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

In the Matter of the First Amended Accusation Against:

FOOTHILLS PROFESSIONAL PHARMACY LTD
dba FOOTHILLS PROFESSIONAL PHARMACY,
PUJAN A. PATEL, DIRECTOR, PRESIDENT and SECRETARY,
Nonresident Pharmacy Permit No. NRP 2041

and

Nonresident Pharmacy Permit No. NRP 2769

Respondents.

Agency Case No. 7145

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval 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 November 13, 2024.

It is so ORDERED on October 14, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
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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**:** **FOOTHILLS PROFESSIONAL PHARMACY LTD DBA FOOTHILLS PROFESSIONAL PHARMACY** **PUJAN A. PATEL, Director, President and Secretary** **4545 E. Chandler Blvd., #100** **Phoenix, AZ 85048** **Nonresident Pharmacy Permit No. NRP 2041** **2727 W. Baseline Rd. Suite 1** **Tempe, AZ 95283** **Nonresident Pharmacy Permit No. NRP 2769** Respondent.	Case No. 7145 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

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 Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Kevin W. Bell, Deputy Attorney General.

2. Respondent Foothills Professional Pharmacy LTD, dba Foothills Professional Pharmacy, (Respondent) is represented in this proceeding by attorney Derek S. Davis, whose address is: 423 Washington Street, 4th Floor, San Francisco, CA 94111-2355.

3. On or about January 25, 2018, the Board issued Nonresident Pharmacy Permit No. NRP 2041 to Respondent. On or about December 31, 2022, the Board granted an application for renewal of Permit No. NRP 2041, as well as for a change of location. The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 7145, and will expire on January 1, 2024, unless renewed.

4. On or about December 30, 2022, the Board issued Nonresident Pharmacy Permit No. 2769 to Respondent. By stipulation, the Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 7145, and expired on January 1, 2024.

JURISDICTION

5. Accusation No. 7145 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 May 24, 2022. Respondent timely filed its Notice of Defense contesting the Accusation. On July 24, 2023, the Board filed and served an Amended Accusation No. 7145. A copy of Amended Accusation No. 7145 is attached as exhibit A and incorporated herein by reference.

6. Respondent submitted an application for renewal of Permit No. NRP 2041, as well as for a change of location. The granting of the change of location application would require the cancellation of Nonresident Pharmacy Permit No. NRP 2041, and issuance of a new permit number to Respondent pursuant to Business and Professions Code section 4201(f). On or about December 30, 2022, Respondent stipulated that, in exchange for issuance of a new permit number, the Board shall have continuing jurisdiction over the new permit issued to Respondent at the change of location such that any disciplinary order issued by the Board in Case No. 7145, including any terms and conditions of probation, shall carry forward and be applicable to that new permit issued to Respondent.

ADVISEMENT AND WAIVERS

7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7145. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

8. 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 be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; 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.

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

CULPABILITY

10. Respondent understands and agrees that the charges and allegations in Accusation No. 7145, if proven at a hearing, constitute cause for imposing discipline upon its Nonresident Pharmacy Permits.

11. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest those charges.

12. Respondent agrees that its Nonresident Pharmacy Permits are subject to discipline and Respondent agrees to be bound by the Disciplinary Order below.

CONTINGENCY

13 This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to

or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they 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 Settlement and Disciplinary Order for Public Reproval 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.

14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

15. This Stipulated Settlement and Disciplinary Order for Public Reproval 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 Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

16. 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 Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Nonresident Pharmacy Permit No. NRP 2769 shall be PUBLICLY REPROVED. Respondent is required to report this reproval as discipline.

IT IS FURTHER ORDERED that Nonresident Pharmacy Permit No. NRP 2041 is surrendered to the Board. This surrender is not a disciplinary action but reflects the Board's issuance of Nonresident Pharmacy Permit No. NRP 2769 after Respondent submitted a change of location permit application. Respondent acknowledges, however, that to the extent necessary to enforce this Order, the Board retains jurisdiction over Permit No. 2041.

Cost Recovery. No later than 14 DAYS from the effective date of the Decision, Respondent shall pay $15,000 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew their Nonresident Pharmacy Permit until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Education. Within 90 days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to USP Chapter 795 and Critical Points Nonsterile Compounding. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists. This term applies to all staff involved in compounding activities, shall consist of no less than 6 hours instruction, and shall be no less than 50% live or in-person instruction.

Failure to timely submit for approval or complete the approved remedial education shall be considered a separate Cause for Discipline. Following the completion of each course, the board or its designee may require the Respondent, at their own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination the course shall not count towards satisfaction of this term.

Full Compliance. As a resolution of the charges in Accusation No. 7145, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Nonresident Pharmacy Permit No. NRP 2769.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Derek S. Davis. I understand the stipulation and the effect it will have on my Nonresident Pharmacy Permit. I enter into this

Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

FOOTHILLS PROFESSIONAL PHARMACY
LTD DBA FOOTHILLS PROFESSIONAL
PHARMACY,
Respondent

By:_____

Print Name and Title:_____

I have read and fully discussed with Respondent Foothills Professional Pharmacy LTD dba Foothills Professional Pharmacy, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval, and I approve its form.

DATED: _____

DEREK S. DAVIS
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,
ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General

KEVIN W. BELL
Deputy Attorney General
Attorneys for Complainant

Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 7-30-2024

FOOTHILLS PROFESSIONAL PHARMACY LTD DBA FOOTHILLS PROFESSIONAL PHARMACY,
Respondent

By: _____

Print Name and Title: PUSHAN PATEL, PRESIDENT

I have read and fully discussed with Respondent Foothills Professional Pharmacy LTD dba Foothills Professional Pharmacy, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____

DEREK S. DAVIS
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,
ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General

KEVIN W. BELL
Deputy Attorney General
Attorneys for Complainant

FoothillsStip Reproval FINAL.docx

Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

FOOTHILLS PROFESSIONAL PHARMACY LTD DBA FOOTHILLS PROFESSIONAL PHARMACY,
Respondent

By: _____

Print Name and Title: _____

I have read and fully discussed with Respondent Foothills Professional Pharmacy LTD dba Foothills Professional Pharmacy, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval, and I approve its form.

