DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	10/20/2014 - 11/10/2014* FEI NUMBER 3005180755

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dr. Rickey L. Chance, Owner

FIRM NAME	STREET ADDRESS
Coastal Meds, LLC.	1759 Medical Park Drive, Suite C
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Biloxi, MS 39532	Producers of Sterile Drug Products

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 I OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A) the firm has not performed any smoke studies to determine airflow patterns in the clean room where aspectic processing occurs and the firm has no LAFH.
B) the firm does not monitor viable microbiological contamination in the firm's clean room during processing.
C) the firm does not monitor non-viable particulates in the firm's clean room during processing.
D) the firm does not measure microbial contamination on product work surfaces during processing
E) the firm does not monitor personnel for microbial contamination during processing.
F) the firm does not monitor the pressure differential between the clean room/ante room and unclassified areas during processing.

OBSERVATION 2

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

Specifically,

A) The firm has not validated the sterilization process (b) (4)) for (b) (4) sterilized products and closures.

B) The depyrogenation process (b) (4)) for glass vials and other processing glassware has not been validated.

C) The firm does not perform media fills for aseptically filled products.

D) (b) (4) aspectic processed injectable drug products are not (b) (4) (b) (4) after use by the firm.

E) Drug products that are to be (b) (4) sterilized by the firm's (b) (4) are processed (compounded and

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filled/sealed in vials) in an unclassified room.

OBSERVATION 3

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, approximately (b)(4) lots of finished injectable drug products processed by the firm since 01/2014 failed finished product specifications (high and low potency test results). These lots were released/distributed by the firm. No investigations were performed by the firm for these failing test results.

For example:

A) The testing result for Lipo-Plex Lot #LP/020414 for the active ingredient Cyanocobalamin was 145.0% and the firm's specification is (b) (4)

B) The testing result for Lipo-Den Lot #LD/020714 for the active ingredient Cyanocobalamin was 137.3% and the firm's specification is (b) (4)

C) The testing result for Methylcobalamin Lot #MC/022814 for the active ingredient Methylcobalamin was 75.6% and the firm's specification (b) (4)

In addition, the firm has had several complaints regarding discoloration of drug products and one with an adverse drug event. No investigations /follow-ups were performed by the firm regarding these complaints.

OBSERVATION 4

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

Specifically, the sterility and endotoxin testing is not performed per USP 71 and USP 85, respectively.

OBSERVATION 5

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, the firm's finished injectable drug products all bear a one year expiration date. The potency/sterility of drug products at expiration are not supported by stability indicating testing data.

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OBSERVATION 6

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, the firm has no written stability protocols for finished drug products and no lots of drug products have been tested for stability.

OBSERVATION 7

Separate or defined areas to prevent contamination or mix-ups are deficient regarding the packaging and labeling operations.

Specifically, on 10/20/2014 I observed a plastic tote that contained filled/sealed unlabeled vials with no type of identification of the product contained in the vials. On 10/21/2014, I observed that the firm had properly labeled this tote.

OBSERVATION 8

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, the firm has not established any time limits for the completion of each processing phase. For example, during this inspection I observed a bulk batch of the injectable drug product Lipo-Den Plus being stored in the firm's clean room. This product was obsevered for (b) (4) days in this bulk form.

OBSERVATION 9

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically, on 10/20/14, I observed the sink located in the firm's ante room to be used for trash storage. There is no trash receptacle in this room.

*** DATES OF INSPECTION:**
10/20/2014(Mon), 10/21/2014(Tue), 10/22/2014(Wed), 10/23/2014(Thu), 11/10/2014(Mon)

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