rooms) when entering the ISO 6 area from the ISO 8 area. We observed the technician making a non-sterile product in a non-classified area before entering the sterile area.

D. We observed that the technician's lab coat sleeves, chest, and head were partially inside ISO 5 hood which did not have a sash.

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OBSERVATION 6

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the to produce aseptic conditions.

Specifically,

A. The following procedures relating to cleaning are inadequate

a. Per P&P No. (b) (4) titled "The Quality Assurance Program" section (b) (4) "cleaning and sanitizing - cleaning, sanitiing and organizing of the direct and contiguous compounding areas must be (b) (4)." This SOP does not indicate if the firm should rotate cleaning with different cleaning reagents. The firm logs their cleaning on an unprotected excel spreadsheet.

b. Per P&P No. 7.060, effective date (not stated) titled "Sterilization of Work Station" (ISO 5 hood)

i. Section 6.2.1 states (b) (4) (b) (4)' – we observed non-sterile (b) (4) being used during cleaning of the hood on 07/13/15.

ii. Section 6.2.2 states (b) (4) – we observed (b) (4) non-sterile wipes being used to clean the hood on 07/13/15 after sterile preparation of HCG lot # t07092015@42.

B. The firm also uses (b) (4)) which is further diluted for cleaning of sterile preparation areas including ISO 5 hood. There are no other cleaning or sanitizing agents used which are sporocidal. The diluted (b) (4) recipe contains (b) (4) to make approximately (b) (4) used to clean surfaces including ISO 5 area. The firm has no surface contact time requirement for any of the cleaning reagents.

C. The firm also uses non-sterile mops (b) (4) duster and (b) (4) mop) to clean ISO 6 and ISO 8 areas and store the mops against the wall in ISO 8 ante room to re-clean the clean rooms. The (b) (4) duster and (b) (4) mop are not detailed in any of the firm's SOP.

D. The firm has a clean log but the log does not specify which areas such as floor, wall, ISO 5 hood, or plastic dividing curtain are cleaned. Per the PIC, the firm has no written procedure requiring the plastic dividing curtain to be cleaned and that the curtain is not cleaned during any of the firm's clean room cleaning process.

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OBSERVATION 7

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, the firm has no stability study to show that products with or without preservatives are stable up to the beyond use date assigned. For example,

Product	Date Made	Beyond Use Date	Preservative(s)
Dihydroergotamine Mesylate 1mg/ml injectable	04/13/15	10/10/15	(b) (4)
Vitamin B Complex B1/B3/B2/B5/B6/B12 100/100/2/2/2/3 mg/ml injectable	04/20/15	10/17/15	(b) (4)
Estradiol 20mg/ml injectable	05/20/15	11/16/15	(b) (4)
Hydroxocobalamin (preservative free) unit dose syringes 1.5mg/0.25ml injectable	05/20/15	08/18/15	None
Edetate Calcium Disodium (single use only) 300mg/ml injectable	07/06/15	08/05/15	None
Chorionic Gonadotropin (b) (4) Solution	06/15/15	09/13/15	(b) (4)

OBSERVATION 8

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

A. The incubator (b) (4) has not been qualified. Per P&P No. 3.030 dated 04/24/03 titled "Monitoring of the Pharmaceutical Incubator" section 4.0 "Frequency" and section 4.1 "To be completed (b) (4)." In actual practice, the firm only monitors the incubator reading (b) (4). The (b) (4) without any record of who records and who signs off on the readings.

B. The (b) (4) (b) (4), (b) (4) has not been qualified. The (b) (4) is operated as on/off function without (b) (4) of (b) (4). There's no validation of (b) (4) (b) (4) to show that the (b) (4) can sterilize equipment to be used for sterile production activities. The firm does not use the (b) (4) for any product sterilization process. In addition, the firm does not follow P&P No. 3.080, effective 05/01/03 titled "Validation of (b) (4)

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	Santos E. Camara, Investigator SEC Binh T. Nguyen, Investigator Eileen A. Liu, Investigator Alicia K. Mckinsey, Investigator Christopher R. Czajka, Investigator CRC Roger F. Zabinski, Investigator	07/21/2015

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425) 302-0340 Fax:(425) 302-0404 Industry Information: www.fda.gov/oc/industry	07/13/2015 - 07/21/2015* FEI NUMBER 3004603767

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Shawn W. Needham, RPh/President/CEO

FIRM NAME	STREET ADDRESS
JD & SN Inc., dba Moses Lake Professional Pharmacy	1555 Pilgrim St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Moses Lake, WA 98837-4623	Producer of Sterile Drug Products

Efficiency" in validating the (b) (4) with (b) (4) In actual practice, the firm uses (b) (4) and not (b) (4) to check for (b) (4) (b) (4) but the firm did not record any of the (b) (4) used.

