BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

COASTAL MEDS LLC; RICKEY CHANCE, MEMBER/PIC, Respondent

Non-Resident Pharmacy Permit No. NRP 1028, and Non-Resident Sterile Compounding Permit No. NSC 99598

Agency Case No. 6530

DECISION AND ORDER

The attached Stipulated Surrender of License Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 26, 2020.

It is so ORDERED on February 25, 2020.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

Greg Lippe
Board President

XAVIER BECERRA
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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against**:** **COASTAL MEDS LLC;** **RICHEY CHANCE, MEMBER/PIC** **1759 Medical Park Dr., Ste. C** **Biloxi, MS 39532** **Non-Resident Pharmacy Permit No. NRP 1028** **Non-Resident Sterile Compounding Permit No. NSC 99598** Respondent.	Case No. 6530 **STIPULATED SURRENDER OF PERMITS AND ORDER**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Interim Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Daniel D. McGee, Deputy Attorney General.

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2. Coastal Meds LLC (Respondent) is represented in this proceeding by attorney Ashli Summer McKeivier (California State Bar No. #230605), whose address is: Chapman Law Group, 1441 W. Long Lake Drive, Suite 310, Troy, MI 48098-4776.

3. On or about May 19, 2010, the Board issued Non-Resident Pharmacy Permit No. NRP 1028 to Coastal Meds LLC to do business as Coastal Meds LLC (Respondent) with Richey Chance as member and pharmacist-in-charge (PIC). The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in the Accusation, expired on May 1, 2018, and has not been renewed.

4. On or about June 1, 2010, the Board issued Non-Resident Sterile Compounding Permit No. NSC 99598 to Respondent. The Non-Resident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in the Accusation, expired on May 1, 2018, and has not been renewed.

JURISDICTION

5. Accusation No. 6530 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on August 7, 2019. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 6530 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6530. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of Permits and Order.

7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against it; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other

rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent admits the truth of each and every charge and allegation in Accusation No. 6530, agrees that cause exists for discipline, and hereby surrenders both its Non-Resident Pharmacy Permit No. NRP 1028 and Non-Resident Sterile Compounding Permit No. NSC 99598 for the Board's formal acceptance.

10. Respondent understands that by signing this stipulation, Respondent enables the Board to issue an order accepting the surrender of its Non-Resident Pharmacy Permit No. NRP 1028 and Non-Resident Sterile Compounding Permit No. NSC 99598 without further process.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board. Respondent understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender of License and Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of Permits and Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Surrender of Permits and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Surrender of Permits and Order

may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

ORDER

IT IS HEREBY ORDERED that Non-Resident Pharmacy Permit No. NRP 1028 and Non-Resident Sterile Compounding Permit No. NSC 99598, each of which are issued to Respondent Coastal Meds LLC, are surrendered and accepted by the Board.

1. The surrender of Respondent's Non-Resident Pharmacy Permit No. NRP 1028 and Non-Resident Sterile Compounding Permit No. NSC 99598, and the acceptance of the surrendered permits by the Board, shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

2. Respondent shall lose all rights and privileges as a Non-Resident Pharmacy and a Non-Resident Sterile Compounding Company in California as of the effective date of the Board's Decision and Order.

3. Respondent shall cause to be delivered to the Board its Non-Resident Pharmacy Permit No. NRP 1028 and Non-Resident Sterile Compounding Permit No. NSC 99598 pocket licenses and, if any were issued, its wall certificates on or before the effective date of the Decision and Order.

4. If Respondent ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure or permit. Respondent must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Accusation No. 6530 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.

5. Respondent shall pay the agency its costs of investigation and enforcement in the amount of $10,003.75 prior to issuance of any new or reinstated license or permit.

6. Pursuant to Business and Professions Code section 4307, any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license or permit has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license or permit was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee. Where, as here, the license (permit) is revoked, this prohibition shall continue until the license (permit) is reinstated. Respondent acknowledges that Richey Chance, while serving as a member of and pharmacist-in-charge for Respondent, had knowledge of or participated in the acts or omissions set forth in Accusation No. 6530. Therefore, pursuant to Business and Professions Code section 4307, Respondent Costal Meds LLC and Richey Chance shall both be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any licensee of this Board.

7. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation No. 6530 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

8. Respondent shall not apply for licensure or permit, or petition for reinstatement, for at least three (3) years from the effective date of the Board's Decision and Order.

ACCEPTANCE

I am a Member of and Pharmacist-In-Charge for the Respondent herein, Coastal Meds LLC (Respondent). I have full authority to act on behalf of and legally bind Respondent. I have

carefully read the above Stipulated Surrender of Permits and Order and have fully discussed it with Respondent's attorney, Ashli Summer McKeivier. I understand the stipulation and the effect it will have on Respondent's Non-Resident Pharmacy Permit No. NRP 1028 and Non-Resident Sterile Compounding Permit No. NSC 99598. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree that Respondent shall be bound by the Decision and Order of the Board of Pharmacy.

DATED: 1/2/2020

RICKEY CHANCE
MEMBER/PHARMACIST-IN-CHARGE
OF COASTAL MEDS LLC
Respondent

I have read and fully discussed with Rickey Chance, Member/Pharmacist-In-Charge for Respondent Coastal Meds LLC, the terms and conditions and other matters contained in the above Stipulated Surrender of Permits and Order. I approve its form and content.

DATED: 1/2/2020

ASHLI SUMMER MCKEIVIER
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Surrender of Permits and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 1/6/2020

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General

DANIEL D. MCGEE
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 6530

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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against**:** **COASTAL MEDS LLC;** **RICHEY CHANCE, MEMBER/PIC** **1759 Medical Park Dr., Ste. C** **Biloxi, MS 39532** **Non-Resident Pharmacy Permit No. NRP 1028** **Non-Resident Sterile Compounding Permit No. NSC 99598** Respondent.	Case No. 6530 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Interim Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

2. On or about May 19, 2010, the Board of Pharmacy issued Original Non-Resident Pharmacy Permit Number NRP 1028 to Coastal Meds LLC to do business as Coastal Meds LLC (Respondent), with Richey Chance as member and pharmacist-in-charge (PIC). The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in the Accusation and expired on May 1, 2018, and has not been renewed.

3. On or about June 1, 2010, the Board of Pharmacy issued Original Non-Resident Sterile Compounding Permit Number NSC 99598 to Respondent. The Non-Resident Sterile Compounding permit was in full force and effect at all times relevant to the charges brought in the Accusation; however, it expired on May 1, 2018, and has not been renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board) under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Code section 4300 states, in pertinent part:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper . . .

6. Code section 4300.1 states:

> The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY AND REGULATORY PROVISIONS

7. Code section 4022 states, in pertinent part:

> "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes any of the following:
>
> (a) Any drug that bears the legend: "Caution: federal law prohibits

dispensing without prescription," "Rx only", or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

8. Code section 4301 states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

(j) The violation of any of the statutes of this state, of any other state, or of the United Sates regulating controlled substances and dangerous drugs.

. . . .

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency . . .

9. Code section 4307 (a) states in pertinent part:

Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

.....

10. Health & Safety Code section 111250 states:

Any drug or device is adulterated if it consists in whole or in part, of any filthy, putrid, or decomposed substance.

11. Health & Safety Code section 111300 states:

It is unlawful for any person to adulterate any drug or device.

12. Health & Safety Code section 111330 states:

Any drug or device is misbranded if its labeling is false or misleading in any particular.

13. California Code of Regulations, title 16, section 1735.2, states in pertinent part:

(d) No pharmacy or pharmacist shall compound a drug preparation that:

. . . .

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

. . . .

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

. . . .

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test;
(B) Container Closure Integrity Test; and
(C) Stability Studies.

. . . .

14. California Code of Regulations, title 16, section 1735.3 states, in pertinent part:

(a) For each compounded drug preparation, pharmacy records shall include:

. . .

(2) A compounding log consisting of a single document containing all of the following:

(A) Name and strength of the compounded drug preparation.

(B) The date the drug preparation was compounded.

(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

(D) The identity of the pharmacist reviewing the final drug preparation.

(E) The quantity of each ingredient used in compounding the drug preparation.

