DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE, Suite 210 Bothell, WA 98021 (425) 302-0340 Industry Information: www.fda.gov/oc/industry	12/10/2018-01/28/2019
	FEI NUMBER 3014597434

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Sammi A. Molvi, RPh, Owner

FIRM NAME	STREET ADDRESS
Health Solutions Pharmacy Center, Inc.	996 NW Circle Blvd., Suite 105
CITY, STATE AND ZIP CODE Corvallis, OR 97330	TYPE OF ESTABLISHMENT INSPECTED Producer of sterile and non-sterile drug products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

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

Specifically, the sterile drug technician demonstrated inadequate aseptic technique during non-sterile to sterile drug production operations on 12/10/2018. For example:

A. Mixing drug components in non-depyrogenated equipment.
B. Disinfecting equipment (vial, (b) (4) and rubber vial stopper) with non-sterile (b) (4) using a non-sterile wipe.
C. Jewelry not removed prior to donning sterile gloves.
D. Donning sterile gloves with gloved fingertips in contact with the non-sterile area of the inside cuff.
E. No disinfection of the ISO5 classified LAFH prior to production.
F. The operator was observed leaning into LAFH during production with facial protection that was not worn appropriately during production to provide an adequate seal.
G. Crimping equipment was used outside the ISO5 classified zone with a vial cap and crimping tool that had not been disinfected prior to use and gloves that were not disinfected prior to vial being sealed.
H. Media fills are conducted but do not include the most challenging process performed as described by the Pharmacist in charge and the sterile drug technician.
I. Dynamic smoke studies have not been conducted to demonstrate airflow during production.

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	Bryan L. Mcguckin -S	Bryan L. McGuckin, Investigator	01/28/2019

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OBSERVATION 2

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

Specifically,

A. On 12/10/2018, sterile drug production was conducted after observing water dripping from the ceiling tile of the clean-room. The ceiling tile was subsequently removed but not re-installed and sealed prior to production. Re-certification of room was not conducted for approximately (b) (4) days.

B. Pressure differentials between classified and unclassified areas are not monitored daily. Magnehelic gauges used were observed to be either non-functional or incorrectly installed.

C. Environmental monitoring of ISO classified zones is conducted on (b) (4) basis and (b) (4) via an unqualified (b) (4) sampling method at unknown locations.

D. Personnel monitoring is conducted using samples taken from the gloved hands of employees following sterile drug production at least (b) (4) but not following each sterile drug product produced.

OBSERVATION 3

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

Specifically,

A. The ISO5 classified zone is cleaned using non-sterile (b) (4)

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

C. The ISO5-7 classified zones are not cleaned with any sporicidal and no dwell time is established for disinfectants used.

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	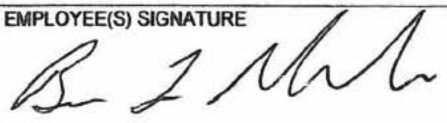	Bryan L. McGuckin, Investigator	01/28/2019

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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 ISO classified zones lack sufficient data to substantiate the current classifications. For example:
A. Certification of your HVAC/HEPA system has never been conducted. You did not provide data to support the design of your clean-room was sufficient to perform sterile drug production prior to production.
B. 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.
C. Multiple ceiling tiles were observed to be labeled with "do not seal" and confirmed to be unsealed.

OBSERVATION 5

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

Specifically,

There is no established testing program for any of your sterile drug products to demonstrate products are indeed sterile and pyrogen free prior to being distributed. For example, the following sterile drug products that were distributed as office stocks did not have sterility testing:

1. Rx (b) (6) for 5 mL Papaverine-Phentolamine-PGE1 22-0.8 mg-8mcg/mL Injection solution; lot 01102018@9; produced 10/1/18.
2. RX (b) (6) for 30 mL Cyclopentolate-Phenylephrine-Tropicamide Ophthalmic Solution; lot 27092018@11; produced 9/27/18.
3. RX (b) (6) for 10 mL Hydroxyprogesterone Caproate 250 mg/mL Oil Injectable Solution; lot 19062018@11; produced 6/19/18.

