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	1/16/2024-1/26/2024* FEI NUMBER 2022073

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ronald M. McGuff, President/CEO

FIRM NAME	STREET ADDRESS
McGuff Pharmaceuticals, Inc.	2921 W Macarthur Blvd Ste 141
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Santa Ana, CA 92704-6995	Sterile Drug Manufacturer

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:
QUALITY SYSTEMS

OBSERVATION 1

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 had two consecutive (b) (4) load verification failures of your (b) (4) (b) (4) (b) (4) decontamination cycle in (b) (4) resulting in the growth of one biological indicator in each (b) (4) and have not fully investigated and assessed the failures. In (b) (4) this (b) (4) was used to manufacture registration batches (b) (4) for your (b) (4) finished drug product. Your firm has not completed a material compatibility assessment of (b) (4) that may affect cycle decontamination efficacy on items that are loaded in the (b) (4). The biological indicator failures were found on a (b) (4) plate (b) (4) made of (b) (4) and (b) (4) (b) (4) packaged in a (b) (4). The root cause was determined by your firm to be rogue biological indicators that may have had a higher than stated and verified spore population. There is no scientific justification for rogue biological indicators to occur in (b) (4) and other modes of failure have not been considered.

(b)Your quality unit failed to establish a trend and investigate continuous particle monitoring excursions identified in your filling line. During the manufacture of (b) (4) registration batches (b) (4) Production Summary Report for the (b) (4) reported multiple "particle counter" alarms that exceeded alert level

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Crystal Monroy, Investigator Heidy C Perales, Investigator Michael T Cyrus, Microbiologist Pearl C Ozuruigbo, Investigator X Crystal Monroy Investigator Signed By: 2003060870 Date Signed: 01-26-2024 15:13:48	1/26/2024

limits for all (b) (4) validation batches and at least three alarms exceeded action level limits for validation batch# (b) (4) However, no investigation was open for the action level limits exceeded in batch# (b) (4) and the alert level excursions in all (b) (4) batches were not trended to establish a risk of high airborne particulate levels in your filling line.

(c)Your firm is not documenting and implementing corrective actions in a timely manner. For example, during the manufacture of (b) (4) registration batch #(b) (4) , deviation report #648 and INV230516-1 were opened for issues with the (b) (4) (b) (4) in visual inspection workstations, EQP-0222 & EQP-0223, and resulted in Corrective Action Report (CAR), CARM230004 to address corrective and preventive actions. The corrective actions included an additional visual inspection for batch# (b) (4) and the replacement of (b) (4) units in (b) (4) by your (b) (4) manufacturer. However, the following items were noted:

1)There is no record of an additional visual inspection performed for Batch (b) (4).

2)The CAR remains open beyond the due date. The original CAR due date was 07/26/23. However, this due date was not met by your firm and on 09/22/23 a (b) (4) extension request was approved to extend the CAR to due date to 10/24/2023. However, the CAR remains open to date and there is no justification for why the CAR remains open beyond the (b) (4) extension.

OBSERVATION 2

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,
Your visual inspection program is inadequate. For example:

(a)Your firm's defect categorization in your batch records does not specify the type of defects that may

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be found during 100% visual inspection of (b) (4) Your batch records list (b) categories of defects, however 4 out of the (b) categories are only defined as critical, major, minor, and other defects and do not explain the type of defects that fall under this category.

(b)Your firm has not established acceptance criteria limits on defect categories which may lead to a quality review and investigation into a batch.

(c)Your firms visual (b) (4) used to qualify visual inspectors is unreliable in that your (b) (4) of (b) (4) (b) (4). Of those (b) (4) 3 (b) (4) contain defects. This is not representative of the overall types of defects that can be identified during visual inspection.

(d)Your firm has maintained the same visual (b) (4) for more than (b) (4). Your visual inspectors are requalified (b) (4) to identify the same (b) defect types.(b) (4), and (b) (4) and your visual inspectors are aware of the defects to look for during requalification. You do not have a process for routine review and maintenance of the visual (b) (4) to ensure the integrity of your exam over time.

(e)Records of visual inspection qualifications, schedules of requalification, and exam proctoring are overseen by a visual inspector who is also part of the program.

(f)Your firm's 100% visual inspection program is co-mingled with your Acceptable Quality Limit (AQL) inspection. Operators who perform 100% visual inspections can alternate and perform AQL inspections.

OBSERVATION 3

Deviations from written production and process control procedures are not recorded and justified.

