

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

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	<small>DATE(S) OF INSPECTION</small> 9/20/2021-9/30/2021*
	<small>FEI NUMBER</small> 3014064135

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
 Peter O. Kohler, President & CEO

<small>FIRM NAME</small> OurPharma LLC	<small>STREET ADDRESS</small> 2512 S City Lake Rd
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<small>CITY, STATE, ZIP CODE, COUNTRY</small> Fayetteville, AR 72701-5013	<small>TYPE ESTABLISHMENT INSPECTED</small> Outsourcing Facility
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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

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

Specifically, your firm has no documented justification for the orientation of the non-viable particle monitoring probes located in the ISO 5 biological safety cabinets (BSC). The placement of the isokinetic probe is not fixed and is bumped and moved during cleaning of the BSCs. Your firm cannot demonstrate that the orientation and placement of the probes provides a meaningful sample.

In addition, your firm has not qualified under actual conditions of use the non-viable particulate probes and the active air samplers within the ISO 5 BSCs. The system was initially qualified in (b) (4) and the BSCs were not installed until sometime in January/February 2019.

OBSERVATION 2

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

Specifically, your firm did not include the material used for the arm rests on the ISO 5 Biological Safety Cabinets (BSC) in your disinfectant efficacy study. Your firm has no documentation to show that the disinfectants used are effective on this material.

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Margaret M Annes, CSO	 Margaret M Annes CSO X 11/22/21	<small>DATE ISSUED</small> 9/30/2021
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In addition, your firm has not evaluated the suitability of the material used for the arm rests for use in an ISO5/ISO 7 cleanroom environment or for use in sterile production.

***DATES OF INSPECTION**

9/20/2021(Mon), 9/21/2021(Tue), 9/22/2021(Wed), 9/23/2021(Thu), 9/24/2021(Fri), 9/27/2021(Mon), 9/28/2021(Tue), 9/29/2021(Wed), 9/30/2021(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Margaret M Annes, CSO	DATE ISSUED 9/30/2021
	X Margaret M Annes CSO Signed By: Margaret M. Annes-G Date Signed: 09-30-2021 11:22:2	

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."