OBSERVATION 9

Routine calibration of equipment is not performed according to a written program designed to assure proper performance.

Specifically, the firm does not have any written procedure requiring the calibration of weights and thermometers. For example, on 07/13/15 we observed

A. The weights used to calibrate the (b) (4) balance (b) (4) is not calibrated against an NIST standard weight. The firm does not use third party vendor to calibrate their balance on a period basis. This balance is used to weigh (b) (4) . There is no SOP for the calibration of (b) (4) balance.

B. The (b) (4) thermometers used to measure the temperature of the (b) (4) refrigerator model # (b) (4) storing drug raw materials, buffers, and bulk drugs were not calibrated to NIST standards.

C. The (b) (4) thermometer # (b) (4) used to record temperature of the incubator and the (b) (4) is not calibrated against NIST standards.

OBSERVATION 10

The master production and control records are deficient in that they do not include complete instructions.

Specifically, the logged formula worksheets do not have clear production instructions. For example,

A. Chorionic Gonadotropin 200 unit/0.1ml injection 2000 units/ml injectable formula # (b) (4)

a. There is no requirement to record (b) (4) test
b. There's no other instructions other than (b) (4) (b) (4) (b) (4) (b) (4) " - in actual practice, we observed the technician (b) (4) (b) (4) with (b) (4) (b) (4)
c. Formula worksheet states to use " (b) (4) (b) (4) per the PIC, vial used was sterile
d. There's no requirement to document container/closure system's expiration dates

B. Alprostadil/Procaine 40mcg/0.1% ml injectable formual # (b) (4) formula instructions state (b) (4) (b) (4) f (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) f (b) (4) " - it is unclear how alprostadil and procaine are (b) (4) .

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
TO: Shawn W. Needham, RPh/President/CEO	
FIRM NAME JD & SN Inc., dba Moses Lake Professional Pharmacy	STREET ADDRESS 1555 Pilgrim St
CITY, STATE, ZIP CODE, COUNTRY Moses Lake, WA 98837-4623	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

OBSERVATION 11

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically, the firm does not always complete all required information on its formula worksheets. For example,

A. Trimix 40mg/2mg/40mcg/ml Injectable, made on 06/03/15 with BUD 11/30/15
   a. Alprostadil (b) (4) - amount used not filled in
   b. (b) (4), (b) (4)) - amount used not filled in

B. Chorionic Gonadotropin (b) (4) Solution Liquid, made on 06/15/15 with BUD 09/13/15
   a. (b) (4), (b) (4) - amount used not filled in
   b. (b) (4) r, (b) (4) - amount used not filled in

C. DMPS - Dimercapto-Propanesulfonic Na (Single Use Only) 50mg/ml Injectable, made on 06/01/15 with BUD 07/01/15
   a. (b) (4), (b) (4) - amount used not filled in

OBSERVATION 12

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically, on 07/13/15 we observed that (b)(6),(b)(7)(C) the sterile compounding technician signed on to " (b) (4) " system to log the preparation of HCG lot # t07092015@42 with the PIC's user name and password. (b) (6) can then select available names from drop down menus. Per the PIC, anyone in the pharmacy can sign on as the PIC and record the information and that pharmacist who signs off on the formula worksheet may not be the same person selected from " (b) (4) " system. For example,

A. Testosterone Cypionate For SubQ Injection 100mg/ml Injectable lot # t06252015@37 - (b)(6),(b)(7)(C) was the signed on as the technician and SN was signed on as the final signed off pharmacist. However, final paper record was signed by (b)(6),(b)(7)(C)

B. Chorionic Gonadotropin 200 units/0.1ml Injection 2000 units/ml injectable lot # t07102015@25 - (b)(6),(b)(7)(C) was signed on as the technician and SN was signed on as the final signed off pharmacist. However, the final paper record was signed by (b)(6),(b)(7)(C)

C. Vitamin D3 Oil 400,000 units/ml injectable lot # t04092015@10 - (b)(6),(b)(7)(C) was signed on as the technician and (b)(6),(b)(7)(was signed on as the final signed off pharmacist. However, the final paper record was signed by (b)(6),(b)(7)(C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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OBSERVATION 13

Procedures designed to assure that correct labeling are used for drug products are not written.

Specifically, the firm has no written procedure to require that individual unit dose produced are labeled. On 07/13/15, we observed (b)(4) of the 0.1 ml syringes of HCG lot # t07092015@42 were made. However, none of the syringes were individually labeled. Instead, all (b)(4) unlabeled syringes were placed in a brown bag and a patient specific label was placed on the brown bag.

*** DATES OF INSPECTION:**
07/13/2015(Mon), 07/14/2015(Tue), 07/15/2015(Wed), 07/16/2015(Thu), 07/20/2015(Mon), 07/21/2015(Tue)

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DATE ISSUED: 07/21/2015