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

In the Matter of the Accusation and Statement of Issues Against**:** **BOOTHWYN PHARMACY LLC; LOUISE M. MICOLUCCI, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ALI ZERAFATI, PHARMACIST-IN-CHARGE (11/24/24-present), MARTIN J. FARRELL, PHARMACIST-IN-CHARGE (10/5/23-11/13/24)** **221 Gale Lane** **Kennett Square, PA 19348** **Nonresident Pharmacy Permit No. NRP 1963** **Nonresident Sterile Compounding Permit No. NSC 101082** **Application for Renewal of Nonresident Sterile Compounding Permit** Respondent.	Case No.s 8175 & 8060 **ACCUSATION** **AND** **STATEMENT OF ISSUES**

PARTIES

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

2. On or about July 10, 2017, the Board issued Nonresident Pharmacy Permit number NRP 1963 (NRP) to Boothwyn Pharmacy with Louise M. Micolucci, President and Chief

Executive Officer; Ali Zerafati, Pharmacist-in-charge (PIC) from November 24, 2024, to present; and Martin J. Farrell, PIC and Director of Pharmacy from October 5, 2023, to November 13, 2024 (Respondent). The NRP was in full force and effect at all times relevant to the charges brought herein and expired on July 1, 2026, and has not yet been renewed.

3. On or about July 10, 2017, the Board issued Nonresident Sterile Compounding Permit Number NSC 101082 (NSC) to Respondent. The NSC was in full force and effect at all times relevant to the charges brought herein and expired on July 1, 2025, and has not been renewed due to the denial of the renewal application set forth in paragraph 4, below.

4. On or about June 12, 2025, the Board received a renewal application for a Nonresident Sterile Compounding Pharmacy Permit from Respondent. On or about June 11, 2025, Louis Micolucci, on behalf of Respondent, certified under penalty of perjury to the truthfulness of all statements, answers, and representations in the applications. The Board denied the application on June 24, 2025, and therefore the NSC was not renewed and expired on July 1, 2025.

JURISDICTION

5. This Accusation and 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.

6. Section 4011 of the Code states:

The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

7. 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. The bard may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the following:

(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.

8. 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.

9. Section 4302 of the Code states:

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.

10. 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.

…

11. Section 4342 of the Code states in pertinent part:

(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 & Safety Code).

STATUTORY PROVISIONS

12. Section 480 of the Code states in pertinent part:

(a) Notwithstanding any other provision of this code, a board may deny a license regulated by this code on the grounds that the applicant has been convicted of a crime or has been subject to formal discipline only if either of the following conditions are met:

. . .

(2) The applicant has been subjected to formal discipline by a licensing board in or outside California within the preceding seven years from the date of application based on professional misconduct that would have been cause for discipline before the board for which the present application is made and that is substantially related to the qualifications, functions, or duties of the business or profession for which the present application is made. However, prior disciplinary action by a licensing board within the preceding seven years shall not be the basis for denial of a license if the basis for that disciplinary action was a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, 1203.42, or 1203.425 of the Penal Code or a comparable dismissal or expungement. Formal discipline that occurred earlier than seven years preceding the date of application may be grounds for denial of a license only if the formal discipline was for conduct that, if committed in this state by a physician and surgeon licensed pursuant to Chapter 5 (commencing with Section 2000) of Division 2, would have constituted an act of sexual abuse, misconduct, or relations with a patient pursuant to Section 726 or sexual exploitation as defined in subdivision (a) of Section 729.

. . .

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:

…

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

…

(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.

…

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(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

(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 4022 of the Code states:

Dangerous drug or dangerous device means any drug or device unsafe for self-use in humans or animals, and includes 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.

15. Section 4076 of the Code states in pertinent part:

(a) A pharmacist shall not dispense a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

. . .

(2)The directions for the use of the drug.

(3)The name of the patient or patients.

. . .

(5)The date of issue.

(6)The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7)The strength of the drug or drugs dispensed.

(8)The quantity of the drug or drugs dispensed.

(9)The expiration date of the effectiveness of the drug dispensed.

. . .

16. Section 4126.8 of the Code 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 adopt regulations to impose additional standards for compounding drug preparations.

17. Section 4127.2 of the Code states in pertinent part:

…

> (c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any 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.
>
> . . .
>
> (e) A pharmacy licensed pursuant to this section shall do all of the following:
>
> …
>
> (3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.
>
> (4) Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.
>
> (f) Adverse effects reported or potentially attributable to a nonresident pharmacy's sterile compounded drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration…

PENNSYLVANIA PHARMACY ACT

18. Section 27.601 of the Pennsylvania Pharmacy Act states:

The compounding of sterile and nonsterile preparations shall be done in accordance with section 503a of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 353a), Federal regulations promulgated thereunder, and the current version of the USP chapters governing compounding.

REGULATORY PROVISIONS

19. California Code of Regulations, title 16, (Regulations) section 1707.5 states in pertinent part:

> (a) Labels on drug containers dispensed to patients in California shall conform to the following format:
>
> (1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:
>
> (A) Name of the patient
>
> (B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the statement "generic for " where the brand name is inserted and the name of the manufacturer. In the professional judgment of the pharmacist:
>
> (i) If the brand name is no longer widely used, the label may list only the generic name of the drug, and
>
> (ii) The manufacturer's name may be listed outside of the patient-centered area.
>
> (C) The directions for the use of the drug.
>
> (D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.
>
> (2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).
>
> (3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.
>
> . . .

20. Regulations section 1736.12 states, in pertinent part:

> (c) A pharmacist performing or who has direct supervision and control of compounding personnel is responsible for ensuring injectable CSPs made from nonsterile components, regardless of USP Category, are tested to ensure that they do not contain excessive bacterial

endotoxins, as established in USP Chapter 85, Bacterial Endotoxins. Results shall be reviewed and documented in the compounding record prior to furnishing.

21. Regulations section 1751.7[1] states, in pertinent part:

> (e)(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.

COST RECOVERY

22. 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.

DEFINITIONS

23. **The United States Pharmacopeia (USP)** is an independent, non-governmental, not-for-profit organization that sets quality, purity and strength standards for medicines, food ingredients and other products sold in the United States. USP is an official quality standard for medicines marketed in the U.S. The Food and Drug Administration (FDA) works closely with USP to enforce USP's standards, which are often called monographs[2].

24. **The United States Pharmacopeia-National Formulary (USP-NF)** is a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). It includes over 5,000 quality standards for medicines, both chemical and biologic; active pharmaceutical ingredients (APIs); and excipients (inactive ingredients). It is the most

[1] Regulations section 1751.7 was repealed effective October 1, 2025. However, new Regulations section 1736.12, subdivision (c), effective October 1, 2025, contains the same relevant requirements. Regulations section 1736.12 is included herein for reference.

[2] Monographs articulate the quality expectations for a medicine including for its identity, strength, purity, and performance. They also describe the tests to validate that a medicine and its ingredients meet these criteria.

comprehensive source for medicine quality standards in the world. The standards in USP-NF[3] are used to help ensure the quality of medicines and their ingredients, and to protect the safety of patients.

25. **Standard Operating Procedure (SOP)** is a documented method or set of written directions to complete a specific process(es).

