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

In the Matter of the Statement of Issues Against: **COLLEGE PHARMACY INC. DBA COLLEGE PHARMACY; JERRY GILLICK, PRESIDENT/TREASURER/ PHARMACIST-IN-CHARGE/CHIEF FINANCIAL OFFICER; KELLIE PLUSH, SECRETARY; JULIE RYDER, DIRECTOR** **3505 Austin Bluffs Pkwy, Ste. 101 Colorado Springs, CO 80918** **Nonresident Pharmacy Permit No. NRP 1034** **Nonresident Sterile Compounding Permit No. NSC 99550** Respondent.	Case No. 7358 **SECOND AMENDED STATEMENT OF ISSUES**

Complainant alleges:

PARTIES

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

2. On or about November 1, 2010, the Board issued Nonresident Pharmacy Permit Number NRP 1034 to College Pharmacy Inc. dba College Pharmacy ("Respondent"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2023, unless renewed.

3. On or about November 1, 2010, the Board issued Nonresident Sterile Compounding Permit Number NSC 99550 to Respondent. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and expired on November 1, 2022, and was not renewed.

4. Since on or about November 1, 2010, Jerry Gillick has been Respondent's President and Pharmacist In-Charge ("PIC"), and since on or about January 3, 2013, he has been Respondent's Treasurer and Chief Financial Officer. Since on or about January 3, 2013, Kellie Plush has been Respondent's Secretary. Since on or about January 12, 2013, Julie Ryder has been Respondent's Director.

5. In a disciplinary action titled *In the Matter of the Accusation Against: College Pharmacy, Inc., dba College Pharmacy,* Case No. 6461 ("*College Pharmacy Case 1*"), the Board issued a Decision and Order effective May 6, 2020, in which Respondent's Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit were revoked for (1) failure to perform method suitability testing, (2) failure to perform container closure integrity testing, (3) failure to perform stability testing, (4) failure to document post-compounding process and procedures, (5) compounding essentially a copy of a drug, (6) failure to properly use equipment, (7) failure to document a written master formula, (8) improper maximum beyond use data, and (9) unprofessional conduct. However, the revocation was stayed and Respondent's Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit were placed on probation for two years with certain terms and conditions. A true and correct copy of the Decision and Order in *College Pharmacy 1* is attached as Exhibit A, and is incorporated by reference as if fully set forth herein..

6. In a disciplinary action titled *In the Matter of the Accusation and Petition to Revoke Probation Against: College Pharmacy, Inc., dba College Pharmacy, et al.*, Case No. 7153

("*College Pharmacy Case 2*"), filed October 17, 2021 (amended February 3, 2022), currently pending, the Board seeks revocation of Respondent's Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit. *College Pharmacy 2* is based on similar continuing and repeated failures as *College Pharmacy 1* that were identified in the Board's 2020 and 2021 annual nonresident sterile compounding permit renewal inspection, in addition to other violations. Although the violations were referred to the Attorney General's Office for the prosecution of *College Pharmacy 2*, Respondent's nonresident sterile compounding permit was renewed in 2020 and 2021. A true and correct copy of the accusation and petition to revoke probation in *College Pharmacy 2* is attached as Exhibit B, and is incorporated by reference as if fully set forth herein.

JURISDICTION

7. This Second Amended Statement of Issues 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.

8. Section 4127.2, subdivision (c) of the Code, states:

> (c) A license to compound sterile drug products shall not be issued or renewed until regulations adopted by the board. The nonresident pharmacy shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually pursuant to subdivision (v) of Section 4400.

9. Section 4300 of the Code states, in pertinent part:

> (a) Every license issued may be suspended or revoked.
>
> . . .
>
> (c) The board may refuse a license to any applicant guilty of unprofessional conduct…
>
> . . .
>
> (e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

10. 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.

11. Section 4342, subdivision (a) of the Code, states:

(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

STATUTORY PROVISIONS

12. Bus. & Prof. Code section 4126.8 states:

The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The board may

13. Section 4169, subdivision (a) of the Code, states:

(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.

. . .

14. 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:

. . .

(j) The violation of any of the statutes of this state, of any other state, or of the United States 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.

15. Section 4306.5, subdivision (b) of the Code, states:

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or

regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

16. Health and Safety Code ("Health & Saf. Code") section 110110, subdivision (a), states:

> All regulations relating to (1) new drug applications, except for abbreviated new drug applications, adopted pursuant to Section 505 of the federal act (21 U.S.C. Sec. 355), (2) applications for premarket approval of new devices, adopted pursuant to Section 515 of the federal act (21 U.S.C. Sec. 360e), (3) postmarketing reports, recordkeeping, and other postapproval requirements for approved new drug applications or approved new device premarket approval applications, adopted pursuant to the federal act, that are in effect on January 1, 1993, or that are adopted on or after that date, shall be the new drug and new device application regulations of this state.

