DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Denver District Office 6th Ave. and Kipling St., Bldg. 20 Denver, CO 80225 303-236-3017 Industry Information: www.fda.gov/oc/industry	02/27/19 - 03/08/19
	FEI NUMBER 3014083318

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Sarah K. Simmers, Owner/PIC

FIRM NAME	STREET ADDRESS
Customceutical Compounding, LLC	4611 E. Shea Blvd., Bldg. 3, #180
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Phoenix, AZ 85028	producer of sterile and non-sterile drugs

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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 adequate. Specifically,

A) Operator (b) (6) did not to sanitize all items immediately prior to introduction into the ISO 5 LAFW. The operator sanitized the outside of a closed plastic bin containing packages of various materials, placed the bin into the LAFW, opened the bin, and then placed the individual packages of materials onto the primary work surface. The packages inside the plastic bin were not sanitized immediately prior to introduction into the LAFW. We observed the operator use items from inside the bin during production on 02/27/19 and 02/28/19. The operator produced intrathecal finished product lots 02272019@13, 02272019@12, and 02272019@1 on 02/27/19. The operator produced lot 02282019@8, dispensed on 02/28/19, and approximately (b) (4) other intrathecal finished product lots on 02/28/19.

B) Both staff pharmacists, who are the primary aseptic production operators, failed their most recent media fill on 01/24/19.

a. The media fill record for operator/staff pharmacist (b) (6) was designated as "pass", but the cumulative result for gloved fingertip samples was 4 CFU. The result exceeded the limit of NMT (b) (4) CFU. There was no variance or deviation opened. Operator (b) (6) has not participated in routine personnel monitoring, i.e., glove contact plates, post-production. This operator produced sterile drug products from 01/25/19 through 03/04/19.

b. The media fill record for operator/staff pharmacist (b) (6) contained the following results for gloved fingertips post media: right hand = 8 CFU, left hand = 6 CFU. These results exceed the limit of NMT (b) (4) CFU for a cumulative result of both gloves. There was no variance or deviation opened. This operator produced sterile drug products from 01/25/19 through 03/06/19.

C) We observed several deficiencies when we watched the most recent airflow visualization study for the LAFW which was conducted 05/25/17.

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		Nicholas L. Hunt, Investigator Christopher M. Jenner, Investigator	03/08/2019

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a. There was insufficient smoke to appropriately assess unidirectional airflow for all operations conducted during the video. The smoke appeared to stagnate and become turbulent at different times during the studies.
b. The dynamic conditions during the study were not representative of production we observed on 02/27/19 and 02/28/19.

OBSERVATION 2
Aseptic processing areas are deficient regarding the systems for environmental monitoring conditions and actionable microbial contamination was present in the ISO 5 area or in adjacent areas during aseptic production without adequate product evaluation and remedial action. Specifically,

A) The gloves for operator (b) (6) were sampled after production in the LAFW on 02/05/19, and the results were above the limit of NMT (b) (4) CFU. The investigation did not include an assessment of microbial quality for the approximately (b) (4) products the operator produced that day and did not identify the microorganism.

B) Operator (b) (6) wore two pair of gloves on 03/04/19 prior to sampling (b) (6) gloved fingertips at the end of production. The operator did not wear two pair of gloves during production on any other day during this inspection, and you stated personnel only wear two pair of gloves for fingertip sampling. The operator produced lot 03042019@10 for intrathecal administration, dispensed 03/04/2019.

C) Your firm did not conduct personnel and surface monitoring every (b) (4) weeks per the approved SOP. There are several examples when your firm did not perform personnel and surface sampling for approximately (b) (4).

OBSERVATION 3
Clothing of personnel engaged in the production of drug products intended to be sterile is not appropriate for the duties they perform, and personnel donned non-sterile coveralls in a way which might have caused the gowning apparel to become contaminated. Specifically, on 02/27/19 and 02/28/19, we observed the following conditions when operator (b) (6) donned gowning apparel and performed aseptic production in the LAFW:

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A) The operator's forehead and cheeks were exposed during production, and the operator repeatedly placed their head into the LAWF on 02/27/19 and 02/28/19. The operator produced intrathecal finished product lots 02272019@13, 02272019@12, and 02272019@1 on 02/27/19. The operator produced lot 02282019@8, dispensed 02/28/19, and approximately (b) (4) other intrathecal finished product lots on 02/28/19.

B) There was an approximately 1-inch tear on the right shoulder of the operator's coverall at the end of production on 02/27/19. The operator produced intrathecal finished product lots 02272019@13, 02272019@12, and 02272019@1 on 02/27/19.

C) The sleeves and other parts of the coverall contacted the floor in the ISO 8 anteroom several times as the operator donned the gowning apparel on 02/27/19. The operator produced intrathecal finished product lots 02272019@13, 02272019@12, and 02272019@1 on 02/27/19.

D) The operator's coverall had an approximate 1 cm tear on the front during preparation of the ISO 5 LAFW and ISO 7 buffer room for production on 03/04/19. The operator did not know the gown was damaged until we notified her through the observation window.

OBSERVATION 4

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

A) The operator (b) (6) failed to sanitize the power cord connected to the (b) (4) inside the LAFW on 02/27/19. The power cord contacted the work surface and was connected to an outlet inside the LAFW. The operator produced intrathecal finished product lots 02272019@13, 02272019@12, and 02272019@1 on 02/27/19.

B) Operator (b) (6) used non-sterile wipes to sanitize the inner surfaces of the ISO 5 LAFW and wipe items prior to introduction into the LAFW on 02/27/19, 02/28/19, 03/04/19. The operator produced lot 02282019@8, dispensed 02/28/19, and approximately (b) (4) other intrathecal finished product lots on 02/28/19. The operator produced lot 03042019@10 for intrathecal administration, dispensed 03/04/2019.

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C) Personnel apply (b) (4) to surfaces with a (b) (4) contact time as their sporicidal agent during (b) (4) cleaning of classified areas. The manufacturer's label specifies a (b) (4) contact time for use as a sporicidal disinfectant. Your firm uses (b) (4) as the sporicidal disinfectant for the ISO 5 LAFW, ISO 7 buffer room, ISO 8 anteroom, and ISO 8 (b) (4) (b) (4).

OBSERVATION 5

Your firm produced hazardous drug products using shared equipment and utensils, and there was inadequate containment and segregation to prevent cross-contamination of non-sterile drug products. Specifically, we observed the following conditions during non-sterile production on 02/27/19:

A) Personnel produced different products without adequately cleaning the (b) (4) hood. Loose (b) (4) remained on the work surface and on the scale inside the hood after personnel cleaned the unit. They placed product contact utensils directly onto the work surface inside the hood. Personnel produced progesterone cream, lot 02262019@19, dispensed 02/27/19; and diazepam and baclofen suppository, lot 02262019@33, dispensed 03/07/2019.

B) We observed loose (b) (4) on the mouse and barcode scanner connected to the computer used by production personnel to log the weight of materials. Personnel contacted these items repeatedly while they produced different drug products without changing their gloves. Personnel produced progesterone cream, lot 02262019@19, dispensed 02/27/2019; and then diazepam and baclofen suppository, lot 02262019@33, dispensed 03/07/2019.

C) We observed soiled/damaged spoons, spatulas, and mixing blades stored as clean and ready for use in production.

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