26. **USP 797** is a publication issued by the United States Pharmacopeia (USP) that sets forth standards for preparing compounded sterile preparations (CSPs).

27. **Endotoxin** is a toxin that is present inside a bacterial cell and is released when the cell disintegrates.

28. **Bacterial Endotoxin testing** (BET) is a quality control process used to detect and quantify bacterial endotoxins, ensuring the safety of pharmaceuticals, medical devices, and injectable products.

DRUG DESCRIPTIONS

29. **Methylcobalamin** (methyl vitamin B12) is the synthetic and active form of cobalamin (vitamin B12). Methylcobalamin can be compounded into an oral or injectable form; however, the injectable form is not an FDA approved drug to treat any disease or disorder. Methylcobalamin is a dangerous drug pursuant to Code section 4022.

30. **Trizepatide** is an injection used for weight loss, weight management and weight related conditions. Trizepatide is FDA-approved for use in adults to treat diabetes. Trizepatide is a dangerous drug pursuant to Code section 4022.

31. **Semaglutide** is the generic name for Ozempic and is used for weight loss and type 2 diabetes treatment. Semaglutide can be compounded into an oral or injectable form. Semaglutide is a dangerous drug pursuant to Code section 4022.

32. **Pentosan Polysulfate** is used to treat bladder pain and discomfort related to interstitial cystitis. Pentosan Polysulfate is a dangerous drug pursuant to Code section 4022.

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[3] USP-NF standards deemed official by USP are enforceable by the FDA for medicines manufactured and marketed in the U.S.

33. **Glucosamine** is a sugar protein that helps your body build cartilage. Glucosamine has been used in alternative medicine as an aid for relieving joint pain, swelling and stiffness caused by arthritis.

34. **Glycine** is an amino acid commonly used as a component of total parenteral nutrition and is also used as irrigation during surgery.

INTRODUCTION

35. This case is about the compounding of prescription drugs, including those designated for sterile administration, in a pharmacy. Pharmacy compounding can be either sterile or nonsterile, but the definition is the same, to combine, admix, dilute, pool, reconstitute other than as provided in the manufacturer's labeling, or otherwise alter a drug product or bulk drug substance to create a nonsterile or sterile preparation. (USP chapters 795 and 797.)

36. Compounding is a form of drug manufacturing subject to the drug manufacturing requirements of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 301 et seq.]. Compounding in a pharmacy as a form of drug manufacturing is permitted under federal law by section 503A of the FDCA [21 U.S.C. § 353a].

37. The Food and Drug Administration (FDA) oversees drug manufacturing, but does not license pharmacies or pharmacists, nor control when or how their licenses permit compounding. The states issue these licenses and have primary jurisdiction. The states also set compounding standards that complement FDA standards for compounding as a form of drug manufacturing.

38. Pharmacists and pharmacies engaging in compounding drug preparations for use in California are subject to both federal and California law, and both federal and California law require compounding pharmacists and pharmacies to comply with applicable Pharmacopeia chapters governing compounding practices. (See Section 503A of the FD&C Act (21 U.S.C. § 353a); see also section 4126.8 of the Code.)

39. California law authorizes the Board to treat violations of federal statutes regulating controlled substances and dangerous drugs, as well as federal laws and regulations governing pharmacy practice, as grounds for discipline. (Bus. & Prof. Code §§ 4301, subds. (j), (o); 4342.)

40. Among the federal law requirements for pharmacy compounding is that bulk drug substances used for compounding: (1) must comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, must be components of drugs already otherwise approved by the Secretary; or (3) if such a monograph does not exist and the substance is not a component of a drug approved by the Secretary, must appear on a list promulgated in regulation by the Secretary. (21 U.S.C. § 353a(b)(1)(A)(i).) Each bulk drug substance must also be manufactured by an FDA registrant and be accompanied by a valid certificate of analysis. (21 U.S.C. § 353a(b)(1)(A)(ii) and (iii).)

41. Under both federal and California law, *any* manufactured drug, including a pharmacy compound, must not be "adulterated" by containing "any filthy, putrid, or decomposed substance" *or* by having been "prepared, packed, or held under insanitary conditions whereby it *may have* been contaminated with filth, or whereby it *may have* been rendered injurious to health." (21 U.S.C. § 351(a)(1) and (a)(2)(A) [definitions of "adulterated"] (emphasis added); 21 U.S.C. § 331(a), (b), (c) [adulterated drug prohibition]; Health & Saf. Code, §§ 111250, 111255 [definitions of "adulterated"] (emphasis added); Health & Saf. Code, § 11295 [adulterated drug prohibition].)

42. Compounds may be either "non-sterile" or "sterile," depending on the intended route of drug administration. Sterile drugs are those intended for parenteral administration (i.e., other than through the digestive system), including injectables and ophthalmic or inhalation drugs in aqueous format. It is important that these drugs be sterile and uncontaminated, because they bypass some of the body's natural defenses against pathogens and impurities.

43. California law allows all licensed pharmacists to compound *non-sterile* drug products in licensed pharmacies. (See e.g., Bus. & Prof. Code, §§ 4037, 4051, 4110.)

44. An additional specialty license is required before any licensed pharmacy is allowed to compound *sterile* drug products. (Bus. & Prof. Code, § 4127 *et seq*.) And particular regulatory requirements apply to preparation, maintenance, and distribution of sterile drug products. (Cal. Code Regs., tit. 16, § 1736 *et seq.*)

45. All compounding, whether sterile or non-sterile, must be consistent with standards in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary (USP-NF), including relevant testing and quality assurance standards. (Bus. & Prof. Code, § 4126.8.) The Pharmacy Law also contains additional standards that supplement the USP-NF standards. (*Id.*; see, e.g., Bus. & Prof. Code, §§ 4126.10, 4127 *et seq*., 4129 *et seq*., Cal. Code Regs., tit. 16, §§ 1736 *et seq*.)

46. Each sterile compounding pharmacy must be inspected prior to each annual renewal of a sterile compounding license to ensure compliance with all compounding and sterile compounding requirements. (Bus. & Prof. Code, § 4127.1, subd. (c).) Out-of-state sterile compounding pharmacies must also have this specialty license and are also annually inspected. (Bus. & Prof. Code, § 4127.2, subd. (c).) All of this demonstrates the attention and resources devoted to sterile drug compounding. This is because of the unique risks posed by sterile drug products. In 2012, for instance, a contaminated sterile drug compound was widely distributed, and caused a nationwide fungal meningitis outbreak, killing 64 people and causing infections in almost 800 others who received the drug.

47. In this case, Respondent has engaged in significant compounding of drug products intended for sterile administration. Respondent significantly exceeded the USP limits on batch sizes, intended to protect the public by ensuring that only a certain number of patients could be affected by adulterated batches, by creating larger "master" batches and then dividing the amount of product that went into each master batch and documenting the creation of smaller, appropriately sized batches. In fact, Respondent could not know that each batch had exactly equal amounts of each product, and this could have caused greater harm to the public by exposing patients to larger adulterated batches. In addition, Respondent falsified end product testing results and submitted those false results to the federal Food and Drug Administration (FDA), dispensed inappropriately labeled drugs, and dispensed drugs before completing end product testing.