(F) The manufacturer, expiration date and lot number of each component….

(G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation.

(H) The beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

(I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

. . .

COST RECOVERY

15. Code section 125.3 provides, in pertinent part, that a Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

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DRUG CLASSIFICATIONS

16. *Cyanocobalamin* is a man-made form of vitamin B12 and is indicated for the treatment of vitamin B12 deficiencies in persons with pernicious anemia, and dietary deficiencies due to malabsorption diseases. It is a dangerous drug pursuant to Code section 4022.

17. *Hydroxocobalamin* is a man-made form of vitamin B12 and is indicated for the treatment of vitamin B12 deficiencies in persons with pernicious anemia, and for the treatment of cyanide poisoning. It is a dangerous drug pursuant to Code section 4022.

18. *Lipo-B* is a mixture of three amino acids (Choline, Methione, and Inositol) that is indicated for weight loss. It is a dangerous drug pursuant to Code section 4022.

19. *Lipo-Den* is a supplement indicated for the enhancement of liver function to speed up weight loss. It is a dangerous drug pursuant to Code section 4022.

20. *Lipo-Den Plus* is a mixture of lipotropics and is indicated for weight loss. It is a dangerous drug pursuant to Code section 4022.

21. *Lipo-Plex* is a combination of Vitamin B-12 and lipotropics and is indicated for weight loss. It is a dangerous drug pursuant to Code section 4022.

22. *Methylcobalamin* is a form of Vitamin B-12 and is indicated for the treatment of anemia and some nutritional diseases. It is a dangerous drug pursuant to Code section 4022.

23. *Pyridoxine* is a water soluble form of Vitamin B-6 and is indicated for the treatment of certain nerve disorders caused by certain medications and for the treatment of anemia. It is a dangerous drug pursuant to Code section 4022.

FACTUAL ALLEGATIONS

24. On April 13, 2018, the Food and Drug Administration (FDA) notified the public that Respondent recalled all products marketed as sterile.

25. From March 12, 2018 to April 6, 2018, FDA conducted an inspection at Respondent and on April 6, 2018, issued a "Notice of Inspectional Observations" (form 483). Inspector CA received records for the following recalled products shipped into California:

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Drug	Lot Number	Discontinued by date	Qty Produced	Qty Shipped	Qty of Vials In-House	Qty Returned
CYANOCOBALAMIN	CAC/020518	4/06/18	203	156	47	1
CYANOCOBALAMIN	CAC/021418	4/15/18	184	184		2
HYDROXOCOBALAMIN	CAH/021218	4/13/18	94	71	23	9
LIPO-B	CALB/021218	4/13/18	236	236		15
LIPO-DEN	CALD/020518	4/06/18	141	141		1
LIPO-DEN	CALD/021418	4/15/18	178	177	1	19
LIPO-DEN PLUS	CALDP/021518	4/16/18	250	139	111	13
LIPO-PLEX	CALP/021218	4/13/18	150	150		24
METHYLCOBALAMIN	CAMC/021518	4/16/18	179	79	100	10
PYRIDOXINE	CAP/020518	4/06/18	141	141		12
PYRIDOXINE	CAP/021418	4/15/18	150	150		7
PYRIDOXINE	CAP/021918	4/20/18	150	18	132	3
TOTALS			**2,056**	**1,642**	**414**	**116**

26. On June 14, 2018, Inspector CA received the compounding log, master formula, and end product testing (QA tests) for the following dangerous drugs, and noted that the compounding logs were illegible:

Drug	Lot Number	Date Compounded	Amount Made	Beyond Use Date[1] assigned	Sterility Release Date[2]
CYANOCOBALAMIN 1000mcg/ml	CAC/020518	2/05/18	6,500ml 200x30ml	4/06/18	2/20/18
HYDROXOCOBALAMIN 1mg/ml	CAH/020218	2/12/18	3,500ml 100x30ml	4/13/16	2/28/18
LIPO-B	CALB/021218	2/12/18	8,500ml 275x30ml	4/13/18	2/28/18

[1] A "Beyond Use Date" ("BUD") is the date after which a compounded medication should be discarded.

[2] A "Sterility Release Date" is the date the pharmacy determined the product was sterile and could be sold/furnished.

