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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| One Montvale Avenue<br>Stoneham, MA 02180<br>(781)587-7500 Fax:(781)587-7556<br>ORAPHARM1_RESPONSES@fda.hhs.gov | 8/1/2023-8/23/2023*<br>FEI NUMBER<br>3012039582 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Michael H. Roberge, Pharmacy In-Charge | |
| FIRM NAME<br>Reliant Compounded Solutions Monroe, LLC | STREET ADDRESS<br>810 Main St |
| CITY, STATE, ZIP CODE, COUNTRY<br>Monroe, CT 06468-2809 | TYPE ESTABLISHMENT INSPECTED<br>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 I OBSERVED:**

## OBSERVATION 1

Personnel were observed moving quickly in a critical area or in an area immediately adjacent to a critical area likely causing disruption of unidirectional airflow.

Specifically,

On August 1, 2023, while observing Pharmacist (b) (6), (b) (7)(C) aseptically processing Triple P (Papaverine, Phentolamine, Prostaglandin) 35/1/12 Injectable lot number 08012023@(b) (4), I noted the following:

- Pharmacist (b) (6), (b) (7)(C) was noted wiping down needed materials with (b) (4) and then "tossing" these materials into the BSC (ISO 5).
- Pharmacist (b) (6), (b) (7)(C) was noted make rapid movements within the BSC (ISO 5) while preparing the compounded drug product.

## OBSERVATION 2

Smoke studies were inadequately performed under dynamic conditions.

Specifically,

On June 2023 and December 2022, the firm had conducted airflow pattern studies (smoke studies) on the Hazardous BSC, Non-Hazardous BSC and the (b) (4) which did not adequately demonstrate dynamic sterile compounding operations in that videos presented were brief (studies (b) (4)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Robert J Martin, Investigator | X Robert J Martin Investigator Signed By: Robert J. Martin -S Date Signed: 08-23-2023 11:12:33 | 8/23/2023 |

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(b) (4) ), did not contain enough smoke to demonstrate airflow over sterile compounding operations and did not demonstrate that the airflow was not interrupted during movement by compounding personnel.

This is a repeat of Observation 9 from FDA 2019 Inspection (8/06/2019 - 08/29/2019)

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**OBSERVATION 3**

Sterile drugs were exposed to lower than ISO 5 quality air.

Specifically,

Stock solutions were stored in an unclassified area for further use after the container closure system had been punctured multiple times, and therefore compromised, throughout the assigned expiry period.

For example, the sterile compounding log shows that on 06/07/2023, a batch of Dexamethasone 12mg/mL Preservative Free (PF) stock solution was produced using (b) (4) (b) (4) in the ISO 5 Cleanroom hood and was assigned lot number 06072023(b) (4) with BUD of 9/05/2023. The stock solution is stored within the refrigerator in the unclassified Storage Room. The firm has conducted(b) (4) punctures of the stock solutions from June to July to compound Dexamethasone OPHTH (PF) 0.01% and0.1% Solutions after which the firm had placed the stock solution back into the unclassified Stock Room refrigerator.

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***DATES OF INSPECTION**

8/01/2023(Tue), 8/02/2023(Wed), 8/03/2023(Thu), 8/04/2023(Fri), 8/07/2023(Mon), 8/08/2023(Tue), 8/09/2023(Wed), 8/23/2023(Wed)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."