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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 22215 26th Ave SE Suite 210<br>Bothell, WA 98021<br>(425)302-0340 Fax:(425)302-0404 | 10/29/2018-11/14/2018* |
| | FEI NUMBER<br>3014745182 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
George Martin Hiers IV, RPh, Owner

| FIRM NAME | STREET ADDRESS |
|---|---|
| Hiers Enterprises, LLC dba Northwest Compounding Pharmacy | 1350 NE Stephens Street, Suite # 42 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Roseburg, OR 97470-6410 | TYPE ESTABLISHMENT INSPECTED<br>Producer of sterile and non-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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically, operators demonstrate inadequate technique during non-sterile to sterile production operations while in an unclassified zone and while under laminar airflow. For example:

A) On 10/29/2018 during production of M.I.C B. Vitamins (25/50/1/1/1MG/ML Liquid) for IM injection, lot 10292018@15, formula ID: 6814, with a BUD of 01/27/2019, the Sterile Drug Tech was observed:

-In an unclassified space, drug components were mixed and drawn from an unsterilized, (b) (4) into a sterile syringe. The syringe was then directly placed into an unsterilized (b) (4) container for final transport from the unclassified space into the ISO5 classified zone

B) On 10/29/2018 during production of M.I.C B. Vitamins (25/50/1/1/1MG/ML Liquid), lot 10292018@15, formula ID: 6814, with a BUD of 01/27/2019, the Pharmacist in charge (PIC) was observed:

-Transporting in-process drug product in a sterile syringe via an unsterilized (b) (4) container from the unclassified zone into the ISO8 classified anteroom while donning non-sterile gloves. In-process product in (b) (4) was placed on a cardboard box used as storage in the ISO8 classified anteroom.

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-Inside the ISO8 classified anteroom the PIC proceeded to don a non-sterile gown hanging on the wall, non-sterile hair net and non-sterile face mask.

-Non-sterile gloves were used to open the door leading into the ISO 7 classified buffer zone.

-The (b) (4) container with the in-process product was placed on a equipment storage rack in the ISO 7 classified buffer zone.

-Equipment ( (b) (4)) was removed from the ISO5 classified hood and placed on top of a storage rack without gloves being disinfected after.

C) Hydroxyprogesterone in Sesame Oil 250 MG/ML for injection, formula ID: 7106 with a BUD of 180 days requires (b) (4) sterilization via a (b) (4) which has not been validated. This equipment was last calibrated on 11/16/2004 with no other record of calibration or service provided to ensure the equipment is operating as designed. There is no biological indicator used and there is no load pattern to reference. Sterility testing is not performed on the Hydroxyprogesterone product.

D) Equipment was gathered ( (b) (4)) in stages and charged into the ISO 5 classified area without being disinfected.

E) Dynamic smoke studies have not been conducted. Smoke studies conducted lack appropriate data necessary for adequate review.

F) A recognized (b) (4) such as " (b) (4)" is not conducted following the production of sterile drug products using a (b) (4) process.

G) Media fills are conducted (b) (4) but do not include the most challenging process performed.

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## OBSERVATION 2

Clothing of personnel engaged in the of drug products is not appropriate for the duties they perform.

Specifically,

During production on 10/29/2018 of Glutathione Sterile 100MG/ML Solution, Lot: 10292018@17, formula ID: 10586, with a BUD of 01/27/2019, the following was observed:

-The Pharmacist in charge was observed to don a previously worn, non-sterile gown hanging on the wall of the ISO 8 classified anteroom that was ill fitting, exposing both skin (unshaven neck and eyes without cover) and personal clothing inside the ISO5 classified LAFH during production.

- The Pharmacist in charge was observed leaning into the ISO5 classified LAFH during aseptic processing with other non-sterile garbing such as gloves, face mask and hairnet.

## OBSERVATION 3

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

Specifically, the ISO classified areas lack appropriate data to support appropriate installation certification and continued ISO classifications.

A) On 10/29/2018 a ceiling tile was observed to be loose in the ISO7 classified buffer zone, exposing sterile drug production areas to unclassified air. Additionally, on 11/01/2018 the HEPA system was viewed via an adjacent

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unclassified area. Openings were observed in the light fixture that would allow unclassified air into the cleanroom.

B) Environmental monitoring of ISO classified zones is conducted on (b) (4) basis only. Monitoring to prevent or detect incursion into the ISO classified zones is not ongoing at your facility and no risk assessment of your facility or processes has ever been conducted. EM data provided is incomplete.

C) Personnel monitoring does not include samples taken from the gloved hands of employees after performing sterile drug production inside the ISO5 classified zone at any time.

