DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	8/9/2017-8/29/2017* FEI NUMBER 3010680515

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Garry Morefield, Ph.D. , Chief Operating Officer

FIRM NAME	STREET ADDRESS
US Specialty Formulations LLC	116 Research Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bethlehem, PA 18015-4731	503(b) 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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Clothing of personnel engaged in the manufacturing, processing and packing of drug products is not appropriate for the duties they perform.

Specifically,

(a) Gowning for aseptic operations are conducted in non-classified areas. The gowning area is not supplied with HEPA filtered air.

Personnel apply sterile gowns, hairnets, foot covers, face masks, and non-sterile gloves in the non-classified gowning area. If proceeding into classified areas, personnel apply sterile gloves in the non-classified area of La (b) (4) If proceeding to work in the ISO 7 area with the ISO 5 (b) (4) personnel apply sterile sleeve covers in the non-classified Lab (b) (4) area.

(b) An employee applying the metal crimping to stoppered vials of Pyridoxine (Lot # 01RJ1532A) in the (b) (4) (ISO 5) did not have their gown fully buttoned and their street clothes were exposed while working.

OBSERVATION 2

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
James M Mason, Investigator

X James M Mason
Investigator
Signed By: 2000408308
Date Signed: 8/29/2017

DATE ISSUED
8/29/2017

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

Specifically,

Your cleaning procedure has insufficient contact time for the use of (b) (4) cleaning agent.

Additionally, your written procedure titled "Cleaning of classified areas" (PR-0003, Version 3.0) is deficient in that it:

(a) does not include instructions for pre-cleaning
(b) does not state the that disinfectants used in ISO 5 areas are required to be sterile
(c) it does not state the recovery time required after the (b) (4) is opened for cleaning.

THIS IS A REPEAT OBSERVATION FROM THE PREVIOUS INSPECTION

OBSERVATION 3

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

The surfaces of the lower shelves on two metal tables, one located in the ISO 7 and one in ISO 8 area of the cleanroom, were observed to be visibly rusted.

The surface of these tables come in contact with processing materials, such as containers of product and equipment, as they proceed into the ISO 5 environment for aseptic processing operations.

OBSERVATION 4

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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,

You have not conducted testing of the preservative content or determined the effectiveness of the preservative in your Betamethasone Acetate 25mg in 10mL/Betamethasone Sodium Phosphate 40mg in 10mL sterile vials.

The following lot numbers of Betamethasone have been released:

Lot #	Size
01RJ1516A	(b) (4) vials
01RJ1524A	(b) (4) vials

THIS IS A REPEAT OBSERVATION BUT RELATED A DIFFERENT PRODUCT.

OBSERVATION 5

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

During inspection of the (b) (4) software (Version (b) (4) used to conduct assay testing with the (b) (4) the following was observed:

a. There was no login required for the computer operating system.
b. Raw data files with assay test results could be deleted in the Windows operating system.
c. The deletion of the raw data was not recorded in the system audit trail.

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d. Three different people, including lab personnel and the Head of Operations, has administrator level privileges in the software.

OBSERVATION 6

Laboratory records are deficient in that they do not include the signature of the second person reviewing the record for accuracy.

Specifically,

Testing conducted by the firm's in-house laboratory are not reviewed by a second person to review the records for accuracy.

OBSERVATION 7

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

The labels for some of your outsourcing facility's drug products do not include information required in section 503B(a)(10)(A).

Specifically,

1. The statement, "This is a compounded drug."
2. The dosage form and strength.
3. The statement of quantity or volume, as appropriate.
4. The inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

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Furthermore, the container for some of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(B).

Specifically,

1. The information to facilitate adverse event reporting (www.fda.gov/medwatch and 1–800–FDA–1088) is incorrectly stated.

Examples of drug products that do not include this information on the label and/or container:

- 10mL Sarracenia Purpurea for Injection (Sarapin)
- 50mL Sarracenia Purpurea for Injection (Sarapin)
- Pyrodoxine Hydrochloride 100 mg/mL
- Medroxyprogesterone 150 mg
- B complex plus Chromic Chloride 30mL Multi-Dose Vial
- Ethanol Injection 95%
- Sodium Phosphates Injection with 3mM Phosphorus/mL and 4mEq Sodium/mL

***DATES OF INSPECTION**

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8/09/2017(Wed),8/10/2017(Thu),8/11/2017(Fri),8/21/2017(Mon),8/22/2017(Tue),8/23/2017(Wed),8/29/2017(Tue)

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EMPLOYEE(S) SIGNATURE

James M Mason, Investigator

X James M Mason
Investigator
Signed By: 2000408308
Date Signed: 8/29/2017

DATE ISSUED
8/29/2017

U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Date: September 14, 2017

Garry Morefield, Ph.D.
US Specialty Formulations LLC
116 Research Dr
Bethlehem, PA 18015-4731

Subject: System Notification

Dear Garry Morefield, Ph.D.,

We are notifying you that due to a technical error related to a software update, the FDA Form 483 you received recently inadvertently included a sentence meant only for medical device firms. That statement says, "Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements."

This statement refers to quality system requirements applicable only to medical device establishments, but was inadvertently included on certain Form 483's issued to non-device establishments for a brief period of time. Please note that the statement has no bearing on the inspection observations themselves, which remain applicable as of the date that you were issued the Form FDA 483.

Should you have any questions, please send to AskORAIT@fda.hhs.gov.

Sincerely,

Lisa Creason
Director, Office of Information Systems Management
Office of Regulatory Affairs
Food and Drug Administration