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 Fax: (425) 302-0404 Industry Information: www.fda.gov/oc/industry	11/13/2019-11/26/2019* FEI NUMBER 3015762738

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Natalie A. Gustafson, PharmD, Director/Owner

FIRM NAME	STREET ADDRESS
Lloyd Central Compounding Pharmacy	2606 NE Broadway St Ste B
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Portland, OR 97232-1898	Producer of Sterile and Non-Sterile Drugs

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) (WE) OBSERVED:

OBSERVATION 1

Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically,

On 11/13/2019 during the production of Hydromorphone HCL 20MG/ML Intrathecal, Lot#: 374767, we observed the use of non-sterile wipes (b) (4) to introduce supplies into the ISO 5 classified area.

In addition, (b) (4) a non-sterile disinfectant, is used inside the ISO 5 classified area on a regular basis for cleaning purposes.

OBSERVATION 2

You produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically,

Your firm currently produces testosterone and estrogen products without adequate cleaning to deactivate any

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		Bryan L. McGuckin, Investigator William Millar, Compliance Officer	11/26/2019

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hazardous drug residues. You firm currently uses store bought soap and water only for these product utensils and work surfaces. A strong oxidizer for deactivation of said residues is not used.

OBSERVATION 3

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

Specifically, not all batches of sterile drug products prepared by your firm were tested for endotoxin before release. For example,

1. Hydromorphone HCL/Clonidine HCL 5MG/60MCG/ML Intrathecal, Lot#: 356530; Rx: (b) (6) .
2. Hydromorphone HCL 7.5MG/ML Intrathecal, Lot#: 359865; Rx: (b) (6) .
3. Morphine Sulfate/Baclofen 10MG/100MCG/ML Intrathecal, Lot#: 363654; Rx: (b) (6) .
4. Fentanyl/Baclofen 4000MCG/350MCG/ML Intrathecal, Lot#: 365966; Rx: (b) (6) .

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