

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax: (303)236-3100	DATE(S) OF INSPECTION 2/11/2019-2/26/2019*
	FEI NUMBER 3012248071

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Tony E. Jones, Owner

FIRM NAME Maple Rose Enterprises, Inc, dba Pencil Pharmacy	STREET ADDRESS 1325 S Colorado Blvd Ste B-024
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CITY, STATE, ZIP CODE, COUNTRY Denver, CO 80222-3303	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs
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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:**  
Laboratory System

**OBSERVATION 1**

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

You have no assurance that the sterility and endotoxin level of your intrathecal drug products are safe. You have no data for these products prior to distribution and use. Your sterility monitoring practices performed via (b) (4) (b) (4) have not been validated nor has the media been subjected to growth promotion. These preparations are made using non-sterile starting materials.

Facilities and Equipment System

**OBSERVATION 2**

Buildings used in the processing of a drug product are not maintained in a good state of repair.

Specifically, your firm's ante room as well as clean rooms where your ISO 5 laminar air flow workbench and biosafety cabinet are located have not been maintained in a good state of repair. For example,

**AMENDMENT 1**

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Zachary A Bogorad, Investigator Zachery L Miller, Investigator	X Zachery L Miller Investigator Signed by Zachery L Miller-S Date Signed 02-26-2019 12:10:43	DATE ISSUED 2/26/2019

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- A) A 1.5 x 0.5-inch dent <sup>(b) (4)</sup> was observed in the wall directly across from the ISO 5 biosafety cabinet workspace opening in Cleanroom <sup>(b) (4)</sup> approximately 3 feet above the floor. The gash was into the sheetrock and the edges appeared to reveal white gypsum.
- B) <sup>(b) (4)</sup> sprinkler heads were found in the ISO 7 buffer rooms and ante room. The metal of the sprinkler heads appeared to be unclean.
- C) The <sup>(b) (4)</sup> <sup>(b) (4)</sup> the anteroom and Cleanroom 2 was observed to have rust-like spots covering the handles and hinges of <sup>(b) (4)</sup>
- D) There is no indication that <sup>(b) (4)</sup> HEPA filters present in the ceiling of the ante room is functional.

This is a repeat FDA 483, Inspection Observation, from inspection ending on 8/22/2016.

**OBSERVATION 3**

Routine calibration, inspection and checking of mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.

- A) Temperature, humidity, and pressure monitoring equipment including the <sup>(b) (4)</sup> door monitoring pressure system and the magnehelic analog pressure gauge calibrations have never been performed.

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B) There is a lack of calibration data for the following equipment:

1. (b) (4) (b) (4) gauge used to perform (b) (4) testing after manufacturing: Your 3rd party calibration service, (b) (4), provided no evidence of the performance of device calibration. More than (b) (4) % of sterile drugs manufactured on site require (b) (4) . Approximately (b) (4) % of drugs manufactured on site are sterile.

2. Asset ID 75475 (b) (4) used in the final step of sterilization of all multi-use equipment and utensils.

This is a repeat FDA 483, Inspection Observation, from inspection ending on 8/22/2016.

**OBSERVATION 4**

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

Specifically, environmental monitoring is insufficiently conducted during aseptic filling operations in order to give information on the quality of the aseptic processing environment.

A) Non-viable air monitoring is only performed during (b) (4) .

B) Viable air monitoring is only performed during (b) (4) regardless of production schedule. There is no time limit for the media deployment and instructions for use of the media recommend that media only be (b) (4) .

C) Pressure, temperature, and humidity monitoring devices installed in each clean room of the suites are not monitored. Although these data points are recorded (b) (4) (b) (4) the data files have never been reviewed or analyzed due software malfunctions and unreliable performance according to your sterile team lead.

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Examples of office stock products produced under these conditions include the following:

1. Brilliant Blue G 0.05% in dextrose 5% PF Intravitreal injection 0.05%, lot BBD2128, Rx (b) (6) made 7/31/18, BUD 4/27/19
2. Moxifloxacin Intracameral 150 mcg/0.1 mL Solution, lot MOXI2348, (b) (6) made 8/22/18, BUD 6/18/19
3. Riboflavin Ophthalmic in BSS 0.1% Solution, Rx (b) (6) lot RIB2818, made 19/8/18, BUD 6/6/19

This is a repeat FDA 483, Inspection Observation, from inspection ending on 8/22/2016.

**OBSERVATION 5**

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

Specifically,

A) The (b) (4) for multi-use equipment components and utensils has not been shown to be validated. Equipment qualifications and load patterns have not been performed for the (b) (4) and (b) (4).

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B) On 2/11/19, I observed your technician apply non-sterile disinfectant cleaner, (b) (4), to all surface area inside your ISO 5 certified biosafety cabinet, prior to compounding Bupivacaine HCl Hyaluronidase Preservative Free Solution (0.75% (b) (4) nit injection). After the application of (b) (4), all surface areas inside the ISO 5 were subsequently cleaned with water for injection and sterile (b) (4) each with a (b) (4) dwell).

This is a repeat FDA 483, Inspection Observation, from inspection ending on 8/22/2016.

Production System

**OBSERVATION 6**

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

Specifically,

A) Your firm does not effectively perform a (b) (4) (b) (4) testing of (b) (4)

B) On 2/11/19, I observed your compounding technician placing her gloved hand and other objects (needles, needle adapter, barrel, plungers, large volume IV bag) into the path of unidirectional "first air" during the compounding of Bupivacaine HCl Hyaluronidase Preservative Free Solution (0.75% (b) (4) nit injection), Lot No. BH0429. The HEPA filtered airflow above the sterile finished product vials was compromised (hands and other objects placed over the pre-sterilized vial septums) during the (b) (4) and the (b) (4) of final product.