LIPO-DEN	CALD/020518 CALD/020418	2/05/18 2/04/18	5,000ml 150x30ml 6,500ml 200x30ml	4/06/18 4/15/18	2/20/18 3/01/18
LIPO-DEN PLUS	CALDP/021518	2/15/18	8,500ml 275x30ml	4/16/18	3/02/18
LIPO-PLEX	CALP/021218	2/12/18	5,500ml 175x30ml	4/13/18	2/28/18
METHYLCOBALAMIN 5mg/ml	CAMC/021518	2/15/18	6,2500ml 200x30mlS Hard to read. May be 6.25L and 50ml vials	4/16/18	3/02/18
PYRIDOXINE 100mg/ml	CAP/020518 CAP/021418 CAP/021918	2/05/18 2/14/18 2/19/18	5,000ml 150x30ml 5,000ml 175x30ml 5,000ml 150x30ml	4/06/18 4/15/18 4/20/18	2/20/18 3/01/18 3/06/18

27. During the investigation, Respondent did not produce any documents to show cyanocobalamin 1000mcg/ml was not commercially available during the compounding and at each dispensing.

28. Inspector CA did not find any current drug shortage of cyanocobalamin in searching the following websites:

- FDA's therapeutic equivalence search for cyanocobalamin, the orange book, and found at least 5 manufacturers of injectable cyanocobalamin 1mg/ml (1,000mcg/ml) at https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm
- FDA and ASHP[3] drugs shortage databases at https//www.accessdata.fda.gov/scripts/drugshortages/dsp_SearchResults.cfm
- ASHP at https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages

[3] ASHP (American Society of Health System Pharmacists)

29. Respondent compounded and sold into California at least 341 vials of cyanocobalamin 1,000mcg/ml, a commercially available drug product, without the required documents.

30. During the investigation, Inspector CA found that Respondent extended the beyond use date of the sterile compounded drug preparations without conducting a Method Suitability Test, Container Closure Integrity Test, and Stability Studies, as is required under California Code of Regulations, title 16, section 1735.2(i)(3).

31. Inspector CA found that some of the compounded prescription-only sterile injectable preparations contained food grade chemicals such as Inositol, Choline Chloride, and Pyroxodine, thus adulterating them.

Drug	**Lot Number**	**Date Compounded**	**Amount Made**	**Beyond Use Date assigned**	**Sterility Release Date**	**Food Grade Chemicals**
LIPO-B	CALB/021218	2/12/18	8,500ml 275x30ml	4/13/18	2/28/18	-Inositol; -Choline Chloride
LIPO-DEN	CALD/020518 CALD/020418	2/05/18 2/04/18	5,000ml 150x30ml 6,500ml 200x30ml	4/06/18 4/15/18	2/20/18 3/01/18	-Inositol -Inositol; -Choline Chloride
LIPO-DEN PLUS	CALDP/021518	2/15/18	8,500ml 275x30ml	4/16/18	3/02/18	-Inositol; -Choline Chloride; -Pyridoxine
LIPO-PLEX	CALP/021218	2/12/18	5,500ml 175x30ml	4/13/18	2/28/18	-Inositol; -Choline Chloride
PYRIDOXINE 100mg/ml	CAP/021918	2/19/18	5,000ml 150x30ml	4/20/18	3/06/18	-Pyridoxine

32. Inspector CA found that LIPO-B lot CALB/021218; LIPO-DEN lots CALD/021418, LIPO-DEN PLUS lot CALDP/021518; LIPO-PLEX lot CALP/021218 were misbranded with a

beyond use date that extended beyond the expiration date of Choline Chloride (expiration date: 4/5/18), one of their components.