D) There is a lack of data to support adequate pressure differentials between the classified and unclassified areas have been verified prior to aseptic filling operations. Pressure differentials between classified and unclassified areas is not being monitored.

## OBSERVATION 4

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

Specifically,

A) Non-sterile (b) (4) is used for the cleaning and sanitation of the ISO classified zones. This (b) (4) is diluted from (b) (4). No procedures were provided to demonstrate how said dilution is conducted nor data provided to demonstrate (b) (4) concentration is achieved.

B) Non-sterile wipes are used to clean the ISO5 classified zone.

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C) Your firm is using " (b) (4) as a sporicidal agent. No data was provided to establish the effectiveness of (b) (4) as a sporicidal disinfectant and no dwell time has been established or proceduralized.

D) Your firm is using sponges and green scratch pads to clean equipment such as beakers, stirring rods, raw ingredient storage containers and measuring utensils used in the production of sterile drug products. The sanitation of equipment used in the production of sterile drug products is purportedly conducted using (b) (4) however there is no procedure to demonstrate an adequate process and no record is kept of instrument cleaning or sanitation.

E) Walls and ceiling design of the ISO classified zones are not constructed of a smooth, easily cleanable surface to allow for adequate sanitation.

## OBSERVATION 5

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

Specifically, the Beyond Use Dates (BUD) extended or otherwise used at your facility, are not associated with any appropriate study intended to demonstrate the stability of finished drug products for characteristics such as potency or sterility.

M.I.C B. Vitamins (25/50/1/1/1MG/ML Liquid) lot:10292018@15 for IM injection, formula ID: 6814, produced on 10/29/2018 was assigned a BUD of 01/27/2019 (90 Days). When asked to provide the source of data for assigning said BUD's the "Pharmacist In Charge" downloaded a formula sheet from (b) (4) website. The firm is currently not following (b) (4) suggested formula processes or guidelines as recommended. Furthermore, under (b) (4) formula provided guidelines, in the absence of passing a sterility test under high-risk conditions (non-sterile to sterile) storage periods cannot exceed the following time periods:

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-Controlled Room Temp (not more than (b) (4))

-Cold Temp (not more than (b) (4))

Referenced literature to support current and extended BUD's is neither associated with your current processes nor associated with finished drugs packaged inside your firm's container closure system.

-There is no data to support any of your BUD's with current processes or practices.

## OBSERVATION 6

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

Specifically, the firm has not established a testing program for any of its sterile drug products in order to regularly demonstrate products are sterile and pyrogen free.

## OBSERVATION 7

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, microbial limits have not been established for non-sterile finished drug products produced at your facility and products are not tested for the presence of objectionable microorganisms.

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## OBSERVATION 8

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, your firm does not conduct any potency testing of sterile or non-sterile drug products produced at your facility. No records could be provided to demonstrate established acceptance criteria data.

## OBSERVATION 9

Each lot of a component that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

Specifically,

A) (b) (4) used in the production of sterile and non-sterile drug products is not tested before use for the presence of microbiological contamination. The (b) (4) comes in commercially available 5 gallon containers and is extracted using a (b) (4) that is attached at the top of the 5 gallon container. (b) (4) is (b) (4) from the 5 gallon container and stored in a (b) (4) in an unclassified zone for use in production until empty. For example:

-On 10/29/2018 during production of Glutathione Sterile 100MG/ML Solution, Lot: 10292018@17, formula ID: 10586, with a BUD of 01/27/2019, the Sterile Lab Tech was observed using (b) (4) stored in the (b) (4) as an ingredient.

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-On 10/31/2018 during production of Fluorouracil 2% Solution, lot 10302018@30, formula ID: 1651 with a BUD of 04/28/2019, the lab technician was observed using (b) (4) from the (b) (4) as an ingredient.

B) On 10/29/2018 during the production of sterile drug products a sterile bottle of (b) (4) for injection, lot (b) (4) manufactured by (b) (4), was observed stored and uncapped on top of the LAFH.

## OBSERVATION 10

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

Specifically, your ISO classified zones lack sufficient data to substantiate the current classifications. For example:

-Validation of your HEPA system has never been conducted.

- (b) (4) HEPA integrity testing results do not provide adequate data to support ongoing qualification of your system.

-Lighting equipment used in your aseptic processing area was observed to be insufficient. Light fixtures used are not designed to maintain ceiling integrity and prevent infiltration of particulate into the clean room under positive pressure.

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## *DATES OF INSPECTION

10/29/2018(Mon), 10/30/2018(Tue), 10/31/2018(Wed), 11/01/2018(Thu), 11/14/2018(Wed)

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