DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE. Suite 210 Bothell, WA 98021 425-302-0340 Industry Information: www.fda.gov/oc/industry	2/7/17 to 3/1/17*
	FEI NUMBER 3012465222

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Robert A. Myers, PhD, RPh, President

FIRM NAME	STREET ADDRESS
RAM Pharma, Inc.	1125 Hollipark Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Idaho Falls, ID 83401	Outsourcing facility

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written or followed. Specifically,

A) An ATRIX VACOMEGASCT ESD 1 gallon vacuum was observed in use by the operator to vacuum the floor of the ISO 7 Cleanroom prior to the production of sterile drug Eylea 2mg/0.05mL injection, lot 201702081 on 2/8/17. Your SOP 05-001 Clean Suite Cleaning and Sanitizing Operation requires that you "***Use UHEPA vacuum to clean floors" for daily cleaning.

B) Media fills for the production operator were not performed prior to conducting sterile drug production of the first batch of sterile drug product on 7/26/16. From 7/26/16 to 2/8/17, 105 batches were produced without media fills being performed for the production operator according to the assigned schedule outlined in the following SOPs:

1) SOP 08-006 Personnel Monitoring – High-Risk Media Fill requires that "***Each person authorized to compound high-risk level CSPs must perform this procedure semiannually."

2) SOP 08-007 Personnel Monitoring – Low-Risk Media Fill requires that "***Persons authorized to compound must perform this procedure at least once annually."

3) SOP 08-008 Personnel Monitoring – Medium-Risk Media Fill requires that "***Persons authorized to compound must perform this procedure at least once annually."

C) On 2/8/17 and 2/10/17 loose individual sterile gloves previously worn during sterile drug production were observed on a table stored next to open autoclaved bags of previously worn sterile gloves.

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OBSERVATION 2

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

A) Your environmental monitoring (EM) procedure SOP 08-004 Environmental Monitoring – Microbial is deficient in that it states to "***Perform surface sampling in all ISO classified areas on a periodic basis." In addition, you are not performing EM according to the following methodologies and frequencies as you currently rely on EM to be performed by a third-party certifier every six months:
1) Viable air sampling is not performed in the Baker EG-4320, S/N 55304 ISO 5 horizontal laminar flow hood (LFH) when sterile drug products are produced.

2) Surface sampling for microbiological monitoring is not performed in the Baker EG-4320, S/N 55304 ISO 5 horizontal LFH when sterile drug products are produced.

3) Personnel monitoring is not conducted of production operators at least daily when sterile drug products are produced.

4) Non-viable air sampling is not performed in the Baker EG-4320, S/N 55304 ISO 5 horizontal LFH and adjacent ISO-classified areas when sterile drug products are produced.

B) You are not following your SOP 09-002 Sterile Production Procedure which requires that "Hoods and aseptic environmental control devices must be certified for operational efficiency as often as recommended by the manufacturer or at least every six (6) months or if relocated." For example:

1) Certification of your Baker EG-4320, S/N 55304 ISO 5 horizontal LFH and adjacent ISO-classified areas expired on 12/31/16. However, from 1/2/17 to 1/27/17 you produced 19 lots of sterile drug product without performing recertification.

2) Viable air and surface sampling of the ISO 8 Egress Room was not performed during certification of the sterile

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drug production suite on 6/17/16.

C) Positive air pressure differentials were not being monitored between the following: unclassified hallway and ISO 8 Pre-Gown Room; ISO 8 Pre-Gown Room and ISO 8 Gowning Room; ISO 8 Gowning Room and ISO 7 Cleanroom; ISO 8 Egress Room and ISO 7 Cleanroom; and ISO 8 Egress Room and unclassified hallway during the production of sterile drug products prior to 9/29/16. In addition, positive air pressure differentials are currently not being monitored between the ISO 7 Cleanroom and ISO 8 Egress Room and the ISO 8 Egress Room and unclassified hallway.

