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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**:** **WELLS PHARMACY NETWORK LLC dba WELLS PHARMACY NETWORK LLC** **NEMOMON LLC, Shareholder;** **THE COLLEEN STACY SHAPIRO 2010 TRUST, Shareholder;** **OB JOYFUL DYNASTY TRUST, Shareholder;** **THE SHAPIRO FAMILY D III TRUST, Shareholder;** **JARRETT TODD BOSTWICK, Shareholder;** **RACHEL ELLYN MCKIM, Shareholder;** **HOWARD BROWN, Pharmacist-in-Charge.** **1210 SW 33rd Ave.** **Ocala, FL 34474** **Nonresident Pharmacy Permit No. NRP 1333** **Nonresident Sterile Compounding Pharmacy Permit No. NSC 99845** Respondent.	Case Nos. 7160 and 7171 **FIRST AMENDED ACCUSATION** **AND** **FIRST AMENDED STATEMENT OF ISSUES**

PARTIES

1. Anne Sodergren (Complainant) brings this First Amended Accusation and First Amended 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 August 20, 2013, the Board issued Nonresident Pharmacy Permit Number NRP 1333 to Wells Pharmacy Network LLC doing business as (dba) Wells Pharmacy Network LLC, with Nemomon LLC 24% shareholder, The Colleen Stacy Shapiro 2010 Trust, 14% shareholder, OB Joyful Dynasty Trust, 9% shareholder, The Shapiro Family D III Trust, 8% shareholder, Jarrett Todd Bostwick, 8% shareholder, Rachel Ellyn McKim, 8% shareholder, and Howard Brown, Pharmacist in Charge (PIC) (Respondent). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2023, unless renewed.

3. On or about August 20, 2013, the Board issued Nonresident Sterile Compounding Pharmacy Permit number NSC 99845 to Respondent. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and expired on August 1, 2021, and was cancelled, the circumstances of which are set forth in paragraph 4, below.

4. Prior to August 1, 2021, Respondent submitted a renewal application for its Nonresident Sterile Compounding Pharmacy Permit number NSC 99845. On or about July 12, 2021, the application for renewal was denied after a renewal inspection found that Respondent was not in compliance with Chapter 9 of the Pharmacy Practice Act and regulations adopted by the Board. On or about July 13, 2021, Respondent timely appealed the denial of the Nonresident Sterile Compounding Permit renewal application.

JURISDICTION

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

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6. 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.

7. 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.

8. Section 4307 of the Code states:

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

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

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

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

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

9. 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 and Safety Code).

STATUTORY PROVISIONS

10. Section 651 of the Code states in pertinent part:

(a) It is unlawful for any person licensed under this division or under any initiative act referred to in this division to disseminate or cause to be disseminated any form of public communication containing a false, fraudulent, misleading, or deceptive statement, claim, or image for the purpose of or likely to induce, directly or indirectly, the rendering of professional services or furnishing of products in connection with the professional practice or business for which he or she is licensed. A "public communication" as used in this section includes, but is not limited to, communication by means of mail, television, radio, motion picture, newspaper, book, list or directory of healing arts practitioners, Internet, or other electronic communication.

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

(1) Contains a misrepresentation of fact.

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

(3)(A) Is intended or is likely to create false or unjustified expectations of favorable results, including the use of any photograph or other image that does not accurately depict the results of the procedure being advertised or that has been altered in any manner from the image of the actual subject depicted in the photograph or image.

. . .

(5) Contains other representations or implications that in reasonable probability will cause an ordinarily prudent person to misunderstand or be deceived.

(6) Makes a claim either of professional superiority or of performing services in a superior manner, unless that claim is relevant to the service being performed and can be substantiated with objective scientific evidence.

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

(8) Includes any statement, endorsement, or testimonial that is likely to mislead or deceive because of a failure to disclose material facts.

. . .

(f) Any person so licensed who violates this section is guilty of a misdemeanor. A bona fide mistake of fact shall be a defense to this subdivision, but only to this subdivision.

. . .

11. 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.

12. 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.

13. Section 4127.8 of the Code states in pertinent part:

(a) A pharmacy licensed pursuant to Section 4127.1 or 4127.2 that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient….

14. Section 4129.2, subdivision (b) of the Code states:

A nonresident outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.

15. 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:

(c) Gross negligence.

. . .

(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.

. . .

(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.

. . .

(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.

. . .

16. 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.

17. Section 4341 of the Code states:

Notwithstanding any other provision of law, prescription drugs or devices may be advertised if the advertisement conforms with the requirements of Section 651.

18. 21 United States Code (U.S.C.) section 351 states in pertinent part:

A drug or device shall be deemed to be adulterated—

(a)Poisonous, insanitary, etc., ingredients; adequate controls in manufacture

(1)If it consists in whole or in part of any filthy, putrid, or decomposed substance; or

(2)(A) if it has 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; or

(B) if it is a drug and the methods used in, or the 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 such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess…

19. 21 U.S.C. section 353a, subdivision (b)(1)(A)(i) states in pertinent part:

(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—

(i) that—

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);….