BACKGROUND INFORMATION

48. Respondent owns and operates a pharmacy in the State of Pennsylvania which is licensed as a nonresident pharmacy by the Board. A nonresident pharmacy license allows

Respondent to ship non-sterile drug preparations into California for use by California consumers. Respondent also had a nonresident sterile compounding pharmacy permit which allowed them to ship sterile compounded drug products into California for use by California consumers.

March 26, 2025, Renewal Inspection

49. This inspection relates to the renewal inspection for Respondent's application for renewal of their NSC license.

50. Between March 27, 2025, and April 23, 2025, the Board received multiple emails from former PIC and Director of Pharmacy Martin Farrell sent on behalf of Respondent that copied the current PIC Zerafati for Respondent pharmacy. These emails contained, but are not limited to, the following: changes in the organization chart, records showing Respondent's dispensing of compounded sterile preparation prescriptions dispensed into California on and between March 1, 2024 to February 28, 2025, information regarding changes to the compounding area since the last inspection, and a copy of inspections performed at Respondent pharmacy in the last twelve months.

51. Upon review of the FDA 438 report issued for an inspection of Respondent pharmacy conducted on and between September 23, 2024, to October 22, 2024, it showed the following findings, including but not limited to:

52. On and between April 20, 2023, to July 11, 2023, Respondent distributed seven (7) batches of drug products using certificates of analysis (COAs) containing passing testing results for BET when in fact, the COAs pulled from Respondent's contracted testing laboratory's database indicated that the results of the BET were out of specification (OOS).

53. On and between March 2023 to August 2024, Respondent pharmacy distributed thirty-one (31) batches of CSPs which had received an OOS result for BET from Respondent's contracted lab.

54. Respondent distributed six (6) batches of CSPs without conducting endotoxin testing.

55. Smoke study videos were not representative of production operations as the second operator did not match SOPs requiring only one trained pharmacist or technician in ISO Class 5

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environment; tubing and connection on videos were touching the product contact end stoppers; first air was being blocked at multiple instances.

56. OOS Investigation reports for 18 of 31 batches of CSPs were generated specifically for the purpose of the FDA Inspection. Firm management stated none of the actions identified in those investigation reports were taken, nor was there an investigation onto the root cause for the failing endotoxin results. Investigations contained call logs indicating patients/prescribers were contacted about the failed BET and to inquire about adverse effects due to contaminated CSPs.

57. Quality unit did not conduct final review or approval of COAs received from contracted lab- of the 31 batches with OOS, 7 results were altered to show passing BET results.

58. Respondent did not verify the conformance of a product to the manufacturer COA for any of the active pharmaceutical ingredients to ensure that components utilized by were pharmaceutical grade.

59. On or around October 22, 2024, Respondent's former PIC and Director of Pharmacy Martin Farrell[4] provide a sworn statement to the FDA in which he admitted, "During an FDA inspection, I made the regrettable decision to alter certain Certificates of Analysis (COAs) for glucosamine-containing Compounded Sterile Preparations (CSPs). I did this in an effort to downplay the extent of the out-of-specification (OOS) results for these CSPs." Farrell went on to further admit, "…call logs were falsely created to demonstrate that all dispensing parties had been informed about the OOS results presented to the FDA. These documents were intended to show that there were no reported adverse effects associated with the OOS results for the glucosamine-containing CSPs."

60. On or around March 27, 2025, Inspector S.P. conducted an onsite inspection for the sterile compounding license renewal at Respondent pharmacy. During the inspection PIC Zerafati and prior PIC Farrell were present. During the inspection, Inspector S.P. observed the following including but not limited to:

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[4] Farrell in a statement sworn statement to the Board stated as a result of his actions Respondent reassigned him to a non-clinical administrative pharmacist role effective November 14, 2024.

61. On or between April 2024 to April 2025, Respondent compounded and dispensed at least 2,783 final yield units of compounded sterile preparations into California by producing false and misleading compounding records, which documented quantities of APIs which were not weighed and manipulated as documented. Respondent instead documented the total quantities weighed and manipulated for each lot's respective stock solution and then assumed that the API was evenly distributed throughout the resulting large batch and documented that each individual batch made from the larger lot was made with an even division of the API as though it had been weighed out individually even though it was not. The chart below shows the 2,783 final yield of compounded sterile preparations:

Table of False Weights on Compounding Records:

Lot Number	Preparation	Weight of API	Dispensing into California
01172025@1	Tirzepatide 10mg/ml inj sol	**11.2 gm**	**563 units**
01172025@2	Tirzepatide 10mg/ml inj sol	**11.2 gm**	
01172025@3	Tirzepatide 10mg/ml inj sol	**11.2 gm**	
01172025@4	Tirzepatide 10mg/ml inj sol	**11.2 gm**	
01172025@17 stock solution	Tirzepatide 10mg/ml inj sol	42.030 gm	
01282025@1	Semaglutide 2.5mg/ml inj sol	**1.25 gm**	**680 units**
01282025@2	Semaglutide 2.5mg/ml inj sol	**1.25 gm**	
01282025@4	Semaglutide 2.5mg/ml inj sol	**0.5 gm**	
01282025@5	Semaglutide 2.5mg/ml inj sol	**0.5 gm**	
01282025@8 stock solution	Semaglutide 2.5mg/ml inj sol	4.803 gm	
03042025@7	Semaglutide 2.5mg/ml inj sol	**1.25 gm**	**345 units**
03042025@8	Semaglutide 2.5mg/ml inj sol	**1.25 gm**	
03042025@29 stock solution	Semaglutide 2.5mg/ml inj sol	2.938 gm	
02112025@1	Tirzepatide 10mg/ml inj sol	**11.2 gm**	**439 units**
02112025@2	Tirzepatide 10mg/ml inj sol	**11.2 gm**	
02112025@3	Tirzepatide 10mg/ml inj sol	**11.2 gm**	
02112025@10 stock solution	Tirzepatide 10mg/ml inj sol	**unknown**	
01292025@1	Semaglutide 2.5mg/ml inj sol	**1 gm**	**756 units**
01292025@2	Semaglutide 2.5mg/ml inj sol	**1 gm**	
01292025@3	Semaglutide 2.5mg/ml inj sol	**0.625 gm**	
01292025@4	Semaglutide 2.5mg/ml inj sol	**0.625 gm**	
01292025@5	Semaglutide 2.5mg/ml inj sol	**0.625 gm**	
01292025@7 stock solution	Semaglutide 2.5mg/ml inj sol	4.312 gm	

62. Respondent shipped the CSPs from various lots into California both before and after the OOS results of release testing were known and failed to immediately notify the prescriber of the OOS test with the potential to cause patient harm, as depicted in the chart below. Additionally, Respondent did not properly execute procedures to investigate if other lots were affected and recall them if necessary.