D) The magnehelic gauges used to monitor the positive air pressure differentials of the sterile drug production suite have not been calibrated and are not on a routine preventative maintenance program. In addition, the doors between the rooms of the sterile drug production suite do not have a lockout mechanism to prevent multiple doors from being opened simultaneously.

E) Your SOP 05-002 Monitoring Daily Measurements Operations and SOP 08-004 Environmental Monitoring – Microbial is deficient in that there are no established alert or action limits for the following:

1) Pressure differential limits of the sterile drug production suite;

2) Viable and non-viable air sample results in the sterile drug production suite;

3) Temperature and humidity of the ISO 7 Cleanroom;

4) Temperatures of the refrigerators and freezers used to store in-process and finished drug products; and

5) Temperatures of the incubators used in the "7 Product Release" room.

OBSERVATION 3

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic

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conditions. Specifically, during the production of Eylea 2mg/0.05mL injection, lot 201702081 conducted on 2/8/17:

A) A piece of apparent exposed particle board measuring approximately three-quarter inches thick, 44 inches wide, and at least six inches deep was observed through the front edge guard vent of the Baker EG-4320, S/N 55304 ISO 5 horizontal LFH in the ISO 7 Cleanroom. The apparent particle board was observed seated on two metal u-channels and adhered to the underside of the metal workbench of the ISO 5 horizontal LFH.

B) Two pieces of apparent plastic were observed missing from a frame installed between the ceiling and metal HEPA filter grate of the Baker EG-4320, S/N 55304 ISO 5 horizontal LFH which exposed a groove that appears to not be smooth or easily cleanable.

OBSERVATION 4

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

A) Your firm uses non-sterile, low-shedding wipes sprayed with sterile 70% isopropyl alcohol (IPA) to clean and wipe down the metal HEPA filter grate and metal workbench of the ISO 5 horizontal LFH prior to sterile drug production. This practice was observed on 2/8/17.

B) You are not following your SOP 05-003 Aseptic Technique and Related Practices Assessment of Compounding Personnel which states in part "***Disinfects components/vials with an appropriate agent prior to placing into ISO Class 5 work area." For example, drug containers, components, closures and equipment used in the production of Eylea 2mg/0.05mL injection, lot 201702081 on 2/8/17 were placed into the Baker EG-4320, S/N 55304 ISO 5 horizontal LFH without first disinfecting the outer surface.

C) The Accel TB wipes used for wiping down the metal bench and interior of the pass-through in the ISO 8 Gowning Room and Accel TB Ready to Use Liquid used in the ISO 7 Cleanroom is not sterile and it is not a sporicidal agent.

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D) Non-sterile 70% isopropyl rubbing alcohol is dispensed from an "EasySat Bucketless Floor Mop" and it is used to clean the floor of the sterile drug production suite on a weekly basis. In addition, a sporicidal agent has not been used to clean the floors of the sterile drug production suite.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process. Specifically,

A) The Tuttnauer Brinkmann 2340E, S/N 2106804 autoclave has not been validated to confirm effective sterilization through the designated sterilization time and temperature cycle of seven minutes at 273° F (134°C) for the syringe capper/de-capper device used in sterile drug production. Biological indicators are also not used during this sterilization process.

B) The production process of using a non-sterile hemostat for handling a sterile dropper bottle in the ISO 5 horizontal LFH without adequate sterilization of the hemostat has not been validated to ensure sterility of the finished sterile ophthalmic products: Vigamox lot 201609202; Phenylephrine Hydrochloride Ophthalmic Solution lot 201609272; Neomycin/Polymyxin B Sulfates/Dexamethasone Ophthalmic Suspension lot 201610051; and Tobramycin/Dexamethasone Ophthalmic Suspension lot 201610052.

C) There is no documentation to support that the in-situ air pattern analysis (smoke study), performed on June 17, 2016, was performed under dynamic conditions and that it was reviewed by firm personnel for adequacy.

OBSERVATION 6

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements. Specifically,

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A) Sterility testing was not performed on each finished or representative finished batches for 20 of 23 drug products produced since 7/26/16 that are purported to be sterile. For example, sterility testing was not performed on the following sterile drug products:

1) Vigamox, beyond use date (BUD) of 1 month ambient, lot 201609202.

