DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	6/18/2019-7/23/2019*
	FEI NUMBER 3010680515

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kyle Y. Flanigan, CEO

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

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, processes used for the compounding and filling of any drug products produced by your firm have not been validated.

Drug products compounded and/or filled using non-validated processes include Betamethasone, Medroxy and Monsel's Paste.

OBSERVATION 2

Results of stability testing are not used in determining expiration dates.

Specifically,

a) Multivitamin lot 01RH0413A was retested after having been expired for 5 months and issued a new label with an additional 6 month expiration date.

Lot 01RH0413A was filled on April 13, 2016 and issued an expiration date of October 13, 2016. On February 21, 2017 the expired product was relabeled as lot 01RJ1506A and issued an expiration date of November 3, 2017. The relabeled lot was released on February 27, 2017.

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b) Expiration dating is not supported by stability data. For example:

- Lot 01RM1504A, Ethanol was labeled with a 2 year expiration; stability data for this drug product is only available for 18 months.
- Lot 01RM1514A, Monsel's Paste was labeled with a 3 year expiration; stability data for this drug product is only available for 18 months.
- Lot 01RK1507A, Pyridoxine was labeled with a 1 year expiration; stability data for this drug product is only available for 9 months.
- Lot 01RK1514A, Methylcobalamin was labeled with a 1 year expiration; stability data for this drug product is only available for 6 months.

OBSERVATION 3

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, release testing for Sarapin is limited to testing for nitrogen content, benzyl alcohol, bacterial endotoxins and sterility. There is no test to quantify the concentration of active pharmaceutical ingredient. Sarapin finished lot 01RM1502A was released on February 26, 2019 without a test to quantify active ingredient concentration.

OBSERVATION 4

Drug products failing to meet established specifications are not rejected.

Specifically, Lot 01RJ1522A(Strong Iodine Solution) and Lot 01RJ1534A(B-Complex w/ Chromic Chloride) were released after failing to meet established finished product specifications.

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Strong Iodine Solution has an established release specification of (b) (4) Iodine concentration. Lot 01RJ1522A contained 5.9% Iodine concentration. Release specifications for Iodine concentration were changed to (b) (4) and the lot was released on August 17, 2017.

B-Complex w/ Chromic Chloride has an established release specification of (b) (4) mg/mL Riboflavin and (b) (4) mg/mL Methylcobalamin. Lot 01RJ1534A contained 0.66 mg/mL Riboflavin and 0.42 mg/ML Methylcobalamin. The lot was released on November 2, 2017.

OBSERVATION 5

Written procedures for sampling and testing plans are not followed for each drug product.

Specifically, OOS retesting for Lot 01RK1517A did not conform with firm's OOS procedure when it invalidated an OOS result. Firm procedure requires the sample be retested (b)(4) times to confirm results. Lot 01RK1517A Betamethasone was retested one time and subsequently released on September 27, 2018.

OBSERVATION 6

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established and documented.

Specifically, test methods for the following finished product tests have not been validated:

- B-Complex – Chromic Chloride potency
- Betamethasone potency
- Medroxyprogesterone potency
- Methylcobalamin potency

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OBSERVATION 7

Procedures prescribing a system for reprocessing batches to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics are not written.

Specifically, your firm has no procedure for reworking products. Lot 01RK1523A, Betamethasone failed finished product testing for betamethasone acetate concentration and was reworked without a procedure or protocol. The lot was released on March 28, 2019.

The investigation into the failed batch did not evaluate the quality impact of the rework procedure.

OBSERVATION 8

GMP training is not conducted on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

Specifically, no GMP training has been provided since 2016. Your firm's training procedure does not require GMP training.

For example, John Issac, Executive Director of Quality performs batch review and release and has not received ongoing GMP training.

OBSERVATION 9

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.

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Specifically, there is no quality review of your firm's laboratory software audit trail. The unreviewed audit trail contained aborted analysis on 4/24/2019, 5/8/2019 and 6/4/2019. To date there has been no deviation opened to assess potential product impact.

OBSERVATION 10

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

Specifically, an employee formulating B-Complex (Lot 01RM1516A) extended their arms into the biological safety cabinet (ISO 5) beyond their sterile sleeve coverings.

OBSERVATION 11

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

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

A list of inactive ingredients identified by established name and the quantity or proportion of each ingredient. An example of your drug product label that does not contain this information is ethanol for injection 95% 67 mL MDV.

***DATES OF INSPECTION**

6/18/2019(Tue), 6/19/2019(Wed), 6/20/2019(Thu), 6/25/2019(Tue), 6/26/2019(Wed), 6/27/2019(Thu), 6/28/2019(Fri), 7/01/2019(Mon), 7/02/2019(Tue), 7/03/2019(Wed), 7/23/2019(Tue)

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