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C) Your firm's in situ air pattern analysis (smoke studies) was not conducted under dynamic conditions that simulate routine production, such as (b) (4) sterilization and IV bag manipulation. Without, there is no assurance critical processing areas are suitable for aseptic manufacturing of sterile drug products. The (b) (4) current smoke study videos (for each of the laminar flow hoods) were filmed 12/22/2017.

D) Your firm's media fills/process simulations are not performed under the most stressful or challenging conditions and do not simulate typical volumes and manipulations to closely simulate the same exposure that the product itself will undergo. In addition, protocols and final reports are not established to describe and evaluate media fills other than (b) (4).

E) From 2/11/19 – 2/26/19 equipment used in the production of sterile injectables including glassware, utensils, and stir components was not processed in a way that eliminates pyrogens. The following sterile drugs were manufactured during the inspection using non-depyrogenated glassware and utensils:

1. Bupivacaine with Hyaluronidase lot BH0429, Rx (b) (6), made (b) (4), (b) (4) x 5cc vials, made 2/11/19, BUD 2/25/19
2. Vitamin B Complex PF Formula Combo Solution lot 3VBC0449, Rx (b) (6), (b) (4) x 20ml vials, made 2/13/19, BUD 3/15/19

F) Sterility and bacterial endotoxin testing is performed only on products whose batch size is greater than (b) (4) units. Approximately (b) (4) % of products have a batch size greater than or equal to (b) (4) units. In conjunction with this, media used for sterility testing, via (b) (4), for products whose batch size is less than (b) (4) units, is not tested for growth promotion prior to use.

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Quality System

**OBSERVATION 7**

The responsibilities and procedures applicable to the quality control unit are not in writing.

Specifically,

A) Procedures impacting the identity, strength, quality, and purity of drug products have not been established. During our inspection, we were provided with a set of comprehensive standard operating procedures (SOPs) for use by the pharmacy staff. The SOPs were provided by (b) (4) - a contractor who provides SOPs tailored for sterile and non-sterile compounding pharmacies. The SOPs are generally written for any compounding pharmacy and are intended to be revised and tailored to the current operations at each individual pharmacy. Your firm has not tailored your contractor provided SOPs for your pharmacy staff to carry out operations correctly and always in the same manner. Procedures were written by (b) (4) and made effective in March 2017.

B) There is no quality control unit. Site activities that lack quality oversight include but are not limited to the following:

1. Complaint Management - receipt, documentation, investigation
2. Equipment Sterilization - review of equipment (b) (4) logs and verification of performance, verification of (b) (4) challenge testing performance and results
3. Incubators - review of equipment logs

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4. 3<sup>rd</sup> Party Calibrations and Certification – review and approval of vendors and resulting data
5. Classified Room Monitoring - review of logged temperature, humidity, and pressure results
6. Media Fills - independent review of competency check (fingertip glove test) results
7. Contract Testing Laboratories - qualification and approval

This is a repeat FDA 483, Inspection Observation, from inspection ending on 8/22/2016.

**OBSERVATION 8**

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

Specifically,

Your firm's beyond use date (BUD) is not based upon completed stability studies. There is no sterility program that 1) Establishes the number and size of batches to be tested, 2) addresses accelerated studies and test intervals, 3) speaks to storage conditions (E.g. store ambient in an upright position) and the integrity of the container closure system; and, 4) specifies the testing attributes of the drug products that are susceptible to change during storage.

- For example, Moxifloxacin Intracameral 150 mcg/0.1 mL Solution has a 300-day BUD based on (b) (4) test performed at (b) (4) days and (b) (4) test performed at (b) (4) days (Lot No. MOX0196).

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Laboratory System

**OBSERVATION 9**

Each lot of a component, drug product containers and closures liable to objectionable microbiological contamination is deficiently subjected to microbiological tests before use.

Specifically,

A) No procedures exist and sterile pharmacist confirmed that none of your drug components or drug product containers and closures are subjected to any microbiological testing or bioburden assessment, after receipt from supplier.

B) Your firm uses non-pharmaceutical grade <sup>(b)(4)</sup> water, purchased from retail stores, in the production of non-sterile drug products.

This is a repeat FDA 483, Inspection Observation, from inspection ending on 8/22/2016.

**OBSERVATION 10**

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, not all your sterile products are released with testing for active ingredient identification and potency. For example, your Tri-mix 30mg/2mg/20mcg/mL (Papaverine, Phentolamine, Prostaglandin) finished drug

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product is dispensed without determining the identification and potency of each active ingredient of the final product.

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**OBSERVATION 11**

The establishment of laboratory control mechanisms including any changes thereto, are not drafted by the appropriate organizational unit and reviewed and approved by the quality control unit.

Specifically,

A) Your firm relies upon contract testing laboratories for testing to confirm the identity, potency, and purity of drug products produced on site. No qualifications have been established for 3rd party testing labs including (b) (4) and (b) (4).

B) You have failed to validate your supplier's certificate analysis and have not developed a program to inspect incoming components, containers, and closures used in producing your drug products, nor the COAs received with them.

**\*DATES OF INSPECTION**

2/11/2019(Mon), 2/12/2019(Tue), 2/13/2019(Wed), 2/14/2019(Thu), 2/15/2019(Fri), 2/19/2019(Tue), 2/20/2019(Wed), 2/21/2019(Thu), 2/26/2019(Tue)

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Zachary A Bogorad  
Investigator  
Signed By: Zachary A. Bogorad -S  
Date Signed: 02-25-2019 12:11:18

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