DATED: August 23, 2024

DEREK S. DAVIS
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: August 27, 2024

Respectfully submitted,
ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General

Kevin W. Bell

KEVIN W. BELL
Deputy Attorney General
Attorneys for Complainant

Exhibit A

Accusation No. 7145

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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**:** **FOOTHILLS PROFESSIONAL PHARMACY LTD DBA FOOTHILLS PROFESSIONAL PHARMACY** **PUJAN A. PATEL, Director, President and Secretary** **4545 E. Chandler Blvd., #100** **Phoenix, AZ 85048** **Nonresident Pharmacy Permit No. NRP 2769** **Nonresident Pharmacy Permit No. NRP 2041** **Nonresident Pharmacy Permit No. NRP 1275** Respondent.	Case No. 7145 **FIRST AMENDED ACCUSATION**

PARTIES

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

2. On or about January 25, 2018, the Board of Pharmacy issued Nonresident Pharmacy Permit Number NRP 2041 to Foothills Professional Pharmacy LTD dba Foothills Professional Pharmacy; and Pujan Patel, Director, President and Secretary (Respondents)**,** located at 4545 E. Chandler Blvd. #100, Phoenix, AZ 85048. On or about December 30, 2022, following receipt of an application for renewal and change of location for Permit No. NRP 2041, the Board issued Nonresident Pharmacy Permit NRP 2769 to Respondents at the new location of 2727 W. Baseline

Rd. Suite 1, Tempe, AZ 95283. The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 7145, and will expire on December 1, 2023, unless renewed.

3. On or about January 31, 2013, the Board of Pharmacy issued Nonresident Pharmacy Permit Number 1275 to Respondents. The Nonresident Pharmacy Permit expired on January 26, 2018, and has not been renewed.

JURISDICTION

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

5. Section 4300 of the Code 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. Section 4300.1 of the Code 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."

7. Section 4307 of the Code states in pertinent part:

> (a) 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 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.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308 , may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

8. On or about December 30, 2022, following receipt of an application for renewal and change of location for Permit No. NRP 2041, the Board issued Nonresident Pharmacy Permit NRP 2769 to Respondents at the new location of 2727 W. Baseline Rd. Suite 1, Tempe, AZ 95283. In exchange for the processing and issuance of the renewal of the permit and for the change of location, Respondent and the Board entered into a stipulation that the Board shall have continuing jurisdiction over the change of location such that the disciplinary proceeding shall be applicable to that new permit regarding the change of location.

STATUTORY PROVISIONS

9. Section 651 provides, in pertinent part:

(a) It is unlawful for any person licensed under this division or under any initiative act referred to in this division to disseminate or cause to be disseminated any form of public communication containing a false, fraudulent, misleading, or

deceptive statement, claim, or image for the purpose of or likely to induce, directly or indirectly, the rendering of professional services or furnishing of products in connection with the professional practice or business for which he … is licensed. A "public communication" as used in this section includes, but is not limited to, communication by means of mail, television, radio, motion picture, newspaper, book, list or directory of healing arts practitioners, Internet, or other electronic communication.

(b) A false, fraudulent, misleading, or deceptive statement, claim, or image includes a statement or claim that does any of the following:

(1) Contains a misrepresentation of fact.

(2) Is likely to mislead or deceive because of a failure to disclose material facts.
. . .

(7) Makes a scientific claim that cannot be substantiated by reliable, peer reviewed, published scientific studies.
. . .

10. Section 4113(c) of the Code provides that in pertinent part that "[t]he pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

11. Section 4129.2, subdivision (b) of the Code provides that a nonresident outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.

12. Section 4169 provides, in pertinent part:

(a) A person or entity shall not do any of the following:

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

13. Section 4301 of the Code states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
. . .

(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.

. . . .

14. Section 4302 of the Code provides that the board may deny, suspend, or revoke any license where conditions exist in relation to any person holding 10 percent or more of the ownership interest or where conditions exist in relation to any officer, director, or other person with management or control of the license that would constitute grounds for disciplinary action against a licensee.

15. Section 4303 of the Code provides that the board may cancel, deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located.

16. Section 111250 of the Health and Safety Code provides that:

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

17. Section 111255 of the Health and Safety Code provides that:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

18. Section 111295 of the Health and Safety Code provides that:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

19. Section 111330 of the Health and Safety Code provides that:

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

/ / /

20. Section 111335 of the Health and Safety Code provides that:

Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

21. California Health and Safety Code section 111395 states in pertinent part:

"Any drug is misbranded in any of the following cases:
. . . .

(c) The contents of the original package have been, wholly or partly, removed and replaced with other material in the package."

22. Section 111440 of the Health and Safety Code provides that:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

REGULATORY PROVISIONS

23. California Code of Regulations, title 16, section 1735 provides, in pertinent part:

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a compounded drug preparation from chemicals or bulk drug substances

24. California Code of Regulations, title 16, section 1735.3 provides, 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:
. . .

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

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

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the

supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (*l*) shall apply.
. . .

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

25. California Code of Regulations, title 16, section 1735.4 provides, in pertinent part:

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:
. . .

(3) Instructions for storage, handling, and administration . . .
. . .

(5) The date compounded . . .

26. California Code of Regulations, title 16, section 1735.6, provides in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.
. . .

(e) Hazardous drug compounding shall be completed in an externally exhausted physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hours or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors) . . .
. . .

