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<br>Nashville, TN 37217-2597<br>(615) 366-7801 Fax:(615) 366-7802<br>Industry Information: www.fda.gov/oc/industry | 09/15/2015 - 09/23/2015*<br>FEI NUMBER<br>3005180755 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dr. Rickey L. Chance, President/Owner

| FIRM NAME | STREET ADDRESS |
|---|---|
| Coastal Meds, LLC. | 1759 Medical Park Dr., Suite C |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Biloxi, MS 39532-2154 | 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 I OBSERVED:

## OBSERVATION 1

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

Specifically,

a) Surface and air monitoring is not performed of the ISO 5 environment (room and laminar flow hood) each day sterile drug products are produced. As stated in your procedure, 1114-02, Air and Surface Sampling, "Air sampling for viable" and non-viable "organisms (bacterial and fungal) shall be performed on a (b) (4) basis".

b) Pressure differentials are not monitored between the ante room (ISO 7) and the clean room (ISO 5) and between the ante room (ISO 7) and the non-classified area due to the absence of pressure gauges. Your procedure, 1114-04, Cleanroom and Anteroom Activities and Specifications, states "(b) (4)
(b) (4)

c) There is no evidence to show airflow has constant pressure in the ante room with sink located just outside the clean room (ISO 5).

d) Certification of the ISO 5 environment does not occur under dynamic conditions.

e) I observed air gaps of approximately 1" at bottom of doors to the ante room and from the ante room to ISO 5 room.

***THIS IS A REPEATED OBSERVATION.***

## OBSERVATION 2

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

Specifically, employees were observed to wear non-sterile lab coats (not full gown/bunny suit), masks, head covers and booties while producing sterile drug products. Clothing used does not cover neck or forehead of employee during aseptic operations. In addition, an employee was observed not wearing a beard cover during the production of sterile drug products on September 15, 2015.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Claire M. Minden, Investigator Claire M. Minden | 09/23/2015 |

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## OBSERVATION 3

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

Specifically,

a) Media fills do not simulate actual production quantities. Currently, your media fills and written procedure, 0415-01 only requires (b) (4) .

b) I also observed personnel engaged in operations in the aseptic processing area on September 15, 2015 reach over filled pre-stoppered vials to fill other vials behind the filled pre-stoppered vials. The sleeve of the non-sterile gown would touch the top of filled pre-stoppered vials during this process.

c) Filled pre-stoppered vials are not sealed in a classified area immediately after filling. (b) (4) batches of filled pre-stoppered vials remained in plastic totes unsealed and unlabeled for up to (b) (4) in an area not monitored for temperature or humidity.

## OBSERVATION 4

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

Specifically,

a) You use non-sterile wipes to clean the ISO 5 equipment, laminar flow hood and room (b) (4)

b) You have not performed disinfectant effectiveness testing.

c) Your procedure, C1, does not include contact times and a schedule of cleaning.

## 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, you assign a one year "Discard by" date on all of your products. This date was determined after analyzing for sterility on (b) (4) at the "Discard by" date and lacked potency and stability data. You have no written stability program for determining the beyond-use-date of one year you assign.

***THIS IS A REPEATED OBSERVATION.***

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## OBSERVATION 6

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,

a) You did not conduct an investigation into lot LE/050815 of Lipo-Den Extreme when the potency results indicated two ingredients did not meet your potency specification of (b) (4)%. This lot was released and distributed by the firm.

b) Your investigation did not extend to other batches of the same drug products for the sterility test failures of lot LP/081015 for Lipo-Plex and lot LE/081315 for Lipo-Den Extreme.

c) You did not follow your procedure, 1114-06, Out-of Specification-investigations that states, "If any of the initial test values fall outside the pre-established specifications, a Laboratory Investigation must be initiated and documented".

***THIS IS A REPEATED OBSERVATION.***

## OBSERVATION 7

There is a lack of written procedures describing in sufficient detail the receipt, identification, storage, and examination of labeling and packaging materials.

Specifically, you do not have a written procedure that explains the receipt, identification, storage and examination of finished product labels prior to use nor do you document the examination of labels against a label proof to verify the accuracy of the label.

## OBSERVATION 8

Complaint procedures are deficient in that they do not include provisions that allow for the review to determine if the complaints represent serious and unexpected adverse drug experiences which are required to be reported to FDA.

Specifically, your complaint or recall procedures do not include directions for defining an adverse event or serious adverse event or what steps you will take if a complaint involves an adverse event.

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**OBSERVATION 9**

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

Specifically,
The following information is not found on some of your drug product labels, as required by section 503B(a)(10)(A):

1. The statement, "This is a compounded drug."
2. The full address of the outsourcing facility.
3. The dosage form of the product.
4. The statement, "Not for resale," and if the drug is dispensed or distributed other than pursuant to a prescription for an individual patient, the statement, "Office Use Only."

The following information is not found on or in the containers for some drug products you produce, as described in section 503B(a)(10)(B):

1. Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088 <http://www.fda.gov/medwatch%20and%201-800-FDA-1088>:

Examples of drug product labels that do not contain this information include:
Lipo-Den Extreme 30mL, Pyridoxine 100 mg/mL, Lipo-Plex 30mL, Lipo-B 30 mL, Lipo-Den Plus 30 mL, Cyanocobalamin 1000 mcg/mL in 30 mL, Methylcobalamin 30 mL, Lipo-Den 30 mL, Hydroxocobalamin 30 mL, Lipo-Den Max 30 mL, Rodex 30 mL, Adeno-Plex 30 mL, Methyl-Plex 30 mL

**OBSERVATION 10**

Your outsourcing facility has not submitted product reports to FDA as required by section 503B(b)(2)(A).

*** DATES OF INSPECTION:**
09/15/2015(Tue), 09/16/2015(Wed), 09/17/2015(Thu), 09/23/2015(Wed)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Claire M. Minden, Investigator *Claire M. Minden* | 09/23/2015 |

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."