Drug	Lot Number	Date Compounded	Amount Made	Beyond Use Date assigned	Sterility Release Date
LIPO-B	CALB/021218	2/12/18	8,500ml 275x30ml	4/13/18	2/28/18
LIPO-DEN	CALD/020518 CALD/020418	2/05/18 2/04/18	5,000ml 150x30ml 6,500ml 200x30ml	4/06/18 4/15/18	2/20/18 3/01/18
LIPO-DEN PLUS	CALDP/021518	2/15/18	8,500ml 275x30ml	4/16/18	3/02/18
LIPO-PLEX	CALP/021218	2/12/18	5,500ml 175x30ml	4/13/18	2/28/18

FIRST CAUSE FOR DISCIPLINE
(Compounding a Commercially Available Drug Product)

33. Respondent is subject to disciplinary action under Code section 4301 subdivision (o) and California Code of Regulations section 1735.2 subdivision (d)(3) in that Respondent unlawfully compounded a commercially available product and did not retain the necessary documents for the required three year period. Specifically, the circumstances are that Respondent compounded, from non-sterile powder and sold into California at least 341 vials of cyanocobalamin 1,000mcg/ml, a commercially available drug product without retaining a copy of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation, and did not produce any documents to show it was not commercially available during the compounding and at each dispensing, as set forth in Paragraphs 27-29, which are incorporated herein by reference. This is a violation of Pharmacy Law.

SECOND CAUSE FOR DISCIPLINE
(Unlawful Extension of a Beyond Use Date)

34. Respondent is subject to disciplinary action under Code section 4301 subdivision (o) and California Code of Regulations section 1735.2 subdivision (i)(3) in that, in violation of Pharmacy Law, Respondent extended the beyond use date of the following sterile compounded

drug preparations without any of the required studies, as set forth in Paragraph 30, which is incorporated herein by reference, and as set forth in the table below:

Drug	Lot Number	Date Compounded	Amount Made	Beyond Use Date assigned	Sterility Release Date
CYANOCOBALAMIN 1000mcg/ml	CAC/020518 CAC/021418	2/05/18	6,500ml 200x30ml	4/06/18	2/20/18
HYDROXOCOBALAMIN 1mg/ml	CAH/021218	2/12/18	3,500ml 100x30ml	4/13/16	2/28/18
LIPO-B	CALB/021218	2/12/18	8,500ml 275x30ml	4/13/18	2/28/18
LIPO-DEN	CALD/020518 CALD/020418	2/05/18 2/04/18	5,000ml 150x30ml 6,500ml 200x30ml	4/06/18 4/15/18	2/20/18 3/01/18
LIPO-DEN PLUS	CALDP/021518	2/15/18	8,500ml 275x30ml	4/16/18	3/02/18
LIPO-PLEX	CALP/021218	2/12/18	5,500ml 175x30ml	4/13/18	2/28/18
METHYLCOBALAMIN 5mg/ml	CAMC/021518	2/15/18	6,2500ml 200x30mlS Hard to read. May be 6.25L and 50ml vials	4/16/18	3/02/18
PYRIDOXINE 100mg/ml	CAP/020518 CAP/021418 CAP/021918	2/05/18 2/14/18 2/19/18	5,000ml 150x30ml 5,000ml 175x30ml 5,000ml 150x30ml	4/06/18 4/15/18 4/20/18	2/20/18 3/01/18 3/06/18

THIRD CAUSE FOR DISCIPLINE
(Failure to Maintain Compounding Records)

35. Respondent is subject to disciplinary action under Code section 4301 subdivision (o) and California Code of Regulations section 1735.2 subdivision (a)(2) in that Respondent failed to document legibly, the identity of any pharmacy personnel engaged in compounding the drug preparation, the quantity of each ingredient used in compounding the drug preparation, the manufacturer, expiration date and lot number of each component, the final quantity or amount of drug preparation compounded for dispensing and quality reviews and required post-compounding process and procedures, for the drugs listed in the table in Paragraph 26, as set forth in Paragraph 26, which are incorporated herein by reference. This is a violation of Pharmacy Law.

FOURTH CAUSE FOR DISCIPLINE
(Adulteration of Compounded Drugs Product)

36. Respondent is subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Health and Safety Code section 111300. Specifically, Respondent compounded LIPO-B lot CALB/021218; LIPO-DEN lots CALD/020518 and CALD/021418, LIPO-DEN PLUS lot CALDP/021518; LIPO-PLEX lot CALP/021218; and pyridoxine 100mg/ml lot CAP/021918, prescription-only sterile injectable preparations with food grade components, thus adulterating it, as set forth in Paragraph 31 and its table, which are incorporated herein by reference. This is a violation of Pharmacy Law.