COST RECOVERY

27. Section 125.3 of the Code states, in pertinent part, that the 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.

/ / /

FACTUAL ALLEGATIONS

28. On or about September 9, 2020, the United States Food and Drug Administration (FDA) issued a warning letter to Respondent alleging several violations, including that Respondent compounded non-sterile drugs for office use; that Respondent held drugs under insanitary conditions (adultered drugs); that Respondent compounded domperidone; that Respondent compounded drugs that were found to be sub-potent, (misbranded drugs); and that Respondent had introduced new drugs into interstate commerce without approval. Because of the FDA warning letter, the Board initiated an investigation. The Board investigation revealed the numerous violations of the Business and Professions Code, the Health and Safety Code, and the California Code of Regulations as set forth in the Causes for Discipline below:

Nonresident Pharmacy Permit No. NRP 2041 / NRP 2769

FIRST CAUSE FOR DISCIPLINE

(Sales of Misbranded Drugs)

29. Respondent is subject to disciplinary action under Code section 4169(a)(3) in that on or about and between January 29, 2018 and December 27, 2020, Respondent sold and shipped into California dangerous drugs that Respondent knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code. The circumstances are as follows:

30. On or about and between January 29, 2018 and December 27, 2020, Respondent sold and shipped into California 30 compounded drugs, 2,152 capsules, labeled "SR" for "Sustained Release." (See Table 1 below) These drugs labeled "SR" were misbranded as the pharmacy did not have studies to back up there designation as sustained release. According to United States Pharmacopeia (USP) <1151>, there are two principal categories of drug release: intermediate release and modified release: there is no category, definition, or mention of "Sustained Release" or "Slow Release." According to USP<1151>, if the medication were deemed extended release, dissolution testing would need to be performed to ensure that the drugs meet dissolution requirements in the drug monograph. Respondents did not produce dissolution testing or drug monographs which specified the dissolution requirements. Specifically, approximately 30

compounded drugs, 2,152 capsules, labeled "SR" were misbranded as the pharmacy did not have studies to back up their designation as sustained release:

Table 1: "SR" designated compounded drugs which did not have studies to back up the "SR" designation which were shipped/sold into California between 1/29/2018 and 12/27/2020:

Prescription number:	Fill date/approximate sale date:	Compounded Drug:	Quantity:
311962	1/29/2018	C-Progesterone SR 100mg capsule	30 caps
310681	1/20/2018	C-Progesterone SR 100mg capsule	90 caps
300332	2/5/2018	C-Progesterone SR 200mg capsule	90 caps
314218	2/21/2018	C-estriol/estradiol/progesterone/testosterone SR 12/2/200/1mg capsules	90 caps
314379	2/22/2018	C-DHEA/7-Keto-DHEA SR 25/20mg capsule	90 caps
306331	2/27/2018	C-BIEST(estriol/estradiol 80:20) SR 2.5mg capsule	90 caps
292842	2/28/2018	C-Progesterone SR 200mg capsule	90 caps
311962	3/7/2018	C-Progesterone SR 100mg capsule	30 caps
311962	4/9/2018	C-Progesterone SR 100mg capsule	30 caps
319475	4/16/2018	C-Progesterone SR 200mg capsule	60 caps
284765	5/2/2018	C-T3 (liothyronine) SR 22.5mg capsule	120 caps
321092	5/8/2018	C-Progesterone SR 100mg capsule	60 caps
322128	5/24/2018	C-Progesterone SR 200mg capsule	60 caps
314218	5/29/2018	C-estriol/estradiol/progesterone/testosterone SR 12/2/200/1mg capsules	90 caps
306331	5/30/2018	C-BIEST(estriol/estradiol 80:20) SR 2.5mg capsule	30 caps
322592	6/1/2018	C-Progesterone SR 100mg capsule	90 caps
319475	6/19/2018	C-Progesterone SR 200mg capsule	60 caps
325097	7/12/2018	C-Progesterone SR 200mg capsule	180 caps
322128	7/20/2018	C-Progesterone SR 200mg capsule	60 caps
321092	7/24/2018	C-Progesterone SR 100mg capsule	60 caps
325810	7/26/2018	C-Progesterone SR 200mg capsule	60 caps
324697	8/3/2018	C-Progesterone SR 200mg capsule	42 caps
319475	8/16/2018	C-Progesterone SR 200mg capsule	60 caps
322128	8/30/2018	C-Progesterone SR 200mg capsule	60 caps
319475	10/23/2018	C-Progesterone SR 200mg capsule	60 caps
330863	10/25/2018	C-Progesterone SR 125mg capsule	90 caps
321092	10/25/2018	C-Progesterone SR 100mg capsule	60 caps
330920	10/25/2018	C-T3(liothyronine) SR 22.5mcg capsule	120 caps
330922	10/25/2018	C-Anastrozole SR 0.5mg capsule	40 caps
334329	12/27/2020	C-estriol/progesterone SR 8/100mg capsule	60 caps

SECOND CAUSE FOR DISCIPLINE

(False Advertising)

31. Respondent is subject to disciplinary action under Code section 651(b)(7) in that Respondent disseminated or cause to be disseminated any form of public communication containing a false, fraudulent, misleading, or deceptive statement, claim, or image for the purpose of or likely to induce, directly or indirectly, the rendering of professional services or furnishing of products in connection with the professional practice or business for which he Respondent is licensed. The circumstances are as follows:

32. On or about and between January 29, 2018 and December 27, 2020, Respondent made a scientific claim on the labels of compounded drugs that cannot be substantiated by reliable, peer reviewed, published scientific studies as more fully set forth in paragraph 25 above.

THIRD CAUSE FOR DISCIPLINE

(Sales of Adultered Drugs)

33. Respondent is subject to disciplinary action under Code section 4169(a)(2) in that on or about and between July 9, 2018 and October 24, 2018, Respondent sold and shipped into California drugs that Respondent knew or reasonably should have known were adulterated, as defined in Section 111250 of the Health and Safety Code. The circumstances are as follows:

34. On or about and between July 9, 2018 and October 24, 2018, Respondent, under Nonresident Pharmacy Permit No. NRP 2041, sold/shipped drugs which were compounded in insanitary conditions thereby adulterating the drugs. (See Table 2) Specifically, in respondent's facility, balance and scales used to weigh ingredients had powder residue on them, and fans and ceiling return vents had powder residue on them. The room where the compounding took place did not have negative pressure and was not externally vented. Fans in the compounding areas move residue throughout a room contaminating anything open to the powder residues being blown in the room. Powder hoods where the compounded drugs were compounded had residues on the inside of the hoods. These drugs are as follows:

Table 2: Adulterated compounded drugs which were shipped/sold into CA between 7/9/2018 and 10/24/2018:

