DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	4/26/2017-5/22/2017* FEI NUMBER 3004486825

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mark H. Mandel , Owner and Pharmacist-in-charge

FIRM NAME	STREET ADDRESS
Snyder Mark Drugs Roselle, Inc. d.b.a. Mark Drugs Pharmacy	384 E Irving Park Rd
CITY, STATE, ZIP CODE, COUNTRY Roselle, IL 60172-2007	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile and 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

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

Specifically, operators demonstrate inadequate aseptic technique during sterile drug production operations being performed under laminar airflow.

- (b) (4) s used in the ISO 5 aseptic processing areas are not sterile. Sterile Lab Technicians use sterile (b) (4) to (b) (4) for disinfecting components being charged from the ISO 7 classified Cleanroom into the ISO 5 classified (b) (4) . (b) (4) are used along with sterile (b) (4) to (b) (4) the interior work surface of the ISO 5 classified areas (b) (4) (b) (4) each sterile drug production batch, and (b) (4) cleaning of the (b) (4) is performed with the (b) (4) by operators donning non-sterile gloves.
- On 5/1/2017, Progesterone in Olive Oil 100mg/mL Injection, an intramuscular sterile drug, was produced under lot number (b) (4) . The Sterile Lab Technician was observed blocking unidirectional airflow to critical sterile components such as post-sterilizing filter syringe tips and uncapped final product containers with gloved hands during finished drug processing being performed inside the (b) (4) .
- On 4/27/2017, (b) (4) 10mg/mL PF Injection, an intrathecal sterile drug, was produced under lot number (b) (4) . The Sterile Lab Technician handled non-sterile (b) (4) autoclave wrap and non-sterile (b) (4) powder that had been (b) (4) (b) (4) before handling other sterilized components using the sterile gloves affixed to the (b) (4) without adequate and frequent glove sanitization.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Christopher D Leach, Investigator Bryan L Mcguckin, Investigator 5/22/2017 X Christopher D Leach Christopher D Leach Investigator Signed by: Christopher D. Leach -S	5/22/2017

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OBSERVATION 2

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

Specifically, employees don non-sterile gloves prior to entering the ISO 7 classified Cleanroom and the ISO 7 classified (b) (4) Room where sterile drug products are produced.

- Inside the Cleanroom, components to be used in aseptic filling operations are charged into an ISO 5 classified (b) (4) by employees wearing non-sterile gloves.
- Human Chorionic Gonadotropin (HCG) Injection is produced at this facility as a sterile lyophilized drug product. (b) (4) vials covered with (b) (4) are carried from the ISO 5 classified (b) (4) (b) (4) to a LAF workbench where they are uncovered and (b) (4) loaded into the firm's lyophilizer by the employees donning non-sterile gloves. This LAF workbench inside of which the lyophilizer is installed has not been certified since 1/20/2015, therefor exposing the vials to conditions which have not been demonstrated to meet ISO 5 classification.
- Mitomycin Ophthalmic Preservative-Free Solution is a sterile chemotherapy drug produced at this facility. In the (b) (4) Room, sterile gloves are not made available for employees performing aseptic filling operations inside the ISO 5 classified (b) (4)

OBSERVATION 3

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

Specifically, routine monitoring of cleanroom areas is not performed each day that sterile drug production occurs.

- Personnel monitoring samples are not collected from the gloved hands of employees performing

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sterile drug processing inside the Cleanroom and the (b) (4) Room on a daily basis. (b) (4) samples are only collected during (b) (4) environmental sampling from those (b) (4) installed in the (b) (4) inside the Cleanroom.

- Integrity inspections are not performed on the (b) (4) installed on the ISO 5 classified (b) (4) between routine replacement. The (b) (4) which may be worn by multiple employees throughout the day, are replaced (b) (4) . The Sterile Lab Manager stated that the (b) (4) are on a replacement schedule, but a frequency has not been documented.
- Environmental monitoring is not performed each day during aseptic processing operations.
- Smoke studies lack the appropriate data necessary for review by quality assurance.
- There is a lack of data to support that adequate pressure differentials between classified and unclassified areas have been verified prior to performing aseptic filling operations.
- There are no magnehelic gauges to monitor pressure between classified and unclassified areas.

OBSERVATION 4

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

Specifically, extended Beyond Use Dates (BUD) are not supported by an appropriate study intended to demonstrate the stability of the finished drug product for characteristics such as potency, sterility, or preservative effectiveness in its final container closure system as dispensed.

- Literature referenced to support current extended BUDs is not associated with finished drugs packaged inside the same container closure system used by this firm, and there is no data to support the firm's general 60 day BUD for intrathecal products produced in syringes.
- Examples of sterile drugs produced at this facility include HCG 12,000 Units for Injection, a lyophilized product, labeled with a six-month BUD or 60 days from reconstitution; Mitomycin 200mcg/mL Ophthalmic 1mL Preservative Free Syringe labeled with a four-month BUD frozen or 7 days refrigerated; and Tri-Mix (2.5mL) MDV Injection, Papaverine 30mg/Phentolamine 1mg/PGE 10mcg/mL, labeled with a four-month BUD frozen or 30 days refrigerated.

- Test results demonstrating a failure to meet potency limits for finished drug products including HCG, Mitomycin, and Tri-Mix were not evaluated to determine the appropriateness of established BUDs.

OBSERVATION 5

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

Specifically, the firm has not established the frequency and method for performing sterility and pyrogen testing on sterile drug products produced at this facility.

- Endotoxin limits have not been established for any of the firm's sterile injectable drugs including intrathecal drugs.
- The test methods used by the firm's contract testing laboratories have not been evaluated to determine their compliance with USP<71> and USP<85>, and certificates of analyses have been received which indicate that compendial methods were not employed.

OBSERVATION 6

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, microbial limits have not been established for non-sterile finished drugs produced at this facility, and they are not sampled and tested for the presence of objectionable microorganisms.

*DATES OF INSPECTION

4/26/2017(Wed),4/27/2017(Thu),5/01/2017(Mon),5/02/2017(Tue),5/03/2017(Wed),5/04/2017(Thu),5/16/2017(Tue),5/22/2017(Mon)