2) Phenylephrine Hydrochloride Ophthalmic Solution; unknown BUD, lot 201609272.

3) Neomycin/Polymyxin B Sulfates/Dexamethasone Ophthalmic Suspension BUD of 30 days ambient, lot 201610051.

4) Tobramycin/Dexamethasone Ophthalmic Suspension BUD of 30 days ambient, lot 201610052.

B) Endotoxin testing was not performed on each finished or representative finished batches for the 23 drug products produced since 7/26/16 that are purported to be pyrogen-free. For example, endotoxin testing was not performed on the following sterile drug products: Oxytocin 30U/500mL NS bag BUD of 6 weeks ambient, lots 201611082, 201611112, 201611291, 201612151, 201701041, 201701111, and 201701241.

C) Your SOP 10-005 Finished Product Sterility Testing is deficient in that there is no established scientific rationale for the release of the following sterile filtered drug products after a passing Day 4 sterility test result:

1) Lidocaine 1%/Phenylephrine 1.5% injection; BUD of 66 days ambient for lots 201609231, 201610061, 201610201, 201611301 and 201702021.

2) Lidocaine 7.5mg/mL/Epinephrine 0.25mg/mL injection; BUD of 45 days frozen for lots 201611181 and 201701061.

OBSERVATION 7

Testing and release of drug product for distribution do not include appropriate laboratory determination of

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satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release. Specifically,

A) Potency testing is not performed for each batch of finished sterile and non-sterile drug products produced prior to release. For example:

1) The following sterile drug products:

a) Lidocaine 1%/Phenylephrine 1.5% injection; BUD of 66 days ambient for lots 201609231, 201610061, 201610201, 201611301 and 201702021.

b) Lidocaine 7.5mg/mL/Epinephrine 0.25mg/mL injection; BUD of 45 days frozen for lots 201611181 and 201701061.

2) The following non-sterile drug products:

a) Lidocaine/Epinephrine/Tetracaine (LET) topical gel BUD of "150 days refrigerated; 21 days room temperature" for lots 201612222 and 201701171.

b) Lidocaine/Prilocaine/Tetracaine/Phenylephrine (TAP) topical gel BUD of 90 days ambient for lot 201612221.

B) Finished preservative content testing is not performed for each batch of non-sterile drug products produced prior to release. For example:

1) LET Gel containing methyl paraben and propyl paraben as a preservative for lots 201612222 and 201701171.

2) TAP Gel containing methyl paraben and propyl paraben as a preservative for lot 201612221.

OBSERVATION 8

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There is no written testing program designed to assess the stability characteristics of drug products. Specifically,

A) Your SOP 12-004 Determination of Beyond Use Dating is deficient in that it does not describe tests that evaluate the sterility and potency for the BUD claimed. For example, stability testing has not been performed for the following sterile drugs:

1) Lidocaine 1%/Phenylephrine 1.5% injection formulated from non-sterile components; BUD of 66 days ambient for lots 201609231, 201610061, 201610201, 201611301 and 201702021.

2) Sterile drugs repackaged in the LFH:

a) Phenylephrine Hydrochloride Ophthalmic Solution 2.5%; BUD is unknown for lot 201609272.

b) Tobramycin/Dexamethasone Ophthalmic Suspension; BUD of 30 days ambient for lot 201610052.

c) Vigamox; BUD of 30 days ambient for lot 201609202.

d) Neomycin/Polymyxin B Sulfates/Dexamethasone Ophthalmic Suspension; BUD of 30 days ambient for lot 201610051.

3) Oxytocin 30U/500mL NS intravenous solution; BUD of 6 weeks ambient, lots 201611082, 201611112, 201611291, 201612151, 201701041, 201701111, and 201701241.

B) The BUD of sterile drug products exceeded the expiry date of a raw material component used in production. For example:

1) Raw material component Vancomycin 500mg vial lot 511058E03; expiry 3/1/17 was formulated into Vancomycin 100mcg/0.1mL injection, lot 201702022; given BUD of 4/20/17.

