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	6/4/2019-6/17/2019* FEI NUMBER 3013854204

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paul F. Reid, Ph.D., Owner & Chief Operating Officer

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 room and equipment to produce aseptic conditions.

Specifically, your firm's SOP: ENV-4.018, Rev. 1, "Cleaning and Disinfection of the Facility is deficient as Section: 6.8-Formulation Lab and Section: 6.10-Cleanroom and Anteroom states (b) (4) (b) (4) shall be cleaned and disinfected at least (b) (4) to include walls, ceilings, benches and floors. In addition, no cleaning records were available for the Cleanroom (where (b) (4) for August 2018, September 2018, December 2018 and February 2019. No cleaning records were available for the Formulation Lab (where drug products intended for terminal sterilization is conducted) for March 2018, April 2018, August 2018, September 2018, December 2018, January 2019 and February 2019.

OBSERVATION 2

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

Specifically, your firm failed to follow SOP: ENV: 4.001, Rev. 2, "Environmental Monitoring Controls", Section: 7.11-Environmental Monitoring of the Formulation Lab as it states, "monitoring of the formulation laboratory shall be completed (b) (4). Since registration as an outsourcing facility (March 2018), your firm has only conducted environmental monitoring (EM) two times (11/29/18 and 3/26/19) within the Formulation Laboratory (cleanroom designated for terminally sterilized products). No EM was conducted during the filling operations for Epinephrine 1mg/mL, 3mL vials, lot numbers: 20190507A (b) (4) vials produced on 5/7/19), 20190507B (b) (4) vials produced on 6/5/19) and 20190507C (b) (4) vials produced on 6/6/19).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jessica L Pressley, Investigator	X Jessica L Pressley Investigator Signed By: Jessica L. Pressley -S Date Signed: 06-17-2019 10:16:55	6/17/2019

In addition, Section: 7.3-Cleanroom (b) (4) (with no production activity) is deficient as it states to (b) (4) (b) (4) (providing unreliable environmental results). Your firm is not following the SOP as EM is being taken (b) (4) and not on a (b) (4) basis when no production activities are taking place.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Specifically, media fills utilizing (b) (4) are deficient as they were conducted outside of the cleanroom (as the firm stated would represent the worst-case scenario) but does not simulate conditions of actual production operations. In addition, no growth promotion testing has been conducted on the media (firm deliberately (b) (4) and no environmental monitoring was conducted. The media fills also failed to document if all vials were incubated and if a 100% visual inspection was conducted.

OBSERVATION 4

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

Specifically,

a. Sterility testing has not been conducted by your firm's Contract Testing Laboratory (CTL), for the Epinephrine, 1mg/mL, 3mL vials, lot numbers: 20190507A (b) (4) vials produced on 5/7/19), 20190507B (b) (4) vials produced on 6/5/19) and 20190507C (b) (4) vials produced on 6/6/19). In

addition, your firm failed to ensure the sterility test method utilized by your firm's CTL is validated or verified under conditions of use utilizing your firm's drug product.

b. On 6/5/19, the (b) (4) (temperature: (b) (4) used for incubating the Epinephrine, 1mg/mL, 3mL vials, lot # 20190507B for endotoxin testing by (b) (4) was observed located on top of a cabinet containing drawers which cause vibrations and can potential lead to the disruption of any (b) (4) formed.

OBSERVATION 5

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, potency testing of the active ingredient has not been conducted by your firm's Contract Testing Laboratory (CTL), for the Epinephrine, 1mg/mL, 3mL vials, lot numbers: 20190507A (b) (4) vials produced on 5/7/19), 20190507B (b) (4) vials produced on 6/5/19) and 20190507C (b) (4) vials produced on 6/6/19) by terminal sterilization. In addition, your firm failed to ensure the analytical test method utilized by your firm's CTL is validated or verified under conditions of use utilizing your firm's drug product.

OBSERVATION 6

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

Specifically, your firm failed to support your applied expiration date of 12 months through analytical data ensuring the Epinephrine, 1mg/mL, 3mL vials, lot numbers: 20190507A (b) (4) vials produced on 5/7/19), 20190507B (b) (4) vials produced on 6/5/19) and 20190507C (b) (4) vials produced on 6/6/19) will continue to meet established specifications for strength and purity throughout its specified shelf-life.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	6/4/2019-6/17/2019* FEI NUMBER 3013854204

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paul F. Reid, Ph.D., Owner & Chief Operating Officer

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

OBSERVATION 7

Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, the ISO 5 LAFH within the Formulation Lab contained the HEPA filter gasket (black lining around the HEPA filter) which appeared to have small pieces missing. This ISO 5 LAFH was used to fill Epinephrine, 1mg/mL, 3mL vials, lot numbers: 20190507A (b) (4) vials produced on 5/7/19), 20190507B (b) (4) vials produced on 6/5/19) and 20190507C (b) (4) vials produced on 6/6/19).

OBSERVATION 8

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

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

- The address and phone number of the outsourcing facility;
- The dosage form;
- The statement "Office Use Only"

Examples of your drug product labels that do not contain this information:

- Epinephrine Injection, USP 1 mg/mL

OBSERVATION 9

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jessica L Pressley, Investigator	X Jessica L Pressley Investigator Signed By: Jessica L. Pressley -S Date Signed: 06-17-2019 10:16:55	6/17/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	6/4/2019-6/17/2019*
	FEI NUMBER 3013854204

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Paul F. Reid, Ph.D., Owner & Chief Operating Officer

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

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

Specifically, the containers of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(B). Your containers do not include the following information:

- A list of active and inactive ingredients identified by established name and the quantity or proportion of each ingredient

Examples of your drug product container labels that do not contain this information:

- Epinephrine Injection, USP 1 mg/mL

***DATES OF INSPECTION**

6/04/2019(Tue), 6/05/2019(Wed), 6/06/2019(Thu), 6/10/2019(Mon), 6/17/2019(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jessica L Pressley, Investigator	X Jessica L Pressley Investigator Signed By: Jessica L. Pressley -S Date Signed: 06-17-2019 10:16:55	6/17/2019