DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	06/23/2014 - 07/02/2014* FEI NUMBER 3003436217

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dennis E. Saadeh, Pharm D, President / Owner

FIRM NAME	STREET ADDRESS
South Coast Specialty Compounding, Inc.	9257 Research Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Irvine, CA 92618-4286	Producer of sterile drugs

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,

A. Active viable air monitoring is not performed in the ISO 5 hood each day during production of injectable drug products, instead viable air monitoring is currently performed (b) (4) according to the firm's procedure #6.5.0 titled "Environmental monitoring".

B. Environmental monitoring of the ISO 5 hood surfaces is not performed at the end of each day that a batch of sterile product is filled, instead surface monitoring is currently performed [redacted] (b) (4) according to the firm's procedure #6.5.0 titled "Environmental monitoring".

C. Microbiological monitoring of the filling technician's fingertips is not performed each day that a batch of sterile product is filled; instead fingertip monitoring is currently performed (b) (4) according to the firm's procedure #6.5.1 titled "Gloved Fingertip Sampling".

D. The firm's current environmental monitoring program does not include any non-viable particulate monitoring during filling of injectable drug products.

OBSERVATION 2

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

Specifically, the coverall and facemask worn in the clean room are not sterile. In addition the firm's procedure #2.5.0, titled "Clean Room Attire and Conduct" allows for the non-sterile gowns to be reused during the course of a day.

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OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically, the Aseptic Technique Personnel Validation which your firm uses to evaluate individual aseptic technique for sterile compounding operations is deficient in that:

A. The firm does not incubate all of the vials which are filled during the validation filling session. Only (b) (4) vials out of (b) (4) filled vials are incubated.

B. The validation does not represent the maximum amount of bulk product which can be aseptically filled during a filling operation. The firm's validation only requires (b) (4) to be aseptically filled into individual vials; however during routine operations a bulk product volume as large as (b) (4) is aseptically filled into individual vials.

C. The validation only requires (b) (4) ml of sterile (b) (4) to be filled into each (b) (4) ml vial, which does not ensure that all surfaces of the vial come into contact with the growth media.

D. The validation does not include a simulation of the loading of the lyophilizer which occurs in the ISO 7 buffer area of the cleanroom.

OBSERVATION 4

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

Specifically,

A. Suitability testing for the sterility test method, necessary to demonstrate that the product does not interfere with the test, has not been performed by the contract testing laboratory which conducts the release test. For example:

   i. Calcium chloride 100mg/ml Preservative Free Injectable was filled on 3/26/2014 and released on 4/9/2014. The firm does not have sterility test suitability data to support the test results obtained.

   ii. Zinc Sulfate Preservative Free Injection (Zinc 10mg/ml) Injectable was filled on 3/12/2014 and released on 3/31/2014. The firm does not have sterility test suitability data to support the test results obtained.

   iii. Inositol 50mg/ml Solution Injection was filled on 3/19/2014 and released on 4/4/2014. The firm does not have sterility test suitability data to support the test results obtained.

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B. The firm has not validated the (b) (4) [redacted] method used as an alternative to USP <71> "Sterility "Tests".

OBSERVATION 5

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

Specifically, stability studies are not performed to support beyond use dates (BUD) of lyophilized drug products. For example:

a. Human Chorionic Gonadotropin 5000 Units/Hydroxocobalamin 2500 mcg lyophilized powder for injection is given a BUD of 180 days.

b. Human Chorionic Gonadotropin 10,000 units/Hydroxocobalamin 5000 mcg lyophilized powder for injection is given a BUD of 180 days.

OBSERVATION 6

The written stability program for drug products does not include test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability.

Specifically,

A. Stability testing performed on injectable drug products does not include sterility at the end of the shelf life, for example:

a. The (b) (4) [redacted] month stability study for Ascorbic Acid Preservative Free Injection 500mg/ml only includes potency.

b. The (b) (4) [redacted] month stability study for Inositol 50mg/ml Injection (multiple dose vial) only includes potency.

B. The (b) (4) [redacted] month stability study for Inositol 50mg/ml Injection in a 30 ml Multiple Dose Vial (preserved with benzalkonium chloride 5%) does not include data to demonstrate that the preservative is effective at the time of release or that it retains antimicrobial effectiveness over the shelf life of the product.

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OBSERVATION 7

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

Specifically, disinfectants and sanitizers used to clean ISO 7 areas of the facility such as the mixing room and the buffer room are not rendered sterile prior to use.

*** DATES OF INSPECTION:**
06/23/2014(Mon), 06/24/2014(Tue), 07/02/2014(Wed)

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