Table of Batches with Failed Testing:

Lot Number	Preparation	Units into CA	End Product Testing	Prescriber Notified Immediately	Recall of dispensed CSPs	Quarantine remaining stock
01172025@1	TIRZEPATIDE 10 MG/ML (4ml)-compounded from stock solution	127	**Potency: 86.8% - failed 1/21/25**	no	no	no
02112025@2	TIRZEPATIDE 10 MG/ML (4ml)-compounded from stock solution	147	**Potency: 89.1% failed 2/17/25**	no	no	no
03042025@8	SEMAGLUTIDE 2.5 MG/ML (2ml)-compounded from stock solution	191	**Potency Failed 79.9%**	no	no	no
03202025@4	Semaglutide 2.5 mg/mL Inj. Vial – compounded from stock solution	88	**Potency failed: (77.1% 1.9285mg/ml** on 3/24/2025) ARL confirmed result 4/2/2025	no	no	Not until 7/10/2025
03272025@17	FLUORESCEIN 2%0PHTH SOLN (3ml)	20	**Potency failed: 75.9% (4/25/25), 76.4% (4/25/25), 76.1% (4/25/25)**	no	no	Not until 7/9/2025
04072025@58	TIRZEPATIDE/GLYCINE/METHYLCOBAL (1ml)	80	ScanRDI: **Failed 5/8/25**	no	no	no
01222025@41	PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML)	15	**Endotoxin failed (18437 vs 416.6**)	no	no	no
04302024@17	ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION	8	**Endotoxin failed-(603.96 EU vs 250 EU)**	no	no	no
10062023@2	HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	2	**Endotoxin failed-(559.99 EU vs 250 EU)**	no	**no**	no
12022024@3	ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION	24	**Endotoxin failed (287EU vs 250)**	no	**no**	no
12302024@14	PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML)	13	**Endotoxin failed (1718.24 EU vs 416.67EU)**	no	**no**	no

63. Respondent compounded and assigned a beyond use date of 120 days under frozen conditions and dispensed at least 2,783 units of the following compounded sterile preparations without stability studies to indicate the stability of the compounded preparations under frozen conditions.

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Table of Non-Compliant BUDs:

Preparation	Date Compounded	Lot Numbers/Yield	BUD (requires sterility testing)	Final yield Units Compounded	Units Dispensed into CA
TIRZEPATIDE 10 MG/ML	1/17/2025	01172025@1/250 x4.1ml; 01172025@2/250x4.1ml; 01172025@3/245x4.1ml; 01172025@4/250x4.1ml	5/17/25 (120days) frozen	995 units	563
SEMAGLUTIDE 2.5 MG/ML INJ	1/28/2025	01282025@1/249x2.1ml; 01282025@2/240x2.1ml; 01282025@4/219x1ml	5/28/25 (120days) frozen	708 units	680
SEMAGLUTIDE 2.5mg/ml	1/29/2025	01292025@1/225x1.7ml; 01292025@2/225x1.7ml; 01292025@3/220x1.2ml; 01292025@3/200x1.2ml; 01292025@5/230x1.2ml.	5/29/25 (120days) frozen	1100 units	756
TIRZEPATIDE 10 MG/ML	2/11/2025	02112025@1/250x4.1ml; 02112025@2/250x4.1ml; 02112025@3/250x4.1ml	6/11/25 (120days) frozen	750 units	439
SEMAGLUTIDE 2.5 MG/ML	3/4/2025	03042025@7/250x2.1ml; 03042025@8/250x2.1ml	7/2/25 (120days) frozen	500 units	345

64. Respondent dispensed at least thirty-six (36) compounded sterile preparations into California, that were compounded using active ingredients that had not been verified to ensure they did not contribute endotoxin contamination. The active ingredient used by Respondent was acetyl-D-Glucosamine, which was manufactured by Jiangsu Aoxin Biotech Co. which was not registered with the FDA as an animal drug manufacture establishment. Additionally, the certificate of analysis had not been verified by Respondent to ensure the active ingredient did not contribute endotoxin contamination that may be dangerous, given its intended use, and endotoxin testing was not conducted on the compounded preparations or produced failing results.

Table of Adulterated/Misbranded drugs shipped into California:

Lot Number	Preparation	Units into CA	API	End Product Testing
01222025@41	PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML)	14	Jiangsu Aoxin Biotechnology Co- lot#0420240301-not FDA registered; No endotoxin specification on COA	**Endotoxin failed (18437 EU vs 416.6EU**)
04302024@17	ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION	8	Letco lots including 2309250011 Mfgd. by Jiangsu Aoxin Biotechnology Co- not FDA registered; No endotoxin specification on COA	**Endotoxin failed (603.96 EU vs 250 EU)**

07252024@ 21	HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	1	Letco lots including 2309250011. Mfgd. by Jiangsu Aoxin Biotechnology Co- not FDA registered; No endotoxin specification on COA	**Failed to conduct BET testing and dispensed**
08212024@ 50	PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	3	Letco lots including 2309250011. Mfgd. by Jiangsu Aoxin Biotechnology Co- not FDA registered; No endotoxin specification on COA	**Failed to conduct BET testing and dispensed**
09102024@ 27	ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION	2	Jiangsu Aoxin Biotechnology Co- lot#0420240301-not FDA registered; No endotoxin specification on COA	**Failed to conduct BET testing and dispensed**
12302024@ 14	PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML)	8	lot#0420240301; changed to 208348 by Medisca-not FDA registered; No endotoxin specification on COA	**Endotoxin failed (1718.24 EU vs 416.67 EU)**

65. Respondent dispensed at least 6 compounded sterile preparations from the following lot numbers into California, without performing the required endotoxin testing as set forth below:

Table of CSPs Dispensed without Endotoxin Testing: Lot Number	**Preparation**	**Beyond Use Date**	**Units Dispensed into CA**	**API** (Acetyl D-Glucosamine)	**End Product Testing**
07252024@ 21	HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	30 days	1	#2309250011 Mfg.: Jiangsu Aoxin Biotech Co- not FDA registered as an animal drug mfg. COA does not test API for endotoxin	**Failed to conduct BET testing and dispensed**
08212024@ 50	PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	30 days	3	#2309250011, Mfg.: Jiangsu Aoxin Biotech Co- not FDA registered as an animal drug mfg. COA does not test API for endotoxin	**Failed to conduct BET testing and dispensed**
09102024@ 27	ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION	#30 Days	2	#0420240301 Mfg.: Jiangsu Aoxin Biotech Co- not FDA registered as an animal drug mfg. COA does not test API for endotoxin	**Failed to conduct BET testing and dispensed**

66. Respondent issued an urgent recall notice for at least 935 units of compounded sterile dug preparations that were shipped into California. Respondent failed to notify the Board within twelve hours of the issuance of each urgent recall notice. The next chart demonstrates Respondent's recalls and date of notification to the Board:

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Lot Number	Product	Date Recalled	CA Board Notification Date	Exp. Date	Dispensed in California
03202025@4	Semaglutide 2.5 mg/mL Inj. Vial	7/10/2025	7/24/2025	7/18/2025	177
06092025@23	Fluorescein 2% Ophth Sol.	7/9/2025	7/24/2025	9/9/25	8
03202025@2	Semaglutide 2.5 mg/mL Inj. Vial	7/10/2025	none	7/18/2025	130
03202025@3	Semaglutide 2.5 mg/mL Inj. Vial	7/10/2025	none	7/18/2025	132
03202025@5	Semaglutide 2.5 mg/mL Inj. Vial	7/10/2025	none	7/18/2025	90
03202025@6	Semaglutide 2.5 mg/mL Inj. Vial	7/10/2025	none	7/18/2025	142
03202025@7	Semaglutide 2.5 mg/mL Inj. Vial	7/10/2025	none	7/18/2025	75
03202025@8	Semaglutide 2.5 mg/mL Inj. Vial	7/10/2025	none	7/18/2025	99
03202025@9	Semaglutide 2.5 mg/mL Inj. Vial	7/10/2025	none	7/18/2025	82

67. On or around April 29, 2025, former PIC Farrell provide Inspector SP with a statement regarding his actions and the FDAs findings, as well as providing a copy of the statement he provided to the FDA. Farrell represented that the concerns of the Board would be addressed and that he was the individual responsible for the falsification of the end product testing. Farrell represented that as a result of his actions he was relieved as PIC and reassigned to an administrative pharmacist role for a 90-day period.

