DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	11/12/2019-11/22/2019* FEI NUMBER 3005031360

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Si Pham, PharmD, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
McGuff Compounding Pharmacy Services, Inc.	2921 W Macarthur Blvd Ste 142
CITY, STATE, ZIP CODE, COUNTRY Santa Ana, CA 92704-7944	TYPE ESTABLISHMENT INSPECTED Producer of sterile and non-sterile 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

Personnel conducted aseptic manipulations in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically, during production of chromium injection 200 mcg/ml, lot 19K4111, on 13-Nov-19 a technician was observed routinely blocking first pass air by reaching over a tray of sterile stoppers with their hand and forceps. This practice was also observed on 19-Nov-19 during production of sodium bicarbonate injection 8.4% lot 19L1061.

OBSERVATION 2

HEPA filters were not sealed around each perimeter to the support frame.

Specifically,

The "ISO 14664 Cleanroom Performance Test Report" dated 01/17/18, for ISO-5 sterile fill workstation in room 107, stated (b) (4) HEPA filters (which were located directly above the ISO-5 workbench) failed the filter integrity leak test. The failed result was 17%. The allowable passing leak test cannot be more than (b) (4). The leak was located along the housing edge of filter (b) (4). The HEPA filter is measured (b) (4). The section of the housing edge where the leak was located was covered by a (b) (4) patch of silicone. According to the Cleanroom Performance Test Report, the patch was 12.6% of the dimension of the HEPA filter.

You failed to investigate to determine if sterile products made since the previous acceptable qualification dated 08/22/17 had been affected prior to patching the filter.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Linda F Murphy, Consumer Safety Officer Scott N Lim, Consumer Safety Officer	X Linda F Murphy Consumer Safety Officer Signed By: Linda F. Murphy -S Date Signed: 11-22-2019 08:37:46	11/22/2019

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OBSERVATION 3

Your facility was designed and/or operated in a way that permits poor flow of materials.

Specifically,

In Room 111, which is classified as ISO-8, empty polypropylene trays are sprayed with non-sterile (b) (4) and transferred (b) (4) into the ISO-7 classified Room 107, where they are sprayed with sterile (b) (4) and placed onto the ISO-5 workbench during aseptic filling operations. There is no specified contact time with the (b) (4) disinfectant and no environmental monitoring of the polypropylene trays or (b) (4) surface.

Personnel place filled, stoppered vials of drug product into these trays. On 13-Nov-19, a partially filled tray was observed stacked directly on top of a full tray containing filled and stoppered vials of chromium injection 200 mcg/ml, lot 19K4111, which had not yet been capped.

OBSERVATION 4

The use of sporicidal agents in the ISO 5 classified aseptic processing area was inadequate and infrequent.

Specifically,

You do not disinfect the perforated stainless-steel benchtop located in the ISO-5 workstation during (b) (4) cleaning with sterile (b) (4). According to the Supervisor of Pharmacy Technicians, this benchtop is exposed to sporicide during room fogging, which is performed (b) (4) in Room 107 where aspetic filling is performed.

In addition, sporicidal agents are not used for the (b) (4) ISO-5 units which are used to store sterile vials.

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OBSERVATION 5

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,

A. On 19-Nov-19, covered metal trays containing empty finished product vials were transferred from a (b) (4) ISO-5 unit, through the ISO-7 Room 107, and into the ISO 5 workstation during aseptic filling of sodium bicarbonate 8.4%, lot 19L1061, without being sanitized.

B. Single use, non-sterile mop heads are used during the (b) (4) cleaning of the wall and plexiglass of the ISO-5 aseptic fill workstation in Room 107.

OBSERVATION 6

You produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically,

There are no dedicated hoods or utensils in the non-sterile processing laboratory where non-hazardous drug products are prepared in the same (b) (4) (b) (4) hoods, and with the same utensils, as hazardous drug products.

For example, you have not demonstrated that the (b) (4) used to wipe down hood (b) (4) between uses is capable of deactivating hazardous drug products such as testosterone, progesterone, or estradiol, prior to subsequent weighing of non-hazardous products. In addition, you have not demonstrated the (b) (4) detergent used to clean utensils and mixing bowls between uses is capable of deactivating hormone products prior to using these utensils for non-hazardous drug products.

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OBSERVATION 7

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

According to your Raw Material Listing dated 19-Nov-19, you currently use the following dietary grade bulk substances in sterile injectable drug products:

- Choline Chloride
- Alpha Lipoic Acid
- Glucosamine HCl
- Reduced L-Glutathione (Non-Yeast)
- beta-NAD+ [oxidized form]

The following was observed regarding the use of non-pharmaceutical grade bulk substances in your products:

a) On 10-Jan-19, you initiated a recall of Lipoic Acid 40 mg/ml, 30 ml multi-dose vials, lot 18M0991, BUD 15-Jun-19, due to a "filmy/wispy precipitate" found in on-hand vials of released product.

b) You discontinued production of NADH disodium 50 mg/ml after rejecting (b) (4) of this product (produced 25-Apr-19 and 08-Oct-19) due to out of specification (OOS) endotoxin results. You attributed the cause of these results to the raw material, and state in the material review memo (b) (4), dated 18-Oct-19, "NADH raw material is nutraceutical grade", and "it is possible there is variation in presence and quantity of endotoxin from one b-NADH container to the next, within the same vendor's lot".

***DATES OF INSPECTION**

11/12/2019(Tue), 11/13/2019(Wed), 11/14/2019(Thu), 11/15/2019(Fri), 11/18/2019(Mon), 11/19/2019(Tue), 11/20/2019(Wed), 11/21/2019(Thu), 11/22/2019(Fri)

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X Scott N Lim
Consumer Safety Officer
Signed By: 2002819245
Date Signed: 11-22-2019 08:38:32

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