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 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	9/26/2016-10/4/2016*
	FEI NUMBER 3003429652

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ronald P. Dulwick , Owner

FIRM NAME	STREET ADDRESS
Strohecker's Pharmacy	1286 SE Holgate Blvd C1
CITY, STATE, ZIP CODE, COUNTRY Portland, OR 97282	TYPE ESTABLISHMENT INSPECTED Producer of 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

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

Specifically,

- The firm provided a report from the contract vendor on the smoke study qualification of the sterile production suites; however no video was taken of the smoke study and no description of the conditions during the smoke study was provided, so no confirmation of the smoke study could be reviewed. Additionally, no dynamic conditions to mimic sterile compounding were performed during the initial sterile compounding suite qualification.

- Environmental monitoring is only performed (b) (4) . SOP No. 9 "Environmental Monitoring/Testing" Revised/Reviewed: June 8th, 2016 states the following: Section 2 "Air sampling shall be done (b) (4) ", Section 3 "Surface Testing shall be done every (b) (4) ", and Section 6 "Verify the compounding areas meet USP <797> ISO 8, ISO 7, and ISO 5 air quality requirements". "Testing is to be completed every (b) (4) ".

  Additionally, no particulate (non-viable) or microbial (viable) monitoring is performed during sterile production.

- Personnel monitoring is only performed (b) (4) . No personnel microbial monitoring is performed during or after sterile production. SOP No. 12 "Glove fingertip sampling procedure and documentation" Revised/Reviewed: June 27th, 2016 states' "(b) (4) (b) (4) " is deficient in that it does not require operators to roll their

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fingertips from side to side.

SOP No. 13 "Garbing, Gowning and Gloving Process, Aseptic Technique Processes and Cleaning Processes Validation and Documentation" Revised/Reviewed: June 7th, 2016 is deficient in that it does not require any sampling of the gown such as forehead, face, shoulder, or chest areas.

OBSERVATION 2

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

Specifically,

- SOP No. 10 "Garbing Procedure Technique" Revised/Reviewed: June 2nd, 2016 is deficient in that it does not state that face and neck areas should be completely covered. Furthermore, it does not address the exposure of street clothing in the ISO7 room with 1 ISO 5 hood. On 09/26/16, we observed an employee ((b)(6),(b)(7)(C)) working in the ISO 7 room with 1 ISO 5 hood exposed face, neck area, and street clothing while filling sterile Leuprolide Microdose 40 MCG/0.2 ML Injectable, Lot# LM-0926S16, (b) (4) batch.

- There is no written procedure and no qualification of the (b) (4) sterilization for the (b) (4) (b) (4) model (b) (4) (SN(b) (4) 2) or the (b) (4) model (b) (4) (SN (b) (4)) use to sterilize drug products. No (b) (4) has been performed and no (b) (4) qualification has been performed. The following batches were produced and sterilized by (b) (4) :

Product	Date Made	Lot	Sterilization Method
Estradiol Valerate in Cottonseed	7/21/2016	E-0721S16	(b) (4)

Oil (5ML) 20MG/ML Injectable			
Estradiol Valerate in Cottonseed Oil (5ML) 20MG/ML Injectable	7/29/2016	E-0729S16	(b) (4)
Estradiol Valerate in Cottonseed Oil (5ML) 20MG/ML Injectable	8/26/2016	E0826S16	(b) (4)
Progesterone (Ethyl Oleate) 50MG/ML Injectable	7/28/2016	PEO-0728S16	(b) (4)
Progesterone (Ethyl Oleate) 50MG/ML Injectable	8/9/2016	0809S16	(b) (4)
Progesterone (Ethyl Oleate) 50MG/ML Injectable	8/31/2016	PEO-0831S16	(b) (4)
Testosterone Cypionate (Sesame Oil) 200MG/ML Injectable	8/10/2016	T0810S16	(b) (4)

Media fills do not simulate normal sterile production. The media fill for high risk production includes a media fill of (b) (4) which does not represent all vial sizes such as 10 ml in a (b) (4) vial and 2 ml in a (b) (4) vial.

OBSERVATION 3

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

Specifically,

- SOP No. 5 "Cleaning and Disinfection" Revised/Reviewed: June 7th, 2016 is deficient in that it does not state within the procedure the type of cloth to be used when applying the surface disinfectant. On 9/27/2016 we observed (b)(6),(b)(7)(C) cleaning the ISO 5 hood with non-sterile,

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lint free wipes which were sprayed with, in house sterilized with (b) (4) for the cleaning of the ISO 5 hood. Sterile wipes were available within the ISO 7 suite.

- On 9/27/2016 we observed (b)(6),(b)(7)(C) use "(b) (4)" brand duster mop heads to clean the floor of the ISO7 and ISO8 compounding areas with the sterilized (b) (4). The ISO5 hoods are located in the (b) (4). However no evaluation has been made on the particulate load the duster mop heads may introduce into the ISO 7 and ISO 5 environments.

- According to SOP No. 5 the firm uses (b) (4) for the (b) (4) cleaning of the sterile compounding suites and ISO 5 hoods. The firm (b) (4), on a (b) (4) basis, (b) (4) for the (b) (4) cleaning. (b) (4) is labeled as a (b) (4) (b) (4) agent. SOP No. 5 does not specific application of the cleaner and surface contact time and no evaluation has been performed to demonstrate the efficacy of the cleaning agents used.

OBSERVATION 4

Master production and control records lack complete manufacturing and control instructions.

Specifically, the firm does not have a light box for the examination of compounded vials for the presence of particulate matter. As described by (b)(6),(b)(7)(C), the examiner (b) (4) and (b) (4) looking for particulate matter. The majority of the firm's sterile production is within amber vials which may be difficult to observe for particulate matter. The firm only uses a (b) (4) for the presence of particulate matter; there is no dark background to inspect for particulate matter that would not be visible with a white or light background. (Additionally, there is no eye examination or personnel qualification requirement for the examination of vials for particulate matter.

***DATES OF INSPECTION**

9/26/2016(Mon),9/27/2016(Tue),9/28/2016(Wed),9/30/2016(Fri),10/03/2016(Mon),10/04/2016(Tue)

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