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Nashville, TN 37217-2597 Tended (615) 366-7801 Fax: (1613) 366-7802 3005180755 Industry Information: www.fda.gov/oc/industry 3005180755 TO: Dr. Rickey L. Chance, President/Owner Tendes Coastal Meds, LLC. Information This Decount weight services Trips Medical Park Dr., Suite C What Medication Information Biloxi, MS 39532-2154 Outsourcing Facility This document liss observations, and by the FDA representative(s) during the inspection of your facility. They are inspection or south facility. They are inspection or south facility of the information regarding your compliace. If you have and becieve any questions, place context FDA at the phone number and address above. DURNG AN INSPECTION OF YOUR HIRM I OBSERVED: OBSERVATION 1 Asceptic 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 bod) each day strile and anon-viabk "organisms (bacterial and funga) shall be performed on (D(4) basis". Pressure differentiats are notuced. As stated in your procedure, 1114-02, Air and Surface Sampling. "Air sampling for viable" and anon-viabk "organisms (bacterial and funga) shall be performed on (D(4) basis". 9 Pressure differentiats are notuced. As stated in your procedure, 1114-02, Air and Surface Sampling. "Air sampling for viable" and anon-viabk "organisms (bacterial and funga) shall be	C REACTOR ARTERNATE TIME			an contra Blanco or contra a c	(2025)	
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SEE REVERSE Claire M. Minden, Investigator Claire M. Munden 09/23/2015 OF THIS PAGE	on September 15, 2015.					
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ORM FDA 453 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 OF 4 PAGES	SEE REVERSE OF THIS PAGE		tor Cla	ive M. Menden		
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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	09/15/2015 - 09/23/2015*			
Nashville, TN 37217-2597	FEINUMBER			
(615) 366-7801 Fax: (615) 366-7802	3005180755			
Industry Information: www.fda.gov/oc/indu	astry			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED				
TO: Dr. Rickey L. Chance, President/Owned	er			
FIRM NAME	STREET ADDRESS			
Coastal Meds, LLC.	1759 Medical Park Dr., Suite C			
CITY, STATE, ZF CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED			
Biloxi, MS 39532-2154	Outsourcing Facility			

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 arc	a not monitored for
	temperature or humidity.		

OBSERVATION 4

A septic 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.

~	SEE REVERSE OF THIS PAGE	EMPLOYEE(B)SKRATURE Claire M. Minden,	Investigator	Стт	041E ISSUED 09/23/2015
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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500	09/15/2015 - 09/23/2015*
Nashville, TN 37217-2597	FEIMER
(615) 366-7801 Fax: (615) 366-7802	3005180755
Industry Information: www.fda.gov/oc/indu	lstry
NAME AND TITLE OF INDIVIDUAL TO VALOM REPORT ISSUED	
TO: Dr. Rickey L. Chance, President/Owne	
FIRM MADE	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

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 404 BNA Dr., Bldg. 200, Ste. 500	09/15/2015 - 09/23/201				
Nashville, TN 37217-2597	FEINUMBER	<u>a</u> ^			
(615) 366-7801 Fax: (615) 366-7802 Industry Information: www.fda.gov/oc/inc	dustry 3005180755				
Industry Information: www.fda.gov/oc/ind					
TO: Dr. Rickey L. Chance, President/Own	STREET ADDRESS				
Coastal Meds, LLC.	1759 Medical Park Dr., Suite C				
Biloxi, MS 39532-2154	Outsourcing Facility				
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."					
 The dosage form of the product. The statement, "Not for resale," and if the drug is a 	이상에 상황하는 것 같아요. 이상 것 같아요. 이상 가장 이상 가장 이상 가장 수 있는 것 같아요. 이상 이상 수 있는 것 같아요. 이상 가장 가지 않는 것 같아요. 이상 집 이상				
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): I. Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088 www.fda.gov/medwatch and 1-800-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)					
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OF THIS PAGE	09/	23/2015			
FORM FDA 483 (09/03) PREVIOUS EDITION OBSOLETS: [NS]	PECTIONAL OBSERVATIONS PAGE	JE 4 OF 4 PAGES			

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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."