68. On or around June 9, 2025, the FDA issued a warning letter to Respondent related to their inspection conducted September 23, 2024, to October 22, 2024. The warning letter stated that Respondent produced and distributed adulterated and misbranded animal drugs in violation of the Federal Food, Drug and Cosmetic Act (FD&C Act). The FDA specifically mentioned compounding of unapproved new animal drugs and drug quality violations. The conclusion of the FDA warning letter stated, "All of the animal drugs you produced from BDS (bulk drug substances) violated the FD&C Acts' requirements for approval/indexing adequate directions for use, and CGMP."

May 7, 2025, Investigation

69. On or around May 7, 2025, the Board received a consumer complaint from K.N.. The complaint alleged that K.N. had been using Remedy Meds[5] since February 2025. K.N. stated her

[5] Remedy Meds is not a pharmacy. Remedy Meds is a platform used to connect consumers with providers. Providers then independently contract with pharmacies for fulfillment of prescriptions written by their clinicians to consumers.

last trizepatide prescription came from Respondent, and when the shipment arrived on or around April 21, 2025, the vial was sticky, like something had spilled. K.N. reported that Remedy Meds requested a replacement from Respondent, but after two weeks of not receiving a replacement K.N. canceled her order and requested a refund.

70. Respondent received K.N.'s complaint from Remedy Meds. Respondent's prescription note for Rx 1022399 stated, "patient reported sticky residue on the exterior of a prescription vial. An internal quality assurance review was initiated."

71. On and between August 4, 2025, to November 13, 2025, Board Inspector S.H. emailed a request for documents and information to Respondent.

72. On or around August 4, 2025, Board Inspector S.H. emailed a request to Remedy Meds asking how their telemedicine process works with Respondent as the fulfillment pharmacy.

73. On and between August 18, 2025, to November 13, 2025, Inspector S.H. received numerous documents from Respondent. Upon review of the documents Inspector S.H. discovered the following including, but not limited to:

74. K.N.'s prescription was shipped on April 18, 2025, and delivered on April 21, 2025.

75. Prescription label for Rx 1022399, for the prescription issued to K.N. noted a beyond used date of 6/13/2025 to "store Frozen." The prescription label did not contain the strength of the drugs dispensed in the compounded product, the active ingredients, or meet the requirement for patient centered labeling requiring four items to be in 12-point font and centered in cluster of the label.

76. On or around April 14, 2025, Respondent compounded Rx 1022399 which was delivered to K.N. with a 60-day BUD indicating on the label to keep the product frozen. K.N. would be required to thaw the prescription and then refreeze the prescription after use to adhere to the labeled instructions.

77. On or around April 14, 2025, Respondent prepared a total of 1,959 units in eight lots of tirzepatide, glycine, and methylcobalaimin, exceeding the allowed batch size for sterility testing.

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78. On or around April 14, 2025, Respondent compounded and dispensed 1,959 final yield units of tirzepatide, methylcobalamin, and glycine (17mg/ml, 5mg/ml, 5mg/ml) under lot # 04142025 @32, which documented quantities of API's which were not weighed and manipulated as documented in the compounding records. Instead, as depicted in the table below, Respondent used the total quantities weighed and manipulated to compound a larger, non-compliant batch size and documented under the compounding records for lot #04142025@51.

LOT NUMBER	WEIGHT OF TIRZEPATIDE	WEIGHT OF METHYLCOBALAMIN	WEIGHT OF GLYCINE
04142025@27	**4.675 gm**	**1.375 gm**	**6.25 gm**
04142025@28	**4.675 gm**	**1.375 gm**	**1.375 gm**
04142025@29	**7.0125 gm**	**2.0625 gm**	**2.0625 gm**
04142025@30	**7.0125 gm**	**2.0625 gm**	**2.0625 gm**
04142025@31	**9.35 gm**	**2.75 gm**	**2.75 gm**
04142025@32	**9.35 gm**	**2.75 gm**	**2.75 gm**
04142025@33	**14.025 gm**	**4.125 gm**	**4.125 gm**
04142025@34	**14.025 gm**	**4.125 gm**	**4.125 gm**
04142025@51	76.67 gm	23.6 gm	21.525 gm

79. Respondent received K.N.'s complaint from OpenLoop Health Partners, PC[6]. Respondent's prescription note for Rx 1022399 stated, "patient reported sticky residue on the exterior of a prescription vial. An internal quality assurance review was initiated."

80. On or around May 20, 2025, Respondent refunded $122.00 to Remedy Meds, due to Remedy Meds issuing a refund to K.N.

81. Respondent did not notify the Board that it had received a complaint from K.N.

July 7, 2025, Investigation

82. On or around July 17, 2025, the Board received a consumer complaint from T.M., a California consumer. T.M. alleged that she received a prescription through Remedy Meds for trizepatide that was supposed to last for four weeks. T.M. stated when she went to inject the last dose there was not enough medication in the vial. T.M. stated she contacted Remedy Meds multiple times with her complaint and photographs, and confirmed with one of their nurses that she was injecting the correct dose. Respondent was listed as the dispensing pharmacy on the prescription.

[6] OpenLoop Health Providers is a contracted provider through Remedy Meds.

83. On and between September 17, 2025, and September 26, 2025, Inspector S.P. contacted Respondent and requested information regarding T.M.'s prescription and the dispensing and compounding records associated with the prescription at issue.

84. On and between September 26, 2025, to October 28, 2025, Inspector S.P. received numerous documents from Respondent. Upon review of the documents Inspector S.P. discovered the following, including but not limited to:

85. On or around September 26, 2025, PIC Zerafati provided a statement that they had no record of any communications, inquires, or complaints filed by T.M.. In the statement, PIC Zerafati represented that the request from the Board was the first time they were made aware of any alleged issue involving patient T.M..

86. On or about June 2, 2025, as depicted in the chart below, Respondent compounded and dispensed into California at least 185 CSPs from a batch which had a final yield size greater than 250 final yield units prepared in a single discrete process, using stock solution lot #06022025@28, which Respondent filtered, on the same day and at the same time, into lot numbers 06022025@4 and 06022025@5, each with a final yield of 250 units or less.