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	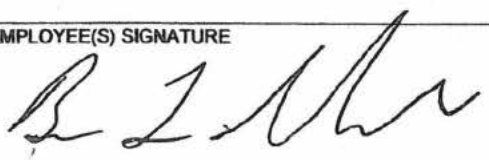	Bryan L. McGuckin, Investigator	01/28/2019

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OBSERVATION 6

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 regularly conduct any potency testing of sterile or non-sterile drug products produced at your facility. For example, the following sterile drug products that were distributed as office stock did not have potency testing:

1. Rx (b) (6) for 5 mL Papaverine-Phentolamine-PGE1 22-0.8 mg-8mcg/mL Injection solution; lot 01102018@9; produced 10/1/18.
2. RX (b) (6) for 30 mL Cyclopentolate-Phenylephrine-Tropicamide Ophthalmic Solution; lot 27092018@11; produced 9/27/18.
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	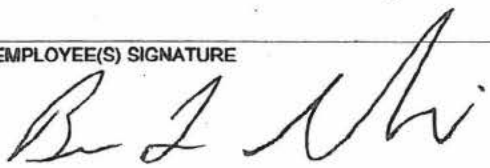	Bryan L. McGuckin, Investigator	01/28/2019

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OBSERVATION 7

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.

When asked to provide data used to establish extended BUD's, formulations by (b) (4) were provided. Per (b) (4) "in the absence of passing a sterility test under high-risk conditions (non-sterile to sterile production) storage periods cannot exceed the following time periods:

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

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	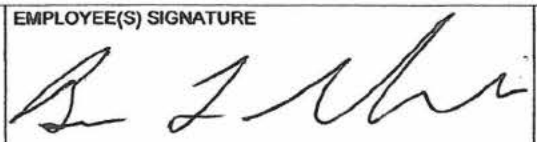	Bryan L. McGuckin, Investigator	01/28/2019

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OBSERVATION 8

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

Specifically,

Re-usable non-sterile gowns, head covers, shoe covers and face covers are utilized in the production of sterile drug products. No eye-cover is used.

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	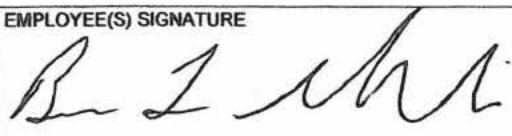	Bryan L. McGuckin, Investigator	01/28/2019

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OBSERVATION 9

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

Specifically, non-sterile drug products produced at your facility for office stock are not tested for the presence of objectionable microorganisms. A (b) (4) is used in the production of non-sterile drug products but the (b) (4) is not tested. Example of a non-sterile drug product for office stock:

1. Rx (b) (6) for 30 GM Lidocaine-Tetracaine-Phenyleph HCL 20-4-2%; lot 22102018@10; produced 10/22/2018.

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	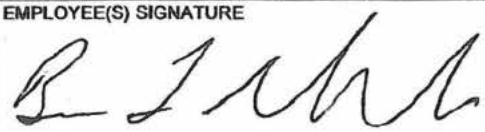	Bryan L. McGuckin, Investigator	01/28/2019

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OBSERVATION 10

You used a non-pharmaceutical grade component in the formulation of a drug product. Specifically, examples of non-pharmaceutical grade components used are:

A)(b) (4) that was processed through a (b) (4) system that was not tested to ensure pharmaceutical quality prior to use for the formulation of non-sterile drug products. An example of a drug product formulated with (b) (4) produced for individually identified patients is Ketoprofen-Ketamine 5-5% Gel; lot 04092018@51.

B) (b) (4). An example of a sterile drug product that was formulated using this non-pharmaceutical grade component and distributed as office stocks and individually identified patients is Prostaglandin 500 mcg/mL injectable under lots 23032018@36 and 03112017@21.

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	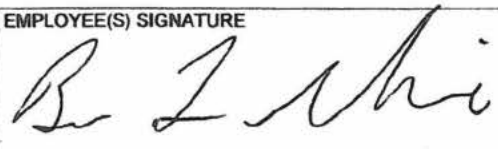	Bryan L. McGuckin, Investigator	01/28/2019