DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Suite 600 Minneapolis, MN 55401 (612) 334-4100 Industry Information: www.fda.gov/oc/industry	9/16/2019 - 9/27/2019* FEI NUMBER 3004486825

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: 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 AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Roselle, IL 60172-2007	Producer of Sterile and Non-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 (I) (WE) OBSERVED:

OBSERVATION 1

ISO 5 classified areas were not certified under dynamic conditions.

Specifically,
The certification documents for your ISO 5 aseptic processing areas do not describe the dynamic conditions under which they were tested. In addition, no smoke study was conducted to show that the air is moving unidirectionally for your ISO 5 aseptic processing areas while simulating your current production and operating processes of the laminar flow hoods which represents your normal processing operations.

OBSERVATION 2

Wipes used in the ISO 5 aseptic processing areas are not sterile.

Specifically,
On September 17th, 2019, we observed an employee use non-sterile wipes in the ISO 5 Hood while aseptically processing of Atropine Sulfate 0.01% Ophthalmic with lot #091719TSEM, and to clean the hood afterwards. Additionally, on September 19th, 2019, we observed an employee use non-sterile wipes in the ISO 5 hood while performing the end of day cleaning.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Anthony J. Ladner, Investigator Norman Starks, Investigator	09/27/2019

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OBSERVATION 3

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically,
1. You do not simulate the maximum number of activities which occur during your production operations.
2. You do not simulate the worst-case activities during your production operations.
3. You do not simulate the maximum number of people which are involved in the aseptic operations and/or are in the environment during your media fill operations.

OBSERVATION 4

You have no assurance that the endotoxin level of your intrathecal drug products are safe, since you do not have any endotoxin data and your firm does not perform endotoxin testing for the finished product. These preparations are made using non-sterile starting material. Furthermore, there is no endotoxin testing data for your API.

Specifically,

Hydromorphone HCl Lot# (b) (4) from (b) (4) used by your firm to make Hydromorphone 10mg/ml lot # 091819JDLEM on 9/18/2019 for intrathecal use for prescription # (b) (6) has not been tested for endotoxins.

*DATES OF INSPECTION
9/16/2019 - 9/20/2019, 9/24/2019, 9/25/2019, 9/27/2019

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