17. Health & Saf. Code section 111250 states: "any drug or device is adulterated if it consists, in whole or in part, of a filthy putrid, or decomposed substance."

18. Health and Saf. Code section 111255 states:

> 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.

19. Health and Saf. Code section 111260 states:

> Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

20. Health & Saf. Code section 111295 states: "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

21. Health and Saf. Code section 111550 states, in pertinent part:

> No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:
>
> (a) It is one of the following:

(1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).

. . .

(b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended. Any person who files a new drug or device application with the department shall submit, as part of the application, all of the following information:

(1) Full reports of investigations that have been made to show whether or not the new drug or device is safe for use and whether the new drug or device is effective in use under the conditions prescribed, recommended, or suggested in the labeling or advertising of the new drug or device.

(2) A full list of the articles used as components of the new drug or device.

(3) A full statement of the composition of the new drug or device.

(4) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new drug, or in the case of a new device, a full statement of its composition, properties, and construction, and the principles of its operation.

(5) Samples of the new drug or device and of the articles used as components of the drug or device as the department may require.

(6) Specimens of the labeling and advertisements proposed to be used for the new drug or device.

REGULATORY PROVISIONS

22. California Code of Regulations ("CCR"), title 16, section 1735.1, subdivision (ae) states:

"Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

23. CCR, title 16, section 1735.2, states, in part:

. . .

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

. . .

(*l*) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

24. CCR, title 16, section 1735.3, subdivision (c) states:

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA- registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any corresponding chemical, bulk drug substance, or drug products received.

25. CCR, title 16, section 1751.7, subdivision (e) states, in part:

(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

26. CCR, title 16, section 1751.8, subdivision (f), states:

(f) The beyond use date for any compounded allergen extracts shall be the

earliest manufacturer expiration date of the individual allergen extracts.

27. CCR, title 16, section 1774, subdivision (a), states, in part:

(a) Unless otherwise directed by the Board, any pharmacy permit which is on probation to the Board shall be subject to the following conditions:

(1) Obey all laws and regulations substantially related to the practice of pharmacy;

. . .

FEDERAL AUTHORITIES

28. United States Code, title 21, section 353a(b)(1)(A)(ii) states:

. . .

(b) Compounded drug

(1) Licensed pharmacist and licensed physician

A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician –

. . .

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations –

. . .

(ii) that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title)

29. Code of Federal Regulations, title 21, section 207.3 states:

Bulk drug substance, as referenced in sections 503A(b)1(A) and 503B(a)(2) of the Federal Food, Drug, and Cosmetic Act, previously defined in § 207.3(a)(4), means the same as "active pharmaceutical ingredient" as defined in § 207.1.

DANGEROUS DRUGS PURSUANT TO BUS. & PROF. CODE SECTION 4022

30. Methylcobalamin (vitamin B12) is a non-FDA approved vitamin supplement.

31. Nicotinamide Adenine Dinucleotide ("NAD") is a non-FDA approved metabolic cofactor.

32. Pyridoxine (vitamin B6) is FDA approved and has several uses including pyridoxine deficiency, prevention or treatment of drug induced neurotoxicity, or metabolic disorders.

33. Hydroxocobalamin (vitamin B12a) is FDA approved and used for cyanide poisoning and as a vitamin B12 supplement.

34. Allergen Extracts (various) are used in diagnostic testing and immunotherapy.

BACKGROUND INFORMATION

35. Respondent is a nonresident specialty compounding pharmacy that provides services such as nonsterile compounding (e.g. topicals such as creams) and nonsterile to sterile compounding (e.g. injectables). Respondent is licensed in approximately 45 states, and sends hundreds of compounded preparations into California annually. Respondent also has an online store selling nutritional supplements.

36. In preparation for Respondent's onsite annual nonresident sterile compounding renewal inspection, on or about July 15, 2022, the Board Inspector requested numerous documents for evaluation, which Respondent provided on or about August 1, 2022. On or about August 16, 2022, the Board conducted Respondent's annual onsite nonresident sterile compounding permit renewal inspection.

37. After review of Respondents records and the onsite inspection, the Board Inspector found that between July 1, 2021 and July 1, 2022, Respondent compounded and shipped to California at least 393 prescriptions for Pyridoxine HCI (MVA) 0.05 mg/ml injectables, 92 prescriptions for NAD PF 100 mg/ml injectables, 12 prescriptions for Methylcobalamin Pres 1 mg/ml injectables, 4 prescriptions of Methylcobalamin Pres 10 mg.ml injectables, and 9 prescriptions for Methylcobalamin Pres 25 mg/ml injectables, all of which lacked quality and were adulterated. These were repeat violations of pharmacy law; in fact, these violations were found during the Board's 2021 and 2020 onsite annual nonresident sterile compounding renewal inspections, and resulted in disciplinary action referenced above.