87. On or around June 2, 2025, Respondent compounded and dispensed 185 final yield units of tirzepatide/ methylcobalamin/ NAD+ 17mg/ml /5mg/ml/ 50mg/ml under lot numbers 06022025@4 and 06022025@5, which documented quantities of APIs which were not weighed and manipulated as documented in the compounding records; instead, the total quantities were weighed and manipulated to compound a larger, non-compliant batch size, which were documented under the compounding record for lot@ 06022025@28. The following demonstrates the false weights reported by Respondent on compounding records:

LOT NUMBER	WEIGHT OF TIRZEPATIDE	WEIGHT OF METHYLCOBALAMIN	WEIGHT OF NAD+
06022025@4	**2.3375 gm**	**0.6875 gm**	**6.25 gm**
06022025@5	**7.0125 gm**	**2.0625 gm**	**18.75 gm**
06022025@28	11.22 gm	3.3 gm	15 gm

88. On or about June 2, 2025, Respondent compounded lot numbers 06022025@4 and 06022025@5 on 6/2/2025 as Category 2, aseptically processed CSPs. Respondent then sent vials for sterility testing under refrigeration and stored the rest of the vials under refrigeration until

6/3/2025 and 6/4/2025. Respondent then proceeded to perform visual and volume inspections and labeled the vials with a beyond use date of 8/1/2025 (60 days), which is outside the limit of 45 days based on the storage conditions. Respondent dispensed a total of 185 vials from the above-mentioned lot numbers into California.

89. On or about June 2, 2025, Respondent compounded and dispensed 185 final yield units of tirzepatide/methylcobalamin/NAD+ 17mg/ml/5mg/ml/50mg/ml into California under lot numbers 06022025@4 and 06022025@5, using a master formulation record which described the physical appearance of the final CSP as a "Clear solution with no particulates," when the actual physical appearance as described in the "patient instruction pamphlet" as 'translucent, dark red to crimson-colored solution', due to the addition of methylcobalamin and NAD+.

90. On or about June 9, 2025, Respondent dispensed Rx 01196126 to T.M.. The prescription label did not have the following items listed in the correct order: name of the drug and strength of the drug; directions for use of the drug. Additionally, the patient's address was listed below the patient's name and within the clustered area, which comprised 50 percent of the label.

January 8, 2026, Investigation

91. On or around March 27, 2025, the Board received a consumer complaint from B.C., a California consumer. B.C. alleged that he received a prescription through an online platform called Good Life Meds[7] for tirzepatide, and when the tirzepatide was received, various shipments were not refrigerated, damaged, delayed, or did not arrive at all. It was later determined that Respondent had filled several prescriptions for B.C. on behalf of Good Life Meds.

92. A Board inspector investigated B.C.'s complaints and due to a lack of documented evidence, no findings were sustained relevant to B.C.'s specific complaints. However, in reviewing the compounding records of the lots from which drugs were sent to B.C., it was discovered that of the four lots of CSPs dispensed to B.C., all four were dispensed by Respondent before the results of the sterility and pyrogen testing were known.

[7] Similar to Remedy Meds, Good Life Meds is not a pharmacy but is an online "telehealth" platform that connects patients to prescribers and then contracts with pharmacies to fulfill the prescriptions issued.

Pennsylvania State Board of Pharmacy Discipline

93. On or about August 28, 2025, the Commonwealth of Pennsylvania, Department of Department of State, before the State Board of Pharmacy (Pennsylvania Board) imposed discipline on Respondent when it issued an order adopting a consent agreement placing Respondent on indefinite probation until certain terms and conditions are met, including Respondent to pay a civil penalty of one million dollars ($1,000,000.00). The circumstances are that in 2024, Respondent violated numerous Pennsylvania regulations when they operated a pharmacy without being granted a pharmacy permit by the Pennsylvania Board and converted pharmacy rooms into compounding areas without submitting plans to the Pennsylvania Board for approval prior to starting to compound medication.

94. Respondent did not notify the Board of the Pennsylvania Board discipline until September 24, 2025, 28 days after the discipline occurred.

Kansas State Board of Pharmacy Discipline

95. On or about January 30, 2026, the Kansas Board of Pharmacy (Kansas Board), imposed discipline on Respondent when it issued an order assessing an administrative fine in the amount of thirty thousand dollars ($30,000.00) and placing Respondent on indefinite probation mirroring the terms of the Pennsylvania Board's Consent Agreement and Order. The circumstances that lead to this discipline are based on the Pennsylvania Board discipline.

96. To date Respondent has not notified the Board of the Kansas Board discipline.

Causes for Discipline based on March 26, 2025, Renewal Inspection

FIRST CAUSE FOR DISCIPLINE

(Falsification of Records)

97. Respondent's licenses are subject to disciplinary action pursuant to Code section 4301, subdivisions (f) and (g), in conjunction with Code section 4126.8, on the grounds that it engaged in unprofessional conduct by knowingly making or signing a certificate or other document that falsely represents the existence or nonexistence of a state of facts, as follows:

a. Respondent compounded and dispensed into California at least 2,783 final yield units of compounded sterile preparations under lot numbers 01172025@1, 01172025@2, 01172025@3,

01172025@4; 01282025@1, 01282025@2, 01282025@4, 01282025@5; 01292025@1, 01292025@2, 01292025@3, 01292025@4, 01292025@5; 02112025@1, 2112025@2, 02112025@3; 03042025@7, and 03042025@8 by producing false and misleading compounding records, which documented quantities of APIs which were not weighed and manipulated as documented, as set forth in paragraph 61, above.

b. Respondent knowingly compounded and dispensed into California at least 2,783 final units of CSPs from large batch stock solutions even though it was required to be limited to lots yielding only 250 units, and then proceeded to filter the large batches in a discrete process into smaller lots of 250 final yield units or less under new lot numbers, as set forth in paragraph 61, above.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain USP-NF Compounding Standards)

98. Respondent's licenses are subject to disciplinary action to Code section 4301, subdivisions (j) and (o), on the grounds that it engaged in unprofessional conduct. Specifically, Respondent failed to follow United States Pharmacopeia-National Formulary (USP-NF) compounding standards in violation of Code section 4126.8, as set forth in paragraphs 50-68, above, and as follows:

a. Respondent dispensed CSPs into California before and after OOS results of release testing were known.

b. Respondent failed to establish consistent adherence to procedures such as endotoxin testing.

c. Respondent failed to ensure quality control measures such as training and competency assessments for documentation practices to address gaps in documentation and false weights documents on compounding records.

d. Respondent failed to establish SOPs which limited the batch size of CSPs requiring sterility testing to 250 final yield units and facilitated the camouflage of this non-compliant practice, by not linking compounding of stock solutions to the sublots that the stock solution was filtered into.

e. Respondent failed to provide adequate SOPs on beyond use dating, to account for storage temperatures and their effects on stability and beyond use dates.

f. Respondent failed to provide adequate training on quality to final verification pharmacists and the pharmacist-in-charge on USP 797-2022 and California regulations as they relate to compounding and QA, QC[8] measures.

g. Respondent failed to execute procedures to immediately notify prescribers of a failure of specifications (recall) for six lots and to adequately execute procedures to investigate if other lots were affected and needed to be recalled.

h. Respondent's standard operating procedures for recall of OOS dispensed CSPs, failed to provide adequate procedures: to determine the severity of the problem; the urgency for implementation of and completion of recall; and to investigate and document the reason for failure.

f. Respondent failed to properly perform stability studies for assigned BUDs prior to dispensing at least 2783 units of CSPs into California.

g. Respondent failed to properly perform the required endotoxin testing for at least 6 CSPs that Respondent shipped into California.