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(a) During media fill run (b) (4), investigation INV220818-1 was opened for (b) (4) (b) (4)(b) (4) (b) (4) part number (b) (4) leaking during the media fill study. Your firm contacted your (b) (4) manufacturer for further investigation and your manufacturer recommended a change to the (b) (4) design from a (b) (4) to a (b) (4) design. Your firm proceeded with the design change; however, you did not create a change control to establish the risk associated with changing the (b) (4) The (b) (4) is a major component for your filling operation and is in direct contact with the drug product. You do not have documented justification to support no change control for this major component change. The new (b) (4) design was used to manufacture the following batches:

- Media Fill Run (b) (4) Batch # (b) (4)
- (b) (4) (b) (4) (b) (4)
- (b) (4) (b) (4) (b) (4)
- (b) (4)(b) (4) (b) (4)
- (b) (4) Media Fill Batch# (b) (4)

(b) Your firm did not follow procedures for documenting alert and action level excursions identified during manufacturing of registration batches. According to SOP-0224 for "Particle Monitoring for Filling Line", Revision 01, Section 9.3 requires quality control personnel to "record any particulate testing event that exceeds the alert or action levels on FRM-0205" as a quality review of alarms that occur during production operations. However, FRM-0205 was only partially completed for registration batch# (b) (4) and was not completed for registration batches (b) (4) There is no documentation supporting that the continuous particle monitoring excursions during registration batch manufacture were reviewed by quality to establish if investigations are required for exceeding action and alert level limits during manufacturing.

(c) Your firm has failed to fully assess and review your critical suppliers according to SOP-0055, "Supplier Ongoing Monitoring and Requalification," Rev. 03, under your requalification frequency matrix.

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OBSERVATION 4

Employees engaged in the manufacture, processing, packing and holding of a drug product lack the education, training and experience required to perform their assigned functions.

Specifically,

Training documentation, logs, procedures do not accurately reflect the current training program within your facility as training records are not current for employees who participate in your manufacturing process. Additionally, according to your quality department management and supporting department managers training is not evaluated, reviewed, or documented for effectiveness. For example:

(a) Your firm does not maintain records and does not have a process to track employee maintained records for specific job functions.

(b) Your firm does not have documentation or a program for a defined on-hands training for aseptic processing.

(c) Your firm does not evaluate the effectiveness of the on-hands training conducted.

LABORATORY SYSTEM

OBSERVATION 5

Established test procedures are not followed.

Specifically,

(a)Your firm has failed to follow your procedures. TM-0008 Test Methods, Microbial Monitoring

(Surfaces and Air) states a growth promotion test is invalid if media shows no growth within (b) (4) in the case of bacteria. Your firm's bacterial growth promotion testing for (b) (4) plates used in the environmental monitoring program for your (b) (4) filling line and surrounding ISO8 classified rooms were found to have been incubated for (b) (4)

(b)Your firm has failed to have an accurate representation of your incubation times between growth promotion and use in production. TM-0008 states (b) (4) plates used during the sampling of microbial environmental monitoring are to be incubated for at least (b) (4) for aerobic bacteria, mold, and yeast. Growth promotion for (b) (4) plates lot# (b) (4) were found to be incubated for (b) (4) These plates were used for (b) (4) environmental monitoring of viable air samples on 12/20/2023 and 01/09/2024 in your ISO8 classified spaces and were read at (b) (4). Your growth promotion testing is (b) (4) longer than your production sampling incubation time. Growth promotion test parameters should correspond to the shortest incubation time for a given test method for which the media is to be used for. There is no assurance your (b) (4) plates used in environmental monitoring sampling will be able to detect microorganisms when incubating for only (b) (4)

(c)Your firm has failed to follow your procedures. TM-0008 states other microorganisms isolated from the controlled environment shall be used as an additional growth promotion challenge. During review of growth promotion test records, this is not performed.

FACILITIES AND EQUIPMENT

OBSERVATION 6

There is a lack of written procedures assigning responsibility, providing cleaning schedules and describing in sufficient detail the methods, equipment and materials to be used for sanitation.

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Your firms sanitation program is lacking documentation for the internal warehouse monitoring during your manufacturing process from May 2023 to July 2023.

***DATES OF INSPECTION**

1/16/2024(Tue), 1/17/2024(Wed), 1/18/2024(Thu), 1/19/2024(Fri), 1/22/2024(Mon), 1/23/2024(Tue), 1/24/2024(Wed), 1/25/2024(Thu), 1/26/2024(Fri)

X Pearl C Ozuruigbo
Investigator
Signed By: Pearl C. Ozuruigbo -S
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X Heidy C Perales
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EMPLOYEE(S) SIGNATURE

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Date Signed: 01-26-2024
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1/26/2024

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."