DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	9/16/2024-9/27/2024* FEI NUMBER 3014064135

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

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

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

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

a) In November 2023, your firm changed manufacturers of the Fentanyl Citrate, USP and in February 2024 your firm changed manufacturers of the Morphine Sulfate, USP. These active pharmaceutical ingredients (API) are used to make various drug products such as Fentanyl Citrate 100mcg (2mcg/mL) + Bupivacaine HCl 0.125% in 0.9% NaCl - 50mL in 60mL syringe, Fentanyl Citrate 500mcg (2mcg/mL) + Bupivacaine HCl 0.125% in SWFI - added to 250mL 0.9% NaCl, Fentanyl Citrate 1mg in SWFI - added to 100mL 0.9% NaCl bag = 10mcg/mL, Fentanyl Citrate 200mcg (2mcg/mL) + Bupivacaine HCl 0.125% in 0.9% NaCl - 100mL cassette, Morphine Sulfate 1mg/mL (API) in 0.9% NaCl - 30mL in 30mL PCA vial, and Morphine Sulfate 1mg/mL (API) in 0.9% NaCl - 30mL in 35 mL monoject plungerless syringe.

   Your firm has no documentation of a change control or performance of an assessment/evaluation to determine the change's potential to impact product quality, including test methods for assay, bioburden, and sterility, and product stability.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Margaret M Annes, CSO X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 09-27-2024 10:48:05	9/27/2024

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b) Your firm has not completed all aspects of equipment qualification for all pieces of equipment. For example, no performance qualification (PQ) has been performed for incubators INCU(b) (4), INCU(b) (4), INCU-(b) (4), INCU-(b) (4), and INCU-(b) (4) used for incubation of environmental and personnel monitoring media plates and media fill containers. In addition, operational qualification (OQ) was performed on empty chambers only and did not include a full chamber.

Your firm has not performed equipment qualification for incubators INCU-(b) (4) and INCU-(b) (4) that have primarily been used to incubate media fill containers.

OBSERVATION 2

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically, positive pressure is not always maintained between rooms of different classifications, when doors are opened e.g. between the ISO 7 Ante Rooms where gowning occurs to enter each suite and the ISO 8 corridor and the ISO 8 corridor and the controlled but not classified Changing Room. Your firm has not performed a risk assessment and/or smoke studies to demonstrate that lower quality air is not entering areas of higher quality air.

OBSERVATION 3

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

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Specifically, the following information is not found on your drug product labels:

a) The name, address, and phone number of the outsourcing facility.

b) The statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only".

Examples of your drug product labels that do not contain this information:

- Ketamine HCl 25 mg/1 ml Injection in a 3 ml Syringe

OBSERVATION 4

The container of your outsourcing facility's drug products does not include information required by section 503B(a)(10)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, your containers do not include the following information:

a) Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088.

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b) Directions for use, including, as appropriate, dosage and administration.

Examples of your container labels that do not contain this information:

- Fentanyl Citrate 10 mcg/ml Injection in a 100 ml bag
- Fentanyl Citrate 100 mcg/50 ml + Bupivacaine HCl 0.125% in 60 ml Syringe
- Hydromorphone HCl 30 mg/30 ml Injection in a 30 ml Syringe
- Ropivacaine HCl 0.2% Injection in a 500 ml bag

OBSERVATION 5

Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the previous six months as required by section 503B(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, the following products were compounded and not identified on your report dated December 2023:

- Fentanyl Citrate 2mcg/mL + Bupivacaine HCl 0.125% (PF) added to NS 250mL Bag

***DATES OF INSPECTION**

AMENDMENT 1

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9/16/2024(Mon), 9/17/2024(Tue), 9/18/2024(Wed), 9/19/2024(Thu), 9/20/2024(Fri), 9/23/2024(Mon), 9/24/2024(Tue), 9/25/2024(Wed), 9/26/2024(Thu), 9/27/2024(Fri)

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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."