FIFTH CAUSE FOR DISCIPLINE
(Misbranding of Preparations)

37. Respondent is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), for violating statutes regulating controlled substances and dangerous drugs and state laws governing pharmacy, in that Respondent misbranded compounded preparations by assigning them a beyond use date which was false and misleading. This was true as to LIPO-B lot CALB/021218; LIPO-DEN lot CALD/021418; LIPO-DEN PLUS lot CALDP/021518; and LIPO-PLEX lot CALP/021218, where a component, namely choline chloride expired before the beyond use date assigned to the final product, as set forth in Paragraph 32 and its table, which are incorporated herein by reference. This is a violation of Pharmacy Law.

MATTERS IN AGGRAVATION

38. To determine the degree of discipline to be assessed against Respondent, if any, Complainant alleges as follows:

a. On or about May 2, 2018, the Board issued a Citation against Respondent's Non-Resident Pharmacy Permit No. NRP 1028. In addition, the Board issued a Citation and $5,000 Fine against Respondent's Non-Resident Sterile Compounding Permit No. NSC 99598. Both Citations were for violating Business and Professions Code section 4301, subdivision (j) as related to 21 U.S. Code section 353b subdivision (a)(8) (Unprofessional Conduct – Violation of any statutes of this state or of the United States regulation controlled substances or dangerous drugs / Outsourcing Facilities and Obtaining License by Fraud or Misrepresentation). Board

records indicate the Citation against Respondent's Non-Resident Pharmacy Permit No. NRP 1028 has been complied with. However, Board records indicate the $5,000 fine (No. CI 2017 79657) has not been paid.

b. On or about May 14, 2018, the Board issued a Citation against Respondent's Non-Resident Pharmacy Permit No. NRP 1028 and a Citation and $5,000 Fine against Respondent's Non-Resident Sterile Compounding Permit No. NSC 99598. Both citations were for violating California Code of Regulations, title 16, section 1735.2, subdivision (h) (The beyond-use date shall not exceed the shortest expiration date or beyond use date of any ingredients in the compounding drug preparation). Board records indicate the Citation against Respondent's Non-Resident Pharmacy Permit No. NRP 1028 has been completed. However, the $5,000 fine (No. CI 2017 70212) has not been paid.

OTHER MATTERS

39. Pursuant to Code section 4307, if discipline is imposed on Non-Resident Pharmacy Permit Number NRP 1028 issued to Coastal Meds LLC, Coastal Meds LLC shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Non-Resident Pharmacy Permit Number NRP 1028 is placed on probation or until Non-Resident Pharmacy Permit Number NRP 1028 is reinstated if it is revoked.

40. Pursuant to Code section 4307, if discipline is imposed on Non-Resident Pharmacy Permit Number NRP 1028 issued to Coastal Meds LLC, while Richey Chance has been a member and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Richey Chance shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Non-Resident Pharmacy Permit Number NRP 1028 is placed on probation or until Non-Resident Pharmacy Permit Number NRP 1028 is reinstated if it is revoked.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Non-Resident Pharmacy Permit Number NRP 1028, issued to Coastal Meds LLC;

2. Revoking or suspending Non-Resident Sterile Compounding Permit Number NSC 99598, issued to Coastal Meds LLC;

3. Prohibiting Coastal Meds LLC from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Non-Resident Pharmacy Permit Number NRP 1028 is placed on probation or until Non-Resident Pharmacy Permit Number NRP 1028 is reinstated if Non-Resident Pharmacy Permit Number NRP 1028 issued to Coastal Meds LLC is revoked;

4. Prohibiting Richey Chance from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Non-Resident Pharmacy Permit Number NRP 1028 is placed on probation or until Non-Resident Pharmacy Permit Number NRP 1028 is reinstated if Non-Resident Pharmacy Permit Number NRP 1028 issued to Coastal Meds LLC is revoked;

5. Ordering Coastal Meds LLC to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

6. Taking such other and further action as deemed necessary and proper.

DATED: August 1, 2019

ANNE SODERGREN
Interim Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant