DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Pharma Division II 404 BNA Drive, Building 200, Suite 500 Nashville, TN 37217 (615) 366-7801 | Email: orapharm2_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	03/12/2018-04/06/2018* FEI NUMBER 3005180755

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dr. Rickey L. Chance, President & Owner	
FIRM NAME Coastal Meds, LLC	STREET ADDRESS 1759 Medical Park Drive, Suite C
CITY, STATE, ZIP CODE, COUNTRY Biloxi, MS 39532	TYPE ESTABLISHMENT INSPECTED 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) (WE) OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Specifically, environmental monitoring (EM) samples are not taken in high-risk areas or so that they represent the conditions of the areas being monitored. For example:

a. The material pass-through box, which is used to transfer materials between the uncontrolled dispensing room and the ISO 7 cleanroom, is not monitored on any frequency.

b. Fingertip samples are taken (b) (4) the pharmacist (b) (4) with sterile (b) (4) The sample is also limited to (b) (4) on his (b) (4)

c. The surface sample taken from the (b) (4) located in the ISO 7 cleanroom, is performed after the (b) (4) has been sanitized with sterile (b) (4)

d. On 3/13/2018, I noted the surface sample taken from surface of the (b) (4) (b) (4) was done in an area still wet with sterile (b) (4)

e. Pressure differential data is not reviewed. It is recorded on a (b) (4) and when anomalies occur. Data is uploaded (b) (4) and printed. The electronic files are not saved and there is no review of the data. As a result, there have been no explanations for or investigations into pressure loss. For example, the following pressure differential excursions were recorded on 12/5/2017:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Samantha J. Bradley	Samantha J. Bradley, Drug Investigator	4/6/2018

ISO 7 Ante Room to General Area

Specification: (b) (4)

Time	Pressure (in-wg)
(b) (4)	0.062
	0.004
	0.008
	0.010
	0.026
	0.064
	0.014
	0.008
	0.025
	0.036
	0.005
	0.028
	0.065

ISO 7 Cleanroom to ISO 7 Ante Room

Specification (b) (4)

Time	Pressure (in-wg)
(b) (4)	0.026
	0.002
	0.002
	0.011
	0.02

METHYLCOBALAMIN, Lot MC/120517, was produced the same day and later distributed. There is no explanation for or investigation into this series of events.

OBSERVATION 2

Protective apparel is not worn as necessary to protect drug products from contamination. Specifically, on 3/13/2018, I observed the aseptic attire worn in the cleanroom does not include goggles, which leaves the skin of personnel exposed around their eyes and forehead.

THIS IS A REPEATED OBSERVATION

OBSERVATION 3

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

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Specifically, the pressure gauges used to monitor the differentials between the cleanroom, ante room, and uncontrolled areas, are not calibrated.

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity. Specifically,

a. Visual examination of finished products is not performed under appropriate conditions to identify potential quality issues with injectable drug products. Per SOP O-16, Rev. 0, Testing and Release Criteria, effective 12/30/2016, visual inspectors should look for fill volume, particulate matter (PM), container seal/closure, or any other defect. It states PM should be identified using a contrasting background illuminated with (b) (4) lights or brighter.

   Visual inspectors are not provided with a contrasting background and sufficient light for inspection. All products are packaged in amber vials and numerous products are light to dark red in color. On 3/13/2018, inspectors were not observed holding vials up to the ceiling lights, the only light source available, during their visual inspection. There is no assurance quality defects are identified during visual inspection of injectable drug products.

b. Finished product release testing does not include (b) (4) content, the preservative used in all injectable drug products.

OBSERVATION 5

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

a. Pharmaceutical grade, sterilizing (b) (4) are (b) (4) after use via a (b) (4) that is not in compliance with the manufacturer's test method and has not been independently validated.

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Per SOP O-14, Rev. 0, Validation of Sterilization Methods, effective 12/30/2016, the used (b) (4) s (b) (4) to a (b) (4) and (b) (4) to (b) (4) of (b) (4) The (b) (4) is reached when (b) (4)

Per the manufacturer, the used (b) (4) must (b) (4) prior to obtaining the (b) (4) There is no assurance the sterilizing (b) (4) results are passing.

b. Media fill records lack significant information. There is no record of media preparation, the materials used (including the vials, tubing, and sterilizing (b) (4) the filling process followed, or the number of vials placed in the incubators. In the most recent revision of the media fill record, there is no record of the number of vials which were filled.