Prescription number:	**Fill date/ approximate sale date:**	**Compounded Drug:**	**Quantity:**
309439	7/9/2018	C-Diclofenac Sodium /Gabapentin/Lidocaine HCl/Prilocaine HCL 3/6/2.5/2.5% cream	60 grams
324606	7/9/2018	Formula 5.0 CF Diclofenac Sodium 2%/Gabapentin 3%/Lidocaine 5% cream	120 grams
324771	7/9/2018	C-Diclofenac Sodium /Gabapentin/Lidocaine HCl/Prilocaine HCL 3/6/2.5/2.5% cream	120 grams
297739	7/10/2018	C-Diclofenac comp 3% cream	142 grams
C320147	7/11/2018	C-Ketamine/Baclofen/Cyclobenzaprine/Diclofenac/Gabapentin/Tetracaine 15/2/2/3/6/2% cream	240 grams
325034	7/11/2018	C-Naltrexone HCL IR 2.5mg capsule	90 caps
325064	7/12/2018	C- Naltrexone IR 4.5mg capsule	180 caps
325063	7/12/2018	C-Naltrexone IR 4.5mg capsule	180 caps
325097	7/12/2018	C-Progesterone SR 200mg capsule	180 caps
322866	7/14/2018	C-Naltrexone HCl IR 2.5mg capsule	30 caps

322104	7/14/2018	C-Nystatin 500,000 IU capsule	120 caps
325195	7/17/2018	C-Progesterone IR 100mg capsule	30 caps
322128	7/20/2018	C-Progesterone SR 200mg capsule	60 caps
318371	7/20/2018	C-Naltrexone IR 4.5mg capsule	90 caps
321092	7/24/2018	C-Progesterone SR 100mg capsule	60 caps
315008	7/24/2018	C-Hexarelin acetate 300 mcg mini-troche	60 troche
C325670	7/24/2018	C-Biest (Estriol/Estradiol 50:50)/DHEA/7-Keto DHEA/Pregnenolone/test1.0/20/20/20/1mg/gm Versa-Pro	30 grams
322131	7/24/2018	C-Magnesium/selenium/glandular/zinc/iodine/k-iodine/glutathione/DHEA 200mg/200mcg/40mg/30mg/1mg/2mg	60 caps
C318927	7/24/2018	C-Chrysin/DHEA/Testosterone 25/25/150mg/gm Lipoderm	60 grams
315014	7/24/2018	C-Hexarelin acetate 300 mcg mini-troche	60 troche
325673	7/24/2018	C-Tadalafil 10mg RDT-Tablet	60 tabs
325675	7/24/2018	C-Luscious Lashes (latanoprost/Tetrahydrozoline) 0.003%/0.05% solution	3.5ml
C325635	7/24/2018	C-Testosterone 4mg/gm cream	30 grams
306259	7/25/2018	C-Diclofenac 3% cream	60grams
325782	7/25/2018	Formula 9.0 CF Baclofen 2%/Diclofenac Sodium 3%/Gabapentin 3%/Lidocaine 5% cream	120 grams
325810	7/26/2018	C-Progesterone SR 200mg capsule	60 caps
C325809	7/26/2018	C-Estriol/Estradiol/Pregnenolone/Testosterone 0.75/0.5/5/1mg mini-troche	60 troche
325966	7/28/2018	C-Magnesium/selenium/glandular/zinc/iodine/k-iodine/glutathione/DHEA/M-Cobalmin (T-mix) 200mg/200mcg/40mg/50	60 caps
325991	7/30/2018	C-Progesterone 200mg Troche	30 troche
326033	7/31/2018	C-Hexarelin acetate 400 mcg mini-troche	60 troche
325745	7/31/2018	C-Naltrexone HCL IR 1.5mg capsule	90 caps
C318244	8/1/2018	C-Ketamine/Baclofen/Clonidine 10/2/0.2% cream	60 grams
326131	8/1/2018	C-Sildenafil 125mg troche	5 tabs
302490	8/2/2018	C-Sumatriptan/Promethazine/Tetracaine 4/1/1% Lipo Base	40 grams
C326190	8/2/2018	C-Estradiol/Testosterone 2/4mg/gm cream	30 grams
C325659	8/3/2018	C-Estradiol/Progesterone/Testosterone 2/50/3mg/gm cream	90 grams
C326320	8/3/2018	C-Biest (Estriol/Estradiol 80:20/Testosterone 2.5/3mg mini-troche	60 troche
324697	8/3/2018	C-Progesterone SR 200mg capsules	42 caps
C326451	8/7/2018	C-Biest (Estriol/Estradiol 80:20/Progesterone/Testosterone 1.25/50/6mg troche	90 troche
324771	8/7/2018	C-Diclofenac Sodium /Gabapentin/Lidocaine HCl/Prilocaine HCL 1.5/3/2/2% cream	120 grams
326484	8/8/2018	C-Squaric Acid (Dibutyl Squarate) in acetone 0.5% solution	10ml
326482	8/8/2018	C-Squaric Acid (Dibutyl Squarate) in acetone 2% solution	10ml
326485	8/8/2018	C-Squaric Acid (Dibutyl Squarate) in acetone 0.1% solution	10ml
326486	8/8/2018	C-Squaric Acid (Dibutyl Squarate) in acetone 0.025% solution	10ml
326487	8/8/2018	C-Squaric Acid (Dibutyl Squarate) in acetone 0.01% solution	10ml
C326790	8/13/2018	C-Testosterone 200mg/gm versa pro	90 grams
325195	8/13/2018	C-Progesterone IR 100mg capsule	60 caps
321095	8/14/2018	C-Naltrexone IR 4.5mg capsule	120 caps
C326659	8/14/2018	C-Ketamine HCl/Diclofenac Sodium/Baclofen/gabapentin/lidocaine/tetracaine HCL 10/3/20/6/3.5/2% cream	120 grams
326925	8/15/2018	C-Progesterone 200mg troche	90 troche
326949	8/15/2018	C-Diclofenac Comp 3% cream	142 grams
311711	8/16/2018	Plantar 200.0 CF Diclofenac Sodium 2%/Gabapentin 3%/Verapamil HCl 2.5% cream	120 grams
323737	8/16/2018	C-Biest (Estriol/Estradiol 50:50) 2.5mg/gm Versabase	60 grams
319475	8/16/2018	C-Progesterone SR 200mg capsule	60 caps
C324465	8/20/2018	C-DHEA/Progesterone/Testosterone 20/100/5mg/gm cream	30 grams
327158	8/20/2018	C-Biest (estriol/Estradiol 80:20) 1mg/gm cream	30 grams
327179	8/21/2018	C-Hexarelin Acetate/HCG 400mcg/150 IU/0.1 ml Nasal Spray	4 ml

