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	9/8/2020-10/5/2020*
	FEI NUMBER 3014577316

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jacqueline A. Biery, Manufacturing Pharmacy Manager

FIRM NAME	STREET ADDRESS
Providence Health and Services Washington Dba Providence Infusion Hospital Services	3333 S 120th Pl Ste 100c
CITY, STATE, ZIP CODE, COUNTRY Tukwila, WA 98168-5134	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

OBSERVATION 1

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

Specifically, your firm has not monitored total particle counts (b) (4) during production in the ISO 5 area between 03/02/2020 to 10/02/2020. In that time, you produced (b) (4) batches and distributed (b) (4) batches for patient use.

Examples of products released under deficient non-viable air monitoring:

- HYDROmorphone ((b) (4)) PCA 30mg per 30mL in 0.9% Sodium Chloride, Lot: (b) (4) , Prep Date: (b) (4) ;
- Buffered Lidocaine (3mL) Syringe, Lot: (b) (4) , Prep Date: (b) (4) ;
- ceFAZolin 2g per 20mL Syringe, Lot: (b) (4) , Prep Date: (b) (4) ; and
- fentaNYL 2 mcg/mL and Bupivacaine 0.1% in 0.9% Sodium Chloride 250mL Bag, Lot: (b) (4) , Prep Date: (b) (4) .

OBSERVATION 2

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

Specifically, your firm does not conduct endotoxin testing prior to releasing drug products intended to be sterile.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kenneth O Gee, Investigator Nathaniel B Phillips Sylvain, Investigator	Kenneth O Gee Investigator Signed By: 2031873661 Date Signed: 10-05-2020 18:01:28 X	10/5/2020

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jacqueline A. Biery, Manufacturing Pharmacy Manager	
FIRM NAME Providence Health and Services Washington Dba Providence Infusion Hospital Services	STREET ADDRESS 3333 S 120th Pl Ste 100c
CITY, STATE, ZIP CODE, COUNTRY Tukwila, WA 98168-5134	TYPE ESTABLISHMENT INSPECTED Outsourcing facility

Examples of products released without endotoxin testing:

- fentaNYL 2 mcg/mL and Bupivacaine 0.1% in 0.9% Sodium Chloride 250mL Bag, Lot: (b) (4), Prep Date: (b) (4); and
- fentaNYL 2 mcg/mL and Bupivacaine 0.125% in 0.9% Sodium Chloride 250mL Bag, Lot: (b) (4), Prep Date: (b) (4).

OBSERVATION 3

Your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the previous six month period.

Specifically, the following products were compounded and not identified on your report dated (b) (4)

- fentaNYL 2 mcg/mL and Bupivacaine 0.1% in 0.9% Sodium Chloride 250mL Bag, Lot: (b) (4), Prep Date: (b) (4) and
- fentaNYL 2 mcg/mL and Bupivacaine 0.125% in 0.9% Sodium Chloride 250mL Bag, Lot: (b) (4), Prep Date: (b) (4).

OBSERVATION 4

The labels of your outsourcing facility's drug products are deficient.

Specifically,

a) the following information is not found on your drug product labels:

- The statement "This is a compounded drug";
- The dosage form and strength; and

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kenneth O Gee, Investigator Nathaniel B Phillips Sylvain, Investigator	DATE ISSUED 10/5/2020

- The quantity or volume.

Example of your drug product label that does not contain this information:

- HYDROmorphone 30 mg/30 mL (1 mg/mL) PCA in 0.9% sodium chloride

b) the following information is not found on your drug product labels:

- The dosage form and strength.

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

- fentaNYL 2 mcg/mL and bupivacaine 0.1% in 0.9% sodium chloride
- fentaNYL 2 mcg/mL and bupivacaine 0.125% in 0.9% sodium chloride
- fentaNYL 1000 mcg/100 mL (10 mcg/mL) in 0.9% sodium chloride
- Midazolam 100 mg/100 mL (1 mg/mL) in 0.9% sodium chloride
- Buffered Lidocaine 3 mL syringe (Lidocaine 0.9%/Sodium Bicarbonate 0.84%)
- Vancomycin 1.25 g added to 250 mL 0.9% sodium chloride bag
- Vancomycin 1.5 g added to 250 mL 0.9% sodium chloride bag

c) the following information is not found on your drug product labels:

- The name, address, and phone number of the outsourcing facility; and

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- The dosage form and strength.

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

- Buffered Lidocaine 10 mL syringe (Lidocaine 0.9%/Sodium Bicarbonate 0.84%)
- ceFAZolin 1 gram per 10 mL (100 mg/mL) syringe
- ceFAZolin 2 gram per 20 mL (100 mg/mL) syringe
- ceFAZolin 3 gram per 30 mL (100 mg/mL) syringe
- Oxytocin 30 units per 500 mL 0.9% Sodium Chloride

***DATES OF INSPECTION**
9/08/2020(Tue), 9/09/2020(Wed), 9/10/2020(Thu), 9/11/2020(Fri), 9/14/2020(Mon), 9/15/2020(Tue), 9/16/2020(Wed), 9/28/2020(Mon), 9/29/2020(Tue), 9/30/2020(Wed), 10/01/2020(Thu), 10/02/2020(Fri), 10/05/2020(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kenneth O Gee, Investigator Nathaniel B Phillips Sylvain, Investigator	X Kenneth O Gee Investigator Signed By: 2001873861 Date Signed: 10-05-2020 16:01:28	10/5/2020

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."