OBSERVATION 6

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning. Specifically, the materials used for equipment within the ISO 7 cleanroom are not appropriate for the cleaning solutions being used. On 3/13/2018, I observed rust on several HEPA return grates, the ante room door handle, and door frame.

OBSERVATION 7

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 already been distributed.

Specifically, since 9/24/2015, there have been at least 23 batches found to have potency failures and 13 found to have sterility failures. Each batch was rejected, but investigations lack significant information and do not extend to other similar batches. The QRE (quality related event) investigation forms were initiated beginning in 2017 and each event was classified as "Minor".

For potency failures, thirteen (13) out of the 23 were presumed to be due to weighing errors. The others had potential root causes of incomplete dissolution, light exposure, or none listed. No evidence was provided in any case to support the conclusions. METHYL-PLEX was discontinued due to potency failures for three (3) consecutive batches in 2018. No other product formulation incompatibilities were considered during the investigations.

For sterility failures, each investigation concludes aseptic technique should be followed and hand hygiene sampling was performed. Organisms were identified in seven (7) out of the 13 events and *Bacillus circulans* was identified as the organism in four (4) out of the seven (7) events. Documentation was not reviewed, environmental conditions were not reviewed, EM sampling results were not reviewed, the identified organisms were not evaluated, and these events did not trigger cleaning.

In all investigations, there is a lack of historical review, trend analysis, extension to other batches, a statement regarding product disposition, and overall quality impact assessment.

THIS IS A REPEATED OBSERVATION

OBSERVATION 8

Each lot of drug product containers and closures is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically, sterile, depyrogenated drug product containers and closures are accepted after confirming they match the purchase order, without requiring sampling, testing, examination, or release. There is no specification for the containers and closures; there is no requirement to obtain and review the manufacturer certificate of analysis (COA) for each batch received.

OBSERVATION 9

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, stability studies have not been initiated for all injectable drug products to support their 6-month (180-day) expiration date. Since 9/24/2015, the following products have been made and distributed without stability studies being initiated/performed:

- ADENO-PLEX
- HYDROXOCOBALAMIN
- L-CARNITINE
- LIPO-DEN EXTREME

- LIPO-DEN MAX
- LIPO-DEN PLUS
- LIPO-PLEX
- LIPO-X
- METHYLCOBALAMIN
- METHYL-PLEX
- PYRIDOXINE
- RODEX

THIS IS A REPEATED OBSERVATION

OBSERVATION 10

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

Specifically, critical equipment has not been qualified for use. Incubators and refrigerators are lacking temperature mapping studies and are not monitored using calibrated thermometers. These include a refrigerator used for media storage, a refrigerator used for bulk drug substance storage, and (b) (4) incubators used for EM sample and media fill vial incubation.

OBSERVATION 11

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

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):

- The dosage strength;
- The statement, "Not for resale".

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In addition, the following information is not found on your drug product container labels, as described in section 503B(a)(10)(B):

- Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088
  Examples of drug product labels that do not contain this information:
  - Adeno-Plex Injectable 30 ml
  - Cyanocobalamin injectable 30 ml
  - Hydroxocobalamin injectable 30 ml MDV
  - Lipo-B injectable 30 ml
  - Lipo-Den injectable 30 ml MDV
  - Lipo-Den Extreme injectable 30 ml MDV
  - Lipo-Den Plus injectable 30 ml MDV
  - Lipo-Plex injectable 30 ml MDV
  - Methylcobalamin injectable 30 ml MDV
  - Pyridoxine injectable 30 ml MDV

***DATES OF INSPECTION:**

03/12/2018 (Mon), 03/13/2018 (Tue), 03/14/2018 (Wed), 03/15/2018 (Thu), 03/16/2018 (Fri), 03/19/2018 (Mon), 04/06/2018 (Fri)

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