2) Raw material component Phenylephrine HCl Powder lot 1403040074; expiry 10/12/16 was formulated into Lidocaine 1%/Phenylephrine 1.5% injection, lot 201609231; given BUD of 11/28/16.

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C) The literature source you used to support the BUD of 66 days ambient for sterile drug Lidocaine 1%/ Phenylephrine 1.5% injection solution is taken from a study that investigated the chemical stability of Lignocaine hydrochloride and Phenylephrine hydrochloride aqueous solution containing preservatives; the sterile drug Lidocaine 1%/Phenylephrine 1.5% intended as an intraocular injection that you produce is preservative-free. In addition, you do not have stability data to ensure sterility for the BUD claimed and that the product is endotoxin-free.

OBSERVATION 9

Clothing of personnel engaged in the manufacturing and processing of drug products is not appropriate for the duties they perform. Specifically,

A) The following attire worn by the operator on 2/8/17 during the production of Eylea 2mg/0.05mL injection, lot 201702081 in the Baker EG-4320, S/N 55304 ISO 5 horizontal LFH was inadequate as follows:

1) Non-sterile boot covers, non-sterile coveralls, non-sterile hair cover, non-sterile surgical mask, and protective eyewear that had not been previously disinfected prior, that were observed worn during sterile drug production.

2) The hood of the non-sterile coverall and non-sterile surgical mask worn did not provide adequate coverage of the forehead, cheeks, and chin of the operator during sterile drug production.

B) An ATRIX VACOMEGASCT ESD 1 gallon vacuum and its power cord, attachments and hose were observed in direct contact with a non-sterile coverall worn by the operator in the ISO 7 Cleanroom during vacuuming of the floor. The vacuum was returned to the ISO 8 Egress Room and the operator was observed returning to the ISO 7 Cleanroom without changing or performing adequate sanitization of his non-sterile coverall or sterile gloves prior to production of Eylea 2mg/0.05mL injection, lot 201702081 in the ISO 5 horizontal LFH.

C) On 2/7/17 two non-sterile gowns previously worn during sterile drug production were observed hanging in the ISO 8 Gowning Room. Per the firm President, the non-sterile gowns are reused after sterile drug production and

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changed every three to five batches produced.

OBSERVATION 10

There is no quality control unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products. Specifically,

A) There is no procedure for the release of finished drug products.

1) Your current practice for the release of sterile filtered drugs are subject to an in-house Day 4 sterility test; however, there are no records to show quality control unit review of such records and no documentation of the date you distributed these sterile filtered drugs:

a) Lidocaine 1%/Phenylephrine 1.5% injection lots 201609231, 201610061, 201610201, 201611301 and 201702021.

b) Lidocaine 7.5mg/mL/Epinephrine 0.25mg/mL injection lots 201611181 and 201701061.

2) You do not have a production batch record for Lidocaine 4%/Epinephrine 0.05%/Tetracaine 0.5% (LET) Topical Gel, lot 201612031 that was produced on 12/3/16. RAM Pharma, Inc. Invoice no. 1055 dated 12/5/16 documented the sale and distribution of 10/3mL LET Gel syringes from this lot.

B) There is no procedure for the review of production batch and control records.

1) The person designated "Quality Assurance" in your organizational chart who had "approved" all executed production batch records since 7/26/16 are reviewing records for "completeness" before or after the distribution of drugs. The batch record reviews are deficient. For example:

a) Your production batch record does not contain accurate representation of products produced. For example: Batch record for Lidocaine 1%/Phenylephrine 1.5% injection lot 201609231 shows 30 syringes produced. RAM

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Pharma Inc. Invoice 1020 shows 34 Lidocaine 1%/Phenylephrine 1.5% syringes under lot 201609231 were distributed.

b) There are no records of the actual drug product labels used in any drug product batches produced since 7/26/16.