C321027	8/22/2018	C-Tramadol/Flurbiprofen/Cyclobenzaprine/Baclofen 5/20/2/2% cream	120 grams
327394	8/23/2018	C-Mupirocin/EDTA/Gentamycin (BEG Spray) 2%/1%/3% Nasal Spray	30 ml
322961	8/23/2018	C-Progesterone IR 50mg capsule	60 caps
C327400	8/23/2018	C-Testosterone 3mg mini-troche	30 troche
C327486	8/24/2018	C-Estradiol/Testosterone 1.5/3mg mini-troche	90 troche
299718	8/28/2018	C-Diclofenac/cyclobenzaprine/gabapentin/lidocaine 3/2/6/5% cream	120 grams
327662	8/29/2018	C-Biest (Estriol/Estradiol 80:20) Progesterone 5/100mg/gm cream	90 grams
322128	8/30/2018	C-Progesterone SR 200mg capsule	60 caps
319033	9/5/2018	C-Biest (Estriol/Estradiol 50:50) Propylene Glycol 20mg/ml drops	30 ml
323030	9/5/2018	C-Dosycyline IR Beef Flavor 200mg capsule	200 caps
328058	9/5/2018	C-Progesterone IR 200mg capsule	90 caps
324771	9/10/2018	C-Diclofenac Sodium/Gabapentin/Lidocaine/Prilocaine 1.5/3/2/2% cream	120 grams
328288	9/10/2018	C-Thyroid IR (T-mix) 4 grains (260 mg) capsule	90 caps
328306	9/11/2018	C-Thyroid IR (T-mix) 0.75 grain (48.75) capsule	90 caps
328452	9/13/2018	C-Progesterone 200mg/gm cream	60 grams
C328451	9/13/2018	C-Biest (Estriol/Estradiol 80:20) 10/15mg/gm cream	30 grams
C328453	9/13/2018	C-Testosterone gel 200mg/gm Versa-Pro	30 grams
C325670	9/13/2018	C-Biest (Estriol/Estradiol 50:50)/DHEA/7-Keto DHEA/Pregnenolone/Test 1.0/20/20/20/1mg/gm Versa-Pro	30 grams
C327821	9/14/2018	C-Biest (Estriol/Estradiol 20:80)/DHEA/Progesterone/Testosterone 2/14/250/5mg gel troche	30 troche
308763	9/14/2018	C-Biest (Estriol/Estradiol 80:20)/DHEA/Progesterone 10/20/20mg/gm cream	30 grams
328567	9/14/2018	C-Progesterone IR 200mg capsule	90 caps
328367	9/15/2018	C-T4/T3 (levothyroxine/Liothyronine) IR Acidophylus 19/4.5 mcg capsule	90 caps
322104	9/17/2018	C-Nystatin 500,000IU capsule	120 caps
328474	9/18/2018	C-Sermorelin Acetate 600mcg mini-troche	60 troche
325232	9/18/2018	C-Progesterone 200mg gel troche	90 troche
C318244	9/18/2018	C-Ketamine/Baclofen/Clonidine 10/2/0.2% cream	60 grams
C328817	9/19/2018	C-Testosterone 5mg/gm Versabase	30 grams
328774	9/20/2018	Formula 9.0 CF Baclofen 2%/Diclofenac Sodium 3%/Gabapentin 3%/Lidocaine 5% cream	120 grams
328910	9/20/2018	C-Naltrexone HCl IR 3mg capsule	90 caps
323955	9/21/2018	Formula 5.0 CF Diclofenac Sodium 2%/Gabapentin 3%/Lidocaine 5% cream	120 grams
317837	9/21/2018	Formula 5.0 CF Diclofenac Sodium 2%/Gabapentin 3%/Lidocaine 5% cream	120 grams
328690	9/26/2018	Formula 130.3 CF Diclofenac Sodium 2% cream	120 grams
329341	9/28/2018	C-Diclofenac Comp 3% cream	142 grams
325991	9/28/2018	C-Progesterone 200mg Troche	30 troche
C324465	9/29/2018	C-DHEA/Progesterone/Testosterone 20/100/5mg/gm cream	30 grams
327158	9/29/2018	C-Biest (Estriol/Estradiol 80:20) 1mg/gm cream	30 grams
329122	10/1/2018	C-Loratadine 5mg/5ml Suspension	300 ml
302490	10/1/2018	C-Sumatriptan/Promethazine/Tetracaine 4/1/1% Lipo Base	20 grams
327179	10/2/2018	C-Hexarelin Acetate/HCG 400mcg/150 IU/0.1ml Nasal Spray	4 ml
324771	10/3/2018	C-Diclofenac Soidum/Gabapentin/Lidocaine/Prilocaine 1.5/3/2/2% cream	120 grams
C329681	10/3/2018	C-Biest (Estriol/Estradiol 80:20)/DHEA/Progesterone/Testosterone 1.25/10/200/2mg troche	90 troche
325782	10/3/2018	Formula 9.0 CF Baclofen 2%/Diclofenac Sodium 3%/Gabapentin 3%/Lidocaine 5% cream	120 grams
319155	10/4/2018	C-Calitriol Beef Flavor 260 mg capsule	60 caps
328663	10/5/2018	Formula 130.3 CF Diclofenac Sodium 2% cream	120 grams
C326320	10/5/2018	C-Biest (Estriol/Estradiol 80:20)/Testosterone 2.5/3mg mini-troche	60 troche
C321027	10/9/2018	C-tramadol/Flurbiprofen/Cyclobenzaprine/Baclofen 5/20/2/2% cream	120 grams
325034	10/9/2018	C-Naltrexone HCl IR 2.5mg capsule	90 caps
329903	10/9/2018	C-Diclofenac Sodium 5% Versa Gel	60 grams

