DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	2/19/2020-2/28/2020* FEI NUMBER 3013854204

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paul Reid, Ph.D., President & Owner

FIRM NAME	STREET ADDRESS
Maitland Labs of Central Florida	7972 Forest City Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Orlando, FL 32810-2907	503B Outsourcing Facility

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

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

Specifically, according to your Pharmacy Technician, your firm is using non-sterile (b) (4) Disinfectant and non-sterile (b) (4) to clean and disinfect the Cleanroom and ISO 5 (b) (4) Flow Hood. In addition, the sterile wipes utilized during cleaning can potentially shed particulates.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

a. Your firm failed to follow your SOP #PRO-7.052 entitled, "Inspection Checks for Parenteral Products", Section 6.4.10 which states, "(b) (4) ". This failure is evidenced by your firm not investigating when 93 vials of Nalbuphine HCL, 10mg/1mL, lot #20200108, compounded 1/8/20, exp: 1/30/21 (b) (4) vials produced) failed visual inspection for fibers. Your firm's Owner stated he believes the fibers were generated by the vial supplier, but no corrective or preventative actions have been taken by the firm.

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b. On 1/8/20, during the (b) (4) ((b) (4) of Nalbuphine HCL, 10mg/1mL, lot #20200108 (b) (4) vials) the (b) (4)) alerted the following alarms: exhaust rate too fast and door unsealed. The firm conducted maintenance of the (b) (4) on 1/13/20 which resulted in the (b) (4) and (b) (4) kit being replaced on the (b) (4) (b) (4) , (b) (4) repair kit and (b) (4) kit replacement, (b) (4) gauge replacement and the (b) (4) located on the (b) (4) repaired. The firm failed to evaluate the impact of the above listed alarms on the batch of Nalbuphine HCL, 10mg/1mL, lot #20200108.

OBSERVATION 3

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

Specifically,

a. Your firm failed to follow the appropriate stability requirements for both temperature and humidity (b) (4) % RH-long term and (b) (4)% RH-accelerated) for the drug product, Nalbuphine HCL, 10mg/1mL, lot #20191111 R&D. As a result, your firm failed to have the stability data to support the over 12-month expiration date applied to the commercial Nalbuphine HCL, 10mg/1mL, lot #20200108, exp.: 1/30/21.

b. Your firm failed to perform the container closure integrity testing to ensure the adequacy of the container closure system to maintain a sterile barrier against potential contaminants.

c. Your firm failed to ensure that the Control Testing Laboratory's (CTL) potency method via (b) (4) is stability indicating and can detect impurities.

Repeated FDA-483 Observation from 6/17/19

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OBSERVATION 4

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically, your firm failed to conduct a smoke study under dynamic conditions within the ISO-5 (b) (4) Flow Hood (b) (4)). This hood was utilized for the production of Nalbuphine HCL, 10mg/1mL, lot #20200108.

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,

c. Your firm failed to ensure the sterility test method utilized by your firm's Control Testing Laboratory (CTL) is validated or verified under conditions of use utilizing your firm's drug product, Nalbuphine HLC.

d. The (b) (4) (b) (4) (b) (4)) used for incubating the product sample for endotoxin testing (b) (4) (b) (4)) was located on top of a hand/equipment washing sink which causes vibrations and can potential lead to the disruption of any (b) (4) formed.

Repeated FDA-483 Observation from 6/17/19

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OBSERVATION 6

The labels of your outsourcing facility's drug products are deficient.

The label of your outsourcing facility's drug product does not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product label:

- The established name of the drug, specifically the salt "HCl"
- The strength, specifically the strength of the inactive ingredient, citric acid (anhydrous), is incorrect: 0.063% vs. 0.63%
- The dosage form
- The storage/handling instructions, specifically "Protect from light" and the storage conditions are not consistent with the batch record: 15-30°C, 59-86°F

Example of your drug product label that do not contain this information:

- Nalbuphine HCl 10 mg/mL in 0.2% Saline

Repeated FDA-483 Observation from 6/17/19

OBSERVATION 7

The container labels of your outsourcing facility's drug products are deficient.

The container of your outsourcing facility's drug product does not include information required by section 503B(a)(10)(B). Specifically, your container does not include the following information:

- The route of administration (i.e., intravenous)

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- The storage/handling instructions, specifically "Protect from light" and the storage conditions are not consistent with the batch record (15-30°C, 59-86°F)
- The inactive ingredients, specifically: Sodium Hydroxide and Hydrochloric Acid, which are listed on the master batch record
- The complete name of the inactive ingredients: Sodium Citrate Dihydrate and Citric Acid Anhydrous
- "Inactive ingredient" appears on the label twice

Example of your drug product label that do not contain this information:

- Nalbuphine HCl 10 mg/mL in 0.2% Saline

***DATES OF INSPECTION**

2/19/2020(Wed), 2/20/2020(Thu), 2/21/2020(Fri), 2/25/2020(Tue), 2/28/2020(Fri)

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