THIRD CAUSE FOR DISCIPLINE

(Adulterated Preparations)

99. Respondent's licenses are subject to discipline pursuant to Code section 4301, subdivisions (j) and (o) on the grounds that it engaged in unprofessional conduct, in that Respondent failed to use active ingredients that had been verified to assure they did not contribute endotoxin contamination that may be objectionable given the CSPs' intended use, in violation of Code section 4127.2, subdivision (e)(3). Specifically, as set forth in paragraph 64, above, Respondent dispensed at least 36 compounded sterile preparations into California, which were compounded using active ingredients that had not been verified to assure they did not contribute endotoxin contamination that may be objectionable given the compounded sterile preparation's intended use; the certificate of analysis had not been verified to ensure the active ingredient did

[8] QA is Quality Assurance and QC is Quality Control.

not contribute endotoxin contamination that may be dangerous, given its intended use; and endotoxin testing was either not conducted on the compounded preparation or produced failing results.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Properly Notify Board of Recall)

100. Respondent's licenses are subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), in conjunction with Code section 4127.2, subdivision (e)(3), in that Respondent did not notify the Board within twelve hours that it had issued an urgent recall for at least 935 units of CSPs that were shipped into California, as set forth further in paragraph 66, above.

Causes for Discipline for May 7, 2025, Investigation

FIFTH CAUSE FOR DISCIPLINE

(Adverse Effects Reporting)

101. Respondent's licenses are subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), in conjunction with Code section 4127.2, subdivision (e)(4), in that Respondent did not notify the Board of a complaint received from patient KN, as set forth in paragraphs 69-80, above.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Properly Label Prescription)

102. Respondent's licenses are subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), in conjunction with Code section 4076, subdivision (a)(1)(9), and USP 707-2022, section 14.2.4, in that on or around April 18, 2025, Respondent failed to properly label prescription number 1022399, a CSP that was dispensed to KN, as set forth further in paragraphs 75-76, above.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Have Compliant Patient Centered Labels on Prescription Drug Containers)

103. Respondent's licenses are subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), in conjunction with Regulations section 1707.5, in that on or around

April 18, 2025, Respondent failed to properly follow the requirements for patient centered labeling when it dispensed prescription number 1022399, a CSP to KN, as set forth further in paragraph 75, above.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain USP-NF Compounding Standards)

104. Respondent's licenses are subject to disciplinary action to Code section 4301, subdivisions (j) and (o), in that Respondent failed to follow USP-NF compounding standards in violation of Code section 4126.8 and USP 707-2022, section 12.2, as set forth in paragraphs 77-78, above, and as follows:

a. On or around April 14, 2025, Respondent manipulated records to compound larger, non-compliant batch sizes and dispensed 1,959 field units using records containing inaccurate active pharmaceutical ingredients.

b. On or around April 14, 2025, Respondent exceeded the maximum batch size for sterility testing when preparing 1,959 units in eight lots of trizepatide, glycine, and methlcobalamin.

NINTH CAUSE FOR DISCIPLINE

(Falsification of Records)

105. Respondent's licenses are subject to disciplinary action pursuant to Code section 4301, subdivisions (f) and (g), in conjunction with Code section 4126.8 on the grounds that it engaged in unprofessional conduct by knowingly making or signing a certificate or other document that falsely represents the existence or nonexistence of a state of facts. To wit:

a. On or around April 14, 2025, Respondent compounded and dispensed into California 1,959 final yield units of tirzepatide, methylcobalamin, and glycine (17mg/ml, 5mg/ml, 5mg/ml) under lot # 04142025 @32, which documented quantities of API's which were not weighed and manipulated as documented in the compounding records. Instead, as depicted in the table below, Respondent used the total quantities weighed and manipulated to compound a larger, non-compliant batch size and documented under the compounding records for lot #04142025@51, as set forth in paragraphs 77-78, above.

Causes for Discipline for July 7, 2025, Investigation

TENTH CAUSE FOR DISCIPLINE

(Falsification of Records)

106. Respondent's licenses are subject to disciplinary action pursuant to Code section 4301, subdivisions (f) and (g), in conjunction with Code section 4126.8 on the grounds that it engaged in unprofessional conduct by knowingly making or signing a certificate or other document that falsely represents the existence or nonexistence of a state of facts. To wit:

a. Respondent compounded and dispensed 185 final yield units of tirzepatide/methylcobalamin/NAD+ 17mg/ml/5mg/ml/50mg/ml under lot numbers 06022025@4 and 06022025@5, producing false and misleading compounding records, which documented quantities of APIs which were not weighed and manipulated as documented in the compounding records, as set forth in paragraphs 86-87, above.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Have Compliant Patient Centered Labels on Prescription Drug Containers)

107. Respondent's licenses are subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), in conjunction with Regulations section 1707.5, subdivision (a), in that on or around June 9, 2025, Respondent failed to properly meet the requirements for patient centered labeling when it dispensed prescription number 01196126, as set forth further in paragraph 90, above.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Maintain USP-NF Compounding Standards)

108. Respondent's licenses are subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), on the grounds that it engaged in unprofessional conduct. Specifically, Respondent failed to follow USP-NF compounding standards in violation of Code section 4126.8, as set forth in paragraphs 88-91, above, and as follows:

a. Respondent failed to use the proper master formula for a CSP when compounding lot numbers 06022025@4 and 06022025@5 on or around June 2, 2025. The master formula used which was used described the physical appearance of the final CSP as 'Clear

solution with no particulates.' However, actual physical appearance of the CSP as described in the 'patient instruction pamphlet' was 'translucent, dark red to crimson-colored solution.'

b. Respondent failed to assign the proper BUDs to CSPs to reflect the storage conditions used.

c. Respondent compounded and dispensed into California at least 185 CSPs from a batch which had a final yield size greater than 250 final yield units prepared in a single discrete process.

Cause for Discipline for January 8, 2026, Investigation

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Compounding Standards)

109. Respondent's licenses are subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), in conjunction with Regulations section 1751.7, subdivision (e)(1), on the grounds that it engaged in unprofessional conduct by failing to comply with laws and regulations governing the practice of pharmacy as set forth in paragraph 92, above, and as follows:

a. Respondent compounded and dispensed CSPs from four lots, lot numbers 02202025@36, 03112025@19, 04092025@55, and 05062025@34 before the results of sterility and pyrogen testing were known.

Causes for Discipline Relating to Out of State Discipline

FOURTEENTH CAUSE FOR DISCIPLINE

(Out of State Discipline)

110. Respondent is subject to disciplinary action under Code section 4301, subdivisions (n) and (o), in that Respondent was disciplined by the Pennsylvania and Kansas Boards, as set forth in paragraphs 93 and 95, above.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Notify the Board of Disciplinary Action)

111. Respondent is subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4127.2 (e), in that Respondent failed to notify and provide the Board a copy of the

Pennsylvania and Kansas Boards' discipline within ten (10) days of the disciplinary actions, as set forth in paragraphs 94 and 96, above.

STATEMENT OF ISSUES

FIRST CAUSE FOR DENIAL

(False Certification/Documentation of Facts)

112. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301 subdivisions (f) and (g), by knowingly making or signing a certificate or other document that falsely represents the existence or nonexistence of a state of facts as set forth in paragraphs 52, 56, 59, 61, 77-78, and 86-87, above.