318371	10/12/2018	C-Naltrexone IR 4.5 capsule	90 caps
330274	10/15/2018	Formula 130.3 CF Diclofenac Sodium 2% cream	120 grams
C330348	10/16/2018	C-Biest (Estriol/Estradiol 80:20)/Testosterone 1.25/3.5mg mini-troche	60 troche
311213	10/16/2018	C-Biest (Estriol/Estradiol 90:10)/Progesterone 3/150mg troche	90 troche
330279	10/16/2018	Formula 130.3 CF Diclofenac Sodium 2% cream	120 grams
330283	10/19/2018	Formula 9.0 CF Baclofen 2%/Diclofenac Sodium 3%/Gabapentin 3%/Lidocaine 5% cream	120 grams
330749	10/23/2018	C-Neomycin Sulfae 500mg capsule	28 caps
323737	10/23/2018	C-Biest (Estriol/Estradiol 50:50) 2.5mg/gm Versabase	60 grams
319475	10/23/2018	C-Progesterone SR 200mg capsule	60 caps
C330777	10/24/2018	C-Estradiol/Testosterone 8/3mg/gm Lipoderm	22.5 grams

FOURTH CAUSE FOR DISCIPLINE

(Lack of ventilation)

35. Respondent is subject to disciplinary action under California Code of Regulations section 1735.6(e)(1) and (2) in that Respondent compounded dangerous drugs in a room without negative pressure and that was not externally vented that were subsequently sold and shipped into California as more fully set forth in paragraph 29 above.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Identify Pharmacy Personnel Involved in Compounding)

36. Respondent is subject to disciplinary action under California Code of Regulations section 1735.3(a)(2)(C) in that on or about and between January 20, 2021 and February 5, 2021, Respondents sold and shipped drugs into California which did not identify any of the pharmacy personnel engaged in compounding the drug preparation. In each of the following instances in Table 3 below, the compounder did not initial the compounding record:

Table 3: No Identity of Compounding Personnel or Reviewing Pharmacist

Date compounded:	Date Sold:	Lot number:	Prescription number:	Drug name and strength:
1/20/21	1/20/2021	01202021:65@71	376316	C-tretinoin/hydroquinone 0.05/4% cream
1/27/2021	1/28/2021	1272021:41@98	376967	C-Clobetasol 0.055% Shampoo
1/13/2021	1/13/2021	01132021:19@73	376002	C-Nystatin 250000u/ml susp.
1/4/2021	1/14/2021	01042021:68@87	376129	C-DHEA/Pregnenolone 50/25mg IR capsule
12/23/2020	1/4/2021	12232020:17@27	375354	C-Calcipotriene/Fluorouracil 0.005/5% cream
1/29/2021	2/1/2021	01292021:52@88	359934	C-Hydroquinone /Tretinoin/Ascorbic Acid 6/0.1/0.05% cream
1/8/2021	1/29/2021	01082021:34@18	377145	C-Tretinoin/Ascorbic Acid 0.1/0.5% cream
1/22/2021	1/26/2021	01222021:59@77	376708	C-Fluorouracil/Salicylic cream 5%/30% cream
1/22/2021	1/25/2021	1/22/2021:07@81	357232	C-Naltrexone IR AviCel 4.5mg capsule
1/13/2021	2/5/2021	1/13/2021:75@52	361779	C-Tacrolimus 0.12% cream

SIXTH CAUSE FOR DISCIPLINE

(Failure to Identify Pharmacist Reviewing Compounding)

37. Respondent is subject to disciplinary action under California Code of Regulations section 1735.3(a)(2)(D) in that on or about and between January 20, 20210 and February 5, 2021, Respondents sold and shipped drugs into California which did not include the identity of the pharmacist reviewing the final drug preparation as set forth more fully in Table 3 above.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Document Correct Expiration Date, Manufacturer, and Lot Number)

38. Respondent is subject to disciplinary action under California Code of Regulations section 1735.3(a)(2)(F) in that on or about and between January 20, 2021 and January 29, 2021, Respondents sold and shipped drugs into California which did not include the correct manufacturer, correct expiration date and correct lot number of each component as set forth in Table 4 below:

Table 4, Compounding records

Date compounded:	Date Sold:	Lot number:	Prescription number:	Drug name and strength:	Issues with compound:
1/20/21	1/20/2021	01202021:65@71	376316	C-tretinoin/hydroquinone 0.05/4% cream	Butylated hydroxytoluene certificate of analysis lists an expiration date of 4/30/23 and the compounding record lists the expiration date as 10/31/23Propylene glycol lot number is listed on the compounding record as 171056/B and the certificate of analysis lists a lot number: 171066,
12/23/2020	1/4/2021	12232020:17@27	375354	C-Calcipotriene/Fluorouracil 0.005/5% cream	Ethyl alcohol on the compounding record has an expiration date: 3/28/2023 and per the certificate of analysis the expiration date was 3/27/2023
1/29/2021	2/1/2021	01292021:52@88	359934	C-Hydroquinone /Tretinoin/Ascorbic Acid 6/0.1/0.05% cream	Butylated hydroxytoluene certificate of analysis lists an expiration date of 4/30/23 and the compounding record lists the expiration date as 10/31/23

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Document Quality Reviews and Post-Compounding Procedures)

39. Respondent is subject to disciplinary action under California Code of Regulations section 1735.3(a)(2)(J) in that on or about and between January 20, 2021 and February 5, 2021, Respondent was found to have compounding records for compounded drugs which were

sold/shipped into California which did not state the quality reviews and required post compounding process and procedures as set forth in Table 5 below:

Table 5 Compounding records with no Quality Review and/or Post Compounding Process/Procedures

