DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	03/17/2014 - 03/27/2014* FEI NUMBER 3006031801

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Eddie W. Glover, PD., Chief Executive Officer/Owner

FIRM NAME	STREET ADDRESS
US Compounding Inc	1270 Don's Lane
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Conway, AR 72032	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

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,
On 3/19/14 during the set-up of Omnipaque (iohexol) 240mg/ml injectable in Clean Room (b), a technician was observed with exposed skin in the ISO 5 laminar flow hood setting up equipment and supplies. Approximately 1/4 inch of skin was exposed across the length of the technician's forehead above the goggles.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,
It was observed on 3/17/14, a technician unnecessarily handling sterile rubber stoppers. A technician was observed hand stoppering vials ((b) vials) of HCG/B12 lot 20141703@3; 10ml CONCENTRATE 10,000 UNITS/1200mcg/ml injectable in the ISO 5 laminar flow hood.

OBSERVATION 3

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically,
It was observed on 3/17 & 18/2014 all (b) of the ISO 5 laminar flow hoods contained white residue streaks and blotches on the metal grid of the HEPA filters. An amber colored residue was observed stuck in the metal grids in ISO laminar flow hood #2 approximately 4 inches in length along the bottom right. Sterile products were being produced in the ISO 5 laminar flow hoods on 3/17/2014.

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	Erika V. Butler, Investigator Erika V. Butler Kimberley A. Hoefen, Investigator	03/27/2014

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OBSERVATION 4

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically,

It was observed on 3/17/14, finished product vials of Betamethasone Sodium Phosphate/Acetate lot 20141302@21 (b) vials), in a tote on the floor underneath the label machine; drying in bins layered in blue wipes. The firm explained that the vials were previously soaked in a tote of [redacted] (b) (4) to remove any residues before labeling. There are no standard operating procedures for this operation. Your firm cannot be assured that the finished drug products soaking in the (b) (4) bath prior to labeling will not be contaminated by the (b) (4)

OBSERVATION 5

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

Specifically,

a) Between 12/20/2013-03/19/2014, your firm has released (b) (4) lots of sterile finished products using an endotoxin test method that has not been validated and is performed by a contract laboratory. Your firm does not supply your contract testing laboratory with information regarding product specific drug dosing and route of administration that would be used to calculate the maximum valid dilution. Without this calculation the testing laboratory is unable to perform a valid assay for endotoxin.

b) Between 12/20/2013-03/19/2014, your firm released [redacted] lots of sterile finished products using USP <71> for sterility testing performed by a contract laboratory. Your firm used bacteriostatic and fungistatic assay suitability testing documented for either other firm's products using the same formulation or using different formulations as the assay suitability confirmation for your products. Since 12/20/2013, the following lots have been released using the sterility testing suitability generated from different products:

1) Morphine Sulphate IVPB 1 mg/ml injectable, lot #1316124 (stock solution), lot #14060119 (finished product)
(Suitability test used a different formulation with additives)

2) Morphine Sulphate IVPB 1 mg/ml injectable, lot #1316124 (stock solution), lot #14140145 (finished product)
(Suitability test used a different formulation with additives)

3) Morphine Sulphate IVPB 1 mg/ml injectable, lot #14160119 (finished product)
(Suitability test used a different formulation with additives)

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4) Sodium Chloride PF Concentration 23.4% 30 mL, lot #: 14120266
(Suitability test used different company's product with the same formulation)

5) Sodium Chloride PF Concentration 23.4% 30 mL, lot #14180239
(Suitability test used different company's product with the same formulation)

6) Sodium Chloride PF Concentration 23.4% 30 mL, lot #14030259
(Suitability test used different company's product with the same formulation)

7) Glycopyrolate 0.2 mg/ml- 2 ml vial, lot #14030233
(Suitability test used different company's product with the same formulation)

OBSERVATION 6

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

A 100% visual or automated inspection of sterile finished products is not documented by your firm. Furthermore, your firm has not established a visual inspection procedure and there is no documentation of visual inspection training qualification of the technicians performing the visual inspection of sterile finished products.

OBSERVATION 7

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

Specifically,
a) [redacted] (b) (4) is the only disinfectant used to clean and disinfect in the ISO 5 Class 100 Laminar flow hood. There is no sporicidal disinfectant used in the ISO 5 Class 100 laminar flow hoods used for sterile drug preparations.

b) On 3/18/14, a pharmacy technician was observed performing an inadequate disinfection of the ISO 5 Laminar flow hood used for aseptic processing of sterile drug products. The pharmacy technician was observed only wiping the table top work surface, ceiling and sides with a sterile wipe containing [redacted] (b) (4) disinfectant. There was no disinfection of the back surface of the laminar flow hood where stains were observed on the metal grid. Standard operating procedure S4, titled "Cleaning and Sanitization of Cleanrooms and Sterile Prep" version 7 section 7.6.1.3.6 effective 2/6/14 requires cleaning of the back metal grid.

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OBSERVATION 8

The labels for the drug products and drug product containers you produce do not contain information required by section 503B(a)(10)
Specifically,

1. The statements, "This is a compounded drug," "Not for resale," and Office use only" are not on your drug product labels. Labels for the following drug products either do not contain these statements or contain variations such as "This medication was compounded in our pharmacy for use by a licensed practitioner only," or "This compounded preparation may not be resold:"
   - ☐ Methylprednisolone/Lidocaine, 40 mg/1%/mL, 10 mL Multi-dose Vial
   - ☐ Atropine Inj PF "COMPOUND" 1ml vial 0.4mg/mL
   - ☐ Lincomycin/Lidocaine Hydrochloride, 300mg/1%/mL, 10mL Sterile Multi-dose Vial
   - ☐ Dexamethasone 4mg/mL, Dexamethasone Sodium Phosphate 120mg/30mL
   - ☐ Trace Elements-4, 10mL Multi-dose Vial

2. Your drug product container label(s) do not contain information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088
   For example:
   - ☐ Atropine sulfate 0.4 mg/mL Preservative Free, Single use 1 mL Vial

*** DATES OF INSPECTION:**
03/17/2014(Mon), 03/18/2014(Tue), 03/19/2014(Wed), 03/27/2014(Thu)

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