SECOND CAUSE FOR DENIAL

(Adulterated Preparations)

113. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivisions (j) and (o), in that Respondent failed to otherwise mitigate known compounding errors, in violation of Code section 4127.2, subdivision (e)(3), as set forth in paragraphs 49-92, above.

THIRD CAUSE FOR DENIAL

(Failure to Provide Board with Notice of Patient Complaint)

114. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivisions (j) and (o) in conjunction with 4127.2, subdivision (e)(4) when it failed to provide the Board with notice of a patient complaint, as set forth in paragraphs 79-81, above.

FOURTH CAUSE FOR DENIAL

(Failure to Provide Board with Timely Notice of Recall)

115. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional

conduct as defined by Code section 4301, subdivisions (j) and (o) in conjunction with 4127.2, subdivision (e)(3) when it failed to provide the Board with timely notice of a recall of its products, as set forth in paragraph 64, above.

FIFTH CAUSE FOR DENIAL

(Failure to Maintain USP-NF Compounding Standards)

116. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivisions (j) and (o). Specifically, Respondent failed to follow USP-NF compounding standards in violation of Code section 4126.8, as set forth in paragraphs 52-58, 61-66, 77-78, 86-89, and 92, above.

SIXTH CAUSE FOR DENIAL

(Failure to Have Compliant Patient Centered Labels on Drug Containers)

117. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivisions (j) and (o) in conjunction with Regulations section 1707.5, in that Respondent failed to properly follow the requirements for patient centered labeling when it dispensed prescriptions as set forth in paragraphs 75-76 and 90, above.

SEVENTH CAUSE FOR DENIAL

(Discipline by the Board of Another State)

118. Respondent's application for renewal is subject to denial pursuant to Code sections 480, subdivision (a)(2), 4300, subdivision (c), and 4301, subdivision (n), in that Respondent's license to practice or operate a pharmacy has been disciplined by the Pennsylvania Board of Pharmacy and Kansas Board of Pharmacy, as set forth in paragraphs 93-96, above.

EIGHTH CAUSE FOR DENIAL

(Unprofessional Conduct)

119. Respondent's application for renewal is subject to denial for unprofessional conduct pursuant to Code section 4127.2, subdivision (c) and Code section 4300, subdivision (c), as

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defined by Code section 4301, subdivision (j), for violating statutes and regulations regulating controlled substances and dangerous drugs as set forth in paragraphs 97-111, above.

NINTH CAUSE FOR DENIAL

(Pending Disciplinary Action)

120. Respondent's application for renewal is subject to denial pursuant to Code section 4302 and Code section 4307, due to the pending disciplinary action set forth in paragraphs 97-111, above. The circumstances are as follows:

a. Pursuant to Code section 4302, if the Accusation results in discipline against Respondent, then Boothwyn Pharmacy LLC, Louise Micolucci, President and Chief Executive Officer, and Ali Zerafati, Pharmacist-in-Charge shall be prohibited from owning 10% or more of, and from managing any pharmacy.

b. Pursuant to Code section 4307, if the Accusation results in discipline against Respondent, then Boothwyn Pharmacy LLC, Louise Micolucci, President and Chief Executive Officer, and Ali Zerafati, Pharmacist-in-Charge shall be prohibited from owning or managing any pharmacy.

DISCIPLINE CONSIDERATIONS

121. To determine the degree of discipline, if any, to be imposed on Respondent, Complainant alleges the following:

122. On or about September 22, 2021, in a prior action, the Board issued Citation Number CI 2019 88705 to Respondent's nonresident pharmacy permit for violation of Code section 4301, subdivision (o), in conjunction with California Code of Regulations section(s) 1751.7, subdivision (e)(1) (batched-produced sterile drug preparations compounded from one or more non-sterile ingredients), 1735.2, subdivision (i)(3)(A)(B)(C) (improperly extended beyond used dates), 1735.2, subdivision (i)(4) (improperly assigning beyond use dates), 1735.2, subdivision (d)(3)(compounding commercially available products), 1735.2, subdivision (e)(3)(compounding limitations and requirements), 1735.3, subdivision (a)(2)(F)(records of compounded drug products). This citation has become final, and Respondent has complied with the fine.

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123. On or about September 22, 2021, in a prior action, the Board issued Citation Number CI 2019 88705 to Respondent's nonresident sterile compounding pharmacy permit for violation of Code section 4301, subdivision (o), in conjunction with California Code of Regulations section(s) 1751.7, subdivision (e)(1) (batched-produced sterile drug preparations compounded from one or more non-sterile ingredients), 1735.2, subdivision (i)(3)(A)(B)(C) (improperly extended beyond used dates), 1735.2, subdivision (i)(4) (improperly assigning beyond use dates), 1735.2, subdivision (e)(3)(compounding commercially available products), 1735.2, subdivision (e)(3)(compounding limitations and requirements), 1735.3, subdivision (a)(2)(F)(records of compounded drug products). The Board issued a $5000 fine as a result of these violations. This citation has become final, and Respondent has complied with the fine.

OTHER MATTERS

124. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 1963 or Nonresident Sterile Compounding Pharmacy Permit Number NSC 101082 issued to Boothwyn Pharmacy LLC; Louise Micolucci, President and Chief Executive Officer, Ali Zerafati, PIC, and Martin J. Farrell, PIC from October 5, 2023, to November 13, 2024, then Boothwyn Pharmacy LLC; Louise Micolucci, Ali Zerafati, and Martin Farrell shall each be prohibited from serving as manager, administer, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five years if either or both of the pharmacy permits are placed on probation; or, 2) if either of the pharmacy permits are revoked, the prohibition shall continue until the revoked permit is reinstated.

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 1963, issued to Boothwyn Pharmacy LLC; Louise Micolucci, President and Chief Executive Officer, and Ali Zerafati, Pharmacist-in-Charge;

2. Revoking or suspending Nonresident Sterile Compounding Permit Number NSC 101082, issued to Boothwyn Pharmacy LLC; Louise Micolucci, President and Chief Executive

Officer, and Ali Zerafati, Pharmacist-in-Charge;

3. Denying the renewal application of Boothwyn Pharmacy LLC; Louise Micolucci, President and Chief Executive Officer, and Ali Zerafati, Pharmacist-in-Charge for a Nonresident Sterile Compounding Pharmacy License;

4. Prohibiting Boothwyn Pharmacy LLC from serving as a manager, administer, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

5. Prohibiting Louise Micolucci, from serving as a manager, administer, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

6. Prohibiting Ali Zerafati, from serving as a manager, administer, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

7. Prohibiting Martin J. Farrell, from serving as a manager, administer, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

8. Ordering Boothwyn Pharmacy 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 if placed on probation, the costs of probation monitoring;

9. Ordering an administrative fine to be assessed against Boothwyn Pharmacy LLC if Boothwyn Pharmacy LLC is placed on probation or the license is revoked; and,

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

DATED: 8/13/2026

Sodergren, Anne@DCA Digitally signed by Sodergren, Anne@DCA Date: 2026.08.13 08:25:35 -07'00'

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

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