Date compounded:	Date Sold:	Lot number:	Prescription number:	Drug name and strength:
1/20/21	1/20/2021	01202021:65@71	376316	C-tretinoin/hydroquinone 0.05/4% cream
1/27/2021	1/28/2021	1272021:41@98	376967	C-Clobetasol 0.055% Shampoo
1/13/2021	1/13/2021	01132021:19@73	376002	C-Nystatin 250000u/ml susp.
1/4/2021	1/14/2021	01042021:68@87	376129	C-DHEA/Pregnenolone 50/25mg IR capsule
12/23/2020	1/4/2021	12232020:17@27	375354	C-Calcipotriene/Fluorouracil 0.005/5% cream
1/29/2021	2/1/2021	01292021:52@88	359934	C-Hydroquinone /Tretinoin/Ascorbic Acid 6/0.1/0.05% cream
1/8/2021	1/29/2021	01082021:34@18	377145	C-Tretinoin/Ascorbic Acid 0.1/0.5% cream
1/22/2021	1/26/2021	01222021:59@77	376708	C-Fluorouracil/Salicylic cream 5%/30% cream
1/22/2021	1/25/2021	1/22/2021:07@81	357232	C-Naltrexone IR AviCel 4.5mg capsule
1/13/2021	2/5/2021	1/13/2021:75@52	361779	C-Tacrolimus 0.12% cream

NINTH CAUSE FOR DISCIPLINE

(Failure to Include Instructions for Storage)

40. Respondent is subject to disciplinary action under California Code of Regulations section 1735.4(a)(3) in that on or about and between January 20, 2021 and February 5, 2021, Respondent was found to have prescription labels for compounded drugs which were sold/shipped into California which did not state the storage instructions on the prescription labels for the following compounded drugs in Table 6 below:

Table 6 Compounding Drugs with no Storage Instructions

Date compounded:	Date Sold:	Lot number:	Prescription number:	Drug name and strength:
1/20/21	1/20/2021	01202021:65@71	376316	C-tretinoin/hydroquinone 0.05/4% cream
1/27/2021	1/28/2021	1272021:41@98	376967	C-Clobetasol 0.055% Shampoo
1/13/2021	1/13/2021	01132021:19@73	376002	C-Nystatin 250000u/ml susp.
1/4/2021	1/14/2021	01042021:68@87	376129	C-DHEA/Pregnenolone 50/25mg IR capsule
12/23/2020	1/4/2021	12232020:17@27	375354	C-Calcipotriene/Fluorouracil 0.005/5% cream
1/29/2021	2/1/2021	01292021:52@88	359934	C-Hydroquinone /Tretinoin/Ascorbic Acid 6/0.1/0.05% cream
1/8/2021	1/29/2021	01082021:34@18	377145	C-Tretinoin/Ascorbic Acid 0.1/0.5% cream
1/22/2021	1/26/2021	01222021:59@77	376708	C-Fluorouracil/Salicylic cream 5%/30% cream
1/22/2021	1/25/2021	1/22/2021:07@81	357232	C-Naltrexone IR AviCel 4.5mg capsule
1/13/2021	2/5/2021	1/13/2021:75@52	361779	C-Tacrolimus 0.12% cream

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TENTH CAUSE FOR DISCIPLINE

(Sales of Misbranded Drugs)

41. Respondent is subject to disciplinary action under Code section 4169(a)(3) in that on or about and between January 20, 2021 and February 5, 2021, Respondent sold and shipped into California dangerous drugs that Respondent knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code, as follows:

A. The following drugs were misbranded as the strength on the prescription label was different than the potency discovered on testing the product:

- C-Testosterone 3mg mini-Troche, lot number: 04172017:31@47NF, date compounded: 4/19/2017, prescription number: C270069, quantity: 30, potency was 79.3%.
- C-T3 Liothyronine sodium, lot number: 04242017:14@2, date compounded: 4/24/2017, used as a component in compounding C-T4/T3 Levothyroxine/liothyronine SR 160/45mcg capsules on 5/9/2017, lot number: 05042017:68@27,prescription number: 282929, quantity: 60 capsules, liothyronine component potency was 111%.
- C-T3 Liothyronine sodium, lot number: 04242017:14@2, date compounded: 4/24/2017, used as a component in compounding C-T3 Liothyronine SR 22.5mcg capsules on 5/30/2017, lot number: 05092017:67@12,prescription number: 284765, quantity: 120 capsules, liothyronine component potency was 111%;

B. The following drug was labeled "SR" which was misbranded as the pharmacy did

- not have studies to back up their designation as "SR":

- C-Progesterone SR 200mg, Prescription no. 311143, fill date 1/19/2018, 180 capsules.

ELEVENTH CAUSE FOR DISCIPLINE

(False Advertising)

42. Respondent is subject to disciplinary action under Code section 651(b)(7) in that Respondent disseminated or cause to be disseminated any form of public communication containing a false, fraudulent, misleading, or deceptive statement, claim, or image for the purpose of or likely to induce, directly or indirectly, the rendering of professional services or furnishing of products in connection with the professional practice or business for which he Respondent is

licensed. The circumstances are as follows:

43. On or about and between January 20, 2021 and February 5, 2021, Respondent made a scientific claim on the labels of compounded drugs that cannot be substantiated by reliable, peer reviewed, published scientific studies as more fully set forth in paragraph 36 above.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Identify Pharmacy Personnel Involved in Compounding)

44. Respondent is subject to disciplinary action under California Code of Regulations section 1735.3(a)(2)(C) in that on or about and between January 20, 20210 and February 5, 2021, Respondents sold and shipped drugs into California which did not identify any of the pharmacy personnel engaged in compounding the drug preparation. In the following instances, the compounder did not initial the compounding record:

- C-Testosterone 3mg mini-Troche, lot number: 04172017:31@47NF, date compounded and sold on or around: 4/19/2017, prescription number: C270069, quantity: 30. There was no initial or signature on the compounding record stating who performed the actual compounding of the drug, nor was the reviewing pharmacist identified.