38. Additionally, Respondent obtained and compounded with bulk drug substances, namely NAD powder and MVA complex solution, that were not manufactured by a Food and Drug Administration ("FDA") registered establishment. This, too, was a repeat violation of pharmacy law, also found during the Board's 2021 and 2020 onsite annual nonresident sterile compounding renewal inspections, resulting in disciplinary action referenced above.

39. On or about August 19, 2022, the Board served on Respondent its notice denying the renewal of Respondent's nonresident sterile compounding permit. On or about August 26, 2022, Respondent served on the Board its appeal of the denial of the renewal of its nonresident sterile compounding permit.

STATEMENT OF ISSUES

FIRST CAUSE FOR DENIAL

(Preparation and Sale of Adulterated Drugs)

40. Respondent's application for renewal is subject to denial pursuant to Code sections 4126.8, 4169, subdivision (a)(2), 4301, subdivisions (j) and (o), and Health and Saf. Code sections 111250, 111255 and 111295, in that at the time of the 2022 annual renewal inspection, Respondent's Methylcobalamin and NAD injectables were made with ungraded Active Pharmaceutical Ingredients[1] (APIs) and its poly-MVA complex solution used in compounding Pyridoxine HCL (MVA) is a dietary grade supplement solution, a repeated violation, as set forth in paragraphs 35 through 39, incorporated herein.

SECOND CAUSE FOR DENIAL

(Bulk Drug Compounding From Nonregistered Establishments)

41. Respondent's application for renewal is subject to denial pursuant to Bus. & Prof. Code section 4301, subdivisions (j) and (o), Health & Saf. Code sections 110110 and 111550 and/or CCR, title 16, section 1735.3, subdivision (c), in that Respondent obtained and compounded with bulk drug substances, namely MVA and NAD complex solution, that were not manufactured by an FDA registered drug establishment. More specifically, the manufacturer for Pyridoxine HCL (MVA) on Respondent's compounding log was El-Gen LLC, and the manufacturer of the NAD powder was Syncozymes, neither of which was found on the FDA's Registered Drug Establishment website. These are repeated violations, as set forth in paragraphs 35 through 39, incorporated herein.

[1] An active pharmaceutical ingredient is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, or prevention of disease, or affect the structure of any function of the body.

THIRD CAUSE FOR DENIAL

(Unprofessional Conduct)

42. Respondent's application for renewal is subject to denial pursuant to Code section 4306.5, subdivision (b), in that Respondent has committed acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of professional services. More specifically, (1) Respondent continues to compound sterile preparations from ungraded APIs (i.e. NAD and Methylcobalamin), (2) Respondent failed and continues to fail to obtain manufacturer's information from its supplier, while continuing to purchase and utilize product from those manufacturers, and (3) Respondent continues compounding sterile preparations from products whose manufacturers are not registered with the FDA; all as set forth in paragraphs 31, 32, 34 and 35 above, and incorporated herein. This is a repeated violation, as set forth in paragraphs 35 through 39, incorporated herein.

FOURTH CAUSE FOR DENIAL

(Failure to Obey All Laws)

43. Respondent's application for renewal is subject to denial under CCR, title 16, section 1774, subdivision (a), in that at all times after the effective date of Respondent's probation, Condition 2 stated, in pertinent part: Respondent shall obey all state and federal laws and regulations. As set forth above, (1) Respondent continues to compound sterile preparations from ungraded APIs (i.e. NAD and Methylcobalamin), (2) Respondent failed and continues to fail to obtain manufacturer's information from its supplier, while continuing to purchase and utilize product from those manufacturers, and (3) Respondent continues compounding sterile preparations from products whose manufacturers are not registered with the FDA; all as set forth in paragraphs 31, 32, 34 and 35 above, and incorporated herein. This is a repeated violation, as set forth in paragraphs 35 through 39, incorporated herein.

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AGGRAVATING FACTORS

44. In addition to the repeated violations set forth above, Complainant alleges that Respondent was disciplined by the Board on or about October 20, 2010, in a prior disciplinary action entitled *In the Matter of the Statement of Issues Against: College Pharmacy,* Case No. 3445. Respondent's permits were issued, revoked, and placed on seven years' probation for out-of-state-discipline in several states. That decision is now final. A copy of the decision is attached as Exhibit C, and is incorporated by reference as if fully set forth herein.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this Second Amended Statement of Issues, and that following the hearing, the Board of Pharmacy issue a decision:

1. Upholding the nonrenewal of Nonresident Sterile Compounding Permit No. NSC 99550, issued to College Pharmacy Inc. dba College Pharmacy, and;

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

DATED: 12/12/2023

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2023.12.12 15:21:16 -08'00'

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

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