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 during production in the ISO 5 area between 03/02/2020 to 10/02/2020. In that time, you produced batches and distributed batches for patient use.

Examples of products released under deficient non-viable air monitoring:
- HYDROMorphone (4) PCA 30mg per 30mL in 0.9% Sodium Chloride, Lot: , Prep Date: ;
- Buffered Lidocaine (3mL) Syringe, Lot: , Prep Date: ;
- ceFAZolin 2g per 20mL Syringe, Lot: , Prep Date: ; and
- fentaNYL 2 mcg/mL and Bupivacaine 0.1% in 0.9% Sodium Chloride 250mL Bag, Lot: , Prep Date: .

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.
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) ...; and
- fentanyl 2 mcg/mL and Bupivacaine 0.125% in 0.9% Sodium Chloride 250mL Bag, Lot: (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) ... and
- fentanyl 2 mcg/mL and Bupivacaine 0.125% in 0.9% Sodium Chloride 250mL Bag, Lot: (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
• 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
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)
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."