- C-T4/T3 Levothyroxine/liothyronine SR 160/45mcg capsules, lot number: 05042017:68@27, date compounded and sold on or around: 5/9/2017, prescription number: 282929, quantity: 60. There was no initial or signature on the compounding record stating who performed the actual compounding of the drug, nor was the reviewing pharmacist identified. There was no expiration date listed for component: methocel E4m from Medisca.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Identify Pharmacist Reviewing Compounding)

45. Respondent is subject to disciplinary action under California Code of Regulations section 1735.3(a)(2)(D) in that on or about and between January 20, 20210 and February 5, 2021, Respondents sold and shipped drugs into California which did not include the identity of the pharmacist reviewing the final drug preparation for those drugs as set forth more fully in paragraph 39 above.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Document the Expiration Date and Manufacturer)

46. Respondent is subject to disciplinary action under California Code of Regulations section 1735.3(a)(2)(F) in that on or about and between January 20, 20210 and February 5, 2021,

Respondents sold and shipped drugs into California which did not include documentation of the expiration date and manufacturer of the drug C-T4/T3 Levothyroxine/liothyronine SR 160/45mcg capsules, lot number: 05042017:68@27, as set forth more fully in paragraph 39 above.

FIFTEENTH CAUSE FOR DISCIPLINE

(Failure to Document Quality Reviews and Post-Compounding Procedures)

47. On or about and between January 20, 2021 and February 5, 2021, Respondent was found to have compounding records for compounded drugs which were sold/shipped into CA which did not state the quality reviews and required post compounding process and procedures in violation of California Code of Regulations section 1735.3(a)(2)(J) for the following compounded drugs:

- C-Testosterone 3mg mini-Troche, lot number: 04172017:31@47NF, date compounded and sold on or around: 4/19/2017, prescription number: C270069, quantity: 30. There was no visual appearance, weight of actual capsules, formula/calculations, integrity, uniformity, expected weights, packaging, storage, labeling, beyond use date or quantity checks.
- C-T4/T3 (levothyroxine/Liothyronine) SR 160/45mcg capsule, lot number: 05042017:68@27, date compounded and sold on or around: 5/9/2017, prescription number: 282929. There was no visual appearance, weight of actual capsules, formula/calculations, integrity, uniformity, expected weights, packaging, storage, labeling, beyond use date or quantity checks.

SIXTEENTH CAUSE FOR DISCIPLINE

(Failure to Include Instructions for Storage)

48. Respondent is subject to disciplinary action under California Code of Regulations section 1735.4(a)(3) in that on or about and between January 20, 2021 and February 5, 2021, Respondent was found to have prescription labels for compounded drugs which were sold/shipped into CA which did not state the storage instructions on the prescription labels for the following compounded drugs:

- C-Testosterone 3mg mini-Troche, lot number: 04172017:31@47NF, date compounded and sold on or around: 4/19/2017, prescription number: C270069, quantity: 30. There were no instructions for storage on the prescription label.
- C-T4/T3 (levothyroxine/Liothyronine) SR 160/45mcg capsule, lot number: 05042017:68@27, date compounded and sold on or around: 5/9/2017, prescription number: 282929. There were no instructions for storage on the prescription label.

- C-T3 (liothyronine) SR 22.5mcg capsules, lot number: 05262017:67@12, date compounded and sold on or around: 5/30/2017, prescription number: 284765, quantity: 120 capsules. There were no instructions for storage on the prescription label.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Failure to Include Date of Compounding on Label)

49. Respondent is subject to disciplinary action under California Code of Regulations section 1735.4(a)(5) in that on or about and between January 20, 2021 and February 5, 2021, Respondent was found to have prescription labels for compounded drugs which were sold/shipped into CA which did not state the date compounded on the prescription label for the following compounded drug:

- C-T3 (liothyronine) SR 22.5mcg capsules, lot number: 05262017:67@12, date compounded and sold on or around: 5/30/2017, prescription number: 284765, quantity: 120 capsules. The date the compounded drug was compounded was 5/30/2017 and this date is not listed on the prescription label.

DISCIPLINE CONSIDERATIONS

50. To determine the degree of discipline, if any, to be imposed on Respondent, Complainant alleges that on or about April 9, 2021, in a prior disciplinary action titled In the Matter of the Letter of Admonishment Against Foothills Professional Pharmacy before the Board of Pharmacy, in Case Number CI 2020 91053. Respondent's license was Admonished for a violation of Business and Professions Code section 4315 and 4301(n), Unprofessional Conduct, for discipline by another state agency. Specifically, on or about January 21, 2021, the Mississippi State Board of Pharmacy revoked Foothill Pharmacy's nonresident pharmacy license, denied their application for a compounding certificate, and issued a $230,000 monetary penalty (with $180,000 stayed) based on the pharmacy shipping approximately 46 compound drugs into the state without a compounding certificate. That decision is now final.

OTHER MATTERS

51. Pursuant to Code section 4307, if discipline is imposed in the Accusation against Nonresident Pharmacy License number NRP 2041 / NRP 2769, issued to Foothills Professional Pharmacy LTD, dba Foothills Professional Pharmacy; and Pujan A. Patel, Director, President and Secretary, shall be prohibited from serving as a manager, administrator, owner, member, officer,

director, associate, or partner of a licensee for five years if Nonresident Pharmacy License number NRP 2041 / NRP 2769 is placed on probation or until Nonresident Pharmacy License number NRP 2041 / NRP 2769 is reinstated if it is revoked.

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 Nonresident Pharmacy Permit Number NRP 2041/ NRP 2769, issued to Foothills Professional Pharmacy LTD dba Foothills Professional Pharmacy, Foothills Professional Pharmacy LTD dba Foothills Professional Pharmacy;

2. Revoking or suspending Nonresident Pharmacy Permit Number NRP 1275, issued to Foothills Professional Pharmacy LTD dba Foothills Professional Pharmacy, Foothills Professional Pharmacy LTD dba Foothills Professional Pharmacy;

3. Prohibiting the owners and managers of Respondent Foothills Professional Pharmacy LTD, dba Foothills Professional Pharmacy; and Pujan A. Patel, Director, President and Secretary, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy License number NRP 2041 / NRP 2769 is placed on probation or until Nonresident Pharmacy License number NRP 2041 / NRP 2769 is reinstated if it is revoked.

4. Ordering Foothills Professional Pharmacy LTD,dba Foothills Professional Pharmacy 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,

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

DATED: 7/24/2023

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2023.07.24 19:43:59 -07'00'

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