20. 42 U.S.C. section 262 states in pertinent part:

(a) Biologics license

(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless-

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product….

21. Health and Safety Code section 111250 states:

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

22. Health and Safety 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.

23. Health and Safety 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.

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REGULATORY PROVISIONS

24. California Code of Regulations, title 16, (Regulations) section 1735.1 states in pertinent part:

> (ae) "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.

25. Regulations section 1735.2 states in pertinent 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.
>
> …
>
> (i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.
>
> …
>
> (3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:
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> (A) Method Suitability Test,
>
> (B) Container Closure Integrity Test, and
>
> (C) Stability Studies….

26. Regulations section 1751.7 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.

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COST RECOVERY

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

DEFINITIONS

28. Peptides are a chain of two or more amino acids linked by peptide bonds. Large peptides, containing many amino acids are called polypeptides. Chains of linked polypeptides are called proteins. Effective February 2020, the FDA considers proteins to be biologic products, requiring a biologics license. Any protein of more than 40 amino acids is considered a biologic product. Any product with 40 or fewer amino acids is considered a peptide and therefore is a drug product.

29. Ipamorelin is a synthetic product derived from GHRP-1 (Growth Hormone Releasing Peptide-1). Ipamorelin is a pentapeptide, consisting of five amino acids and is therefore a peptide. It is a dangerous drug pursuant to Code section 4022.

30. CJC-1295 a synthetic product consisting of 30 amino acids, and is therefore a peptide. It is a dangerous drug pursuant to Code section 4022.

31. BPC-157 is derived from a particular stomach protein, but it is considered a synthetic product because it has a unique peptide chain that does not occur in nature. BPC-157 contains 15 amino acids and is therefore a peptide. It is a dangerous drug pursuant to Code section 4022.

32. Thymosin Alpha 1 is derived from prothymosin alpha, a protein. Thymosin Alpha 1 contains 28 amino acids and is therefore a peptide. It is a dangerous drug pursuant to Code section 4022.

33. Thymosin Beta 4 is a protein consisting of 43 amino acids, and is therefore a biologic product. Thymosin Beta-4 is also known as timbetasin.

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INTRODUCTION

34. This case is about the compounding of prescription drugs, including those designated for sterile administration, in a pharmacy. Pharmacy compounding is when a licensed pharmacist combines, mixes, or alters drug ingredients to create a medication tailored to the needs of an individual patient. (e.g., Cal. Code Regs., tit. 16, § 1735.) 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].

35. 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.

36. 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.)

37. 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 from the manufacturer. (21 U.S.C. § 353a(b)(1)(A)(ii) and (iii).)

38. 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, §§ 11250, 11255 [definitions of "adulterated"] (emphasis added); Health & Saf. Code, § 11295 [adulterated drug prohibition].)

39. 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.

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

41. 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, § 1751 *et seq.*; see also Cal. Code Regs., tit. 16, § 1735 *et seq*.)

42. 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*., 4128 *et seq*., 4129 *et seq*., Cal. Code Regs., tit. 16, §§ 1735 *et seq*., 1751 *et seq*.)

43. 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.

44. Many or all of the bulk drug substances at issue in this case have not met the requirements of federal section 503A, e.g.: they are not the subject of an applicable USP or NF drug monograph, are not a component of a drug already approved by the FDA, and are not on the permissible "503A bulks list" identified by the FDA in regulation; they were not received from FDA-registered manufacturing sites; and/or they were not accompanied by a proper certificate of analysis. Many or all of the bulk drug substances at issue in this case are further questionable for reasons including that they were not intended by the manufacturers (i.e., they were not "graded") for use in pharmaceutical products, let alone sterile compounds. Some were graded for dietary use, a quite different standard. Some were graded for topical use. Some were not graded at all.

45. Lastly, some of the bulk drug substances at issue in this case have been nominated, but not yet incuded, on a list of bulk drug substances identified by the FDA as "Category 1." Over the last several years, the FDA has engaged in a process to receive and review nominations for bulk drug substances to appear on the "503A bulks list" developed by the Secretary via regulation under the third option identified above: bulk drug substances appropriate for section 503A compounding that are neither the subject of an applicable USP or NF drug monograph nor a component of an approved drug. This "503A bulks list" is codified at 21 C.F.R. § 216.23(a). It so far includes only six (6) bulk drug substances approved for use in section 503A compounding,[1] and four (4) disapproved.[2] Accordingly, only those six (6) bulk drug substances listed in this regulation are approved for use in compounding under section 503A.[3] *Any other* bulk drug

[1] (1) Brilliant Blue G, aka Coomassie Brilliant Blue G–250; (2) Cantharidin (topical use only); (3) Diphenylcyclopropenone (topical use only); (4) N–acetyl–D–glucosamine (topical use only); (5) Squaric acid dibutyl ester (topical use only); and (6) Thymol iodide (topical use only).

[2] (1) Oxitriptan; (2) Piracetam; (3) Silver Protein Mild; and (4) Tranilast.