c) You do not have an appropriate drug product container label for any of your drug products. Your production batch records documented the use of a unit, product label as the container label. For example, 21 product labels were used to package Lidocaine 7.5mg/mL/Epinephrine 0.25mg/mL injection, lot 201701061, 20 of which were used on each 2mL finished product vials and "1 for box".

d) Production and control records did not have the observed value of the bubble point test performed on the sterilizing filter used in the production of a sterile drug product. Records show a bubble point test was performed with the results recorded as "PASS" for each lot, for example: Lidocaine 1%/Phenylephrine 1.5% injection lots 201609231, 201610061, 201610201, 201611301, and 201702021; and Lidocaine 7.5mg/mL/Epinephrine 0.25mg/mL injection lot 201701061.

C) You did not follow SOP 10-003 Inspecting and Releasing Incoming Raw Materials for the release of raw materials. For example:

1) Packages of sterile syringes that have not been released that were stored on a shelf labeled "TO BE RELEASED" were used in production. These 8mm, 31G gauge sterile BD insulin syringes under lot 6144783 were used in the production of Eylea 2mg/0.05mL injection lots 201701271, 201701133, and 201701132.

2) The container holding Prilocaine hydrochloride USP lot 1610030044 did not have a released sticker per section 1.1 of SOP 10-003 which address placement of a released sticker if the material has been "cleared by inspection". Prilocaine hydrochloride USP lot 1610030044 was used in the production of TAP Gel lot 201612221.

OBSERVATION 11

Routine calibration of electronic equipment is not performed according to a written program designed to assure

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proper performance. Specifically,

A) The digital balance used in the weighing of raw material components for production, namely Torbal AGZN100 balance, 100g capacity; A&D EJ-123 balance, 120g capacity; and Ohaus Scout Pro balance, 400g capacity have not been calibrated. The calibration weights that are available for use are also not calibrated.

B) The digital thermometers used to monitor temperatures of the refrigerator in the "2 Incoming Release" room; and the refrigerator and freezer in the "8 Shipping" room have not been calibrated.

OBSERVATION 12

The labels of your outsourcing facility's drug products do not include information required by sections 503B(a)(10)(A) and (B). Specifically,

The following information is not found on some of your drug product labels:

A) Product labels consisting of the statement "Compounded Drug" are deficient in that it does not include the statements "This is a compounded drug", quantity or volume, and inactive ingredients. Examples of drug products that do not contain this information are:

1) Ceftazidime 2250mcg/0.1mL

2) Dexamethasone Sodium Phosphate 400mcg/0.05mL

3) Phenylephrine Hydrochloride 2.5mg/mL solution

4) Vancomycin Hydrochloride 1000mcg/0.1mL

B) A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient. Examples of drug products that do not contain this information are:

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RAM Pharma, Inc.	1125 Hollipark Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Idaho Falls, ID 83401	Outsourcing facility

1) Drug product Lidocaine 4%/Epinephrine 0.05%/Tetracaine 0.5% topical gel is identified on the product label as "LET Gel 4%/0.05%/0.5% TOPICAL GEL".

2) Drug product Lidocaine 10%/Prilocaine 10%/Tetracaine 4%/Phenylephrine 2% dental gel is identified on the product label as "TAP Gel 10%/10%/4%/2% DENTAL GEL".

C) The containers of your products do not include the following information required by section 503B(a)(10)(B) in order to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

OBSERVATION 13

The drug product report your outsourcing facility submitted to the FDA as required by section 503B(b)(2)(A) is not accurate. Specifically,

You underreported 6 units of Vancomycin 1000mcg/0.1mL syringe and 6 units of Ceftazidime 2250mcg/0.1mL syringe in the drug product report your outsourcing facility submitted to the FDA on 12/28/16 for drugs produced during the previous six months through 11/30/16.

*Inspection Dates: 2/7/2017, 2/8/2017, 2/9/2017, 2/10/2017, 2/13/2017, 2/15/2017, 3/1/2017.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Tracy K. Li, Investigator Gerard P. De Leon, Investigator Gary C. Pecic, Analyst Lisa T. Michel, Analyst	03/01/2017