[3] Even this approval for use in compounding is expressly limited by subdivision (d): Based on evidence currently available, there are inadequate data to demonstrate the safety or efficacy of

substance that is not the subject of an applicable USP or NF drug monograph, or a component of an approved drug, cannot be used.

46. The FDA has received hundreds of nominations for bulk drug substances to be added to this "503A bulks list." While they are under consideration, nominated bulk drug substances are placed into one of three categories, depending on the amount of information/documentation received along with the nomination, and whether it presents a significant safety risk.

47. The FDA has said that bulk drug substances included in "Category 1" are those that *may be eligible* for inclusion on the "503A bulks list," were nominated with sufficient supporting information for the FDA to evaluate them, and do not appear to present significant safety risks.

48. However, bulk drug substances included on the Category 1 list have not been approved by the FDA for use in compounding under section 503A. By definition, bulk drug substances on this list are not the subject of an applicable USP or NF drug monograph, are not components of FDA-approved drugs, and have not been added to the "503A bulks list." They are therefore not deemed appropriate for use in compounding by the FDA under section 503A.

49. In this case, Respondents have engaged in significant compounding of drug products intended for sterile administration. In numerous instances, they have done so utilizing active pharmaceutical ingredients (APIs) received as bulk drug substances. In many or all cases, they have taken non-sterile bulk drug substances and used them to create compounded preparations intended for sterile administration. Non-sterile to sterile compounding is the most high-risk, and warrants extra precautions, including end-product sterilization and testing. And the quality of the components used in sterile compounding is important. But Respondents have repeatedly used bulk drug substances that have either or both (a) not met the requirements of section 503A, and/or (b) not been graded for pharmaceutical use. The resulting compounds are "adulterated" drug products.

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any drug product compounded using any of the drug substances listed in paragraph (a) of this section, or to establish general recognition of the safety or effectiveness of any such drug product. Any person who represents that a compounded drug made with a bulk drug substance that appears on this list is FDA approved, or otherwise endorsed by FDA generally or for a particular indication, will cause the drug to be misbranded under section 502(a) and/or 502(bb) of the Federal Food, Drug, and Cosmetic Act. (21 C.F.R. § 216.23(d).) In other words, no resulting compound is "FDA-approved."

FACTS - OCTOBER 13, 2020 INVESTIGATION REPORT

50. On or about October 22, 2019, the Board received a complaint through its online portal regarding certain drugs that Respondent was shipping into California. An investigation ensued, conducted by Board Supervising Inspector C.A. Due to the COVID-19 pandemic, the investigation was conducted virtually through reviews of compounding and shipping records, and correspondence with Respondent's employees and officers.

51. On or about April 1, 2020, the FDA issued a warning letter to Tailor Made Compounding LLC (TMC), an entity unrelated to Respondent, notifying TMC that drugs it was compounding pursuant to the exemptions set forth in 21 USC 503A, did not qualify for the exemptions. This letter is public and is posted on the FDA website. Specifically as relates to the drugs being compounded by Respondent, the FDA identified BPC-157, CJC-1295, and Ipamorelin as drug products that were not eligible for compounding as they are not included on the bulks list.

52. On or about July 8, 2020, Respondent's Vice President M.S. stated Respondent was aware of the FDA's position set forth in the public warning letter to TMC and that Respondent had nominated the substances for inclusion on the bulks list and were continuing to compound with these drugs despite the warning letter and the fact that none of the drugs had been approved by the FDA or placed onto the bulks list.

53. In September 2018, the FDA released a draft guidance document called "Insanitary Conditions at Compounding Facilities" which set forth examples of insanitary conditions which "could cause a drug to become contaminated with filth or rendered injurious to health. The drug itself need not actually be contaminated. A drug that is actually contaminated with any filthy, putrid, or decomposed substances is deemed to be adulterated under section 501(a)(1) of the Food Drug and Cosmetic Act (21 U.S.C. 351(a)(1)." One of the examples set forth in this document is: "Using ingredients…that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with "not for pharmaceutical use" or an equivalent statement)."

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54. Respondent maintains a YouTube.com channel/account, on which it posts videos advertising its products. On or about November 21, 2018, a pharmacist employed by Respondent gave a presentation about CJC-1295, Ipamorelin, PT-141, Bremelanotide, and BPC-157. Respondent posted this presentation to its YouTube.com channel. In this presentation, Respondent promotes the referenced drugs as being safe for use in humans and useful for a number of conditions and performing a number of functions, none of which have been proven by any scientific studies.

FIRST CAUSE FOR DISCIPLINE

(Use of Non-Compliant Bulk Drug Substance)

55. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code sections 4301, subdivisions (j) and (o), and 4342, in that Respondent violated laws and regulations governing pharmacy and regulating dangerous drugs by violating 21 U.S.C. section 353a, subdivision (b)(1)(A)(i). The circumstances are that between May 8, 2020 and July 8, 2020, Respondent compounded and dispensed at least 805 orders and 3,088 vials of CJC-1295, BPC-157, and AOD-9604 to California patients that were compounded using ingredients that did not comply with the standards of an applicable USP-NF monograph, was not a component of a drug already approved by the FDA, and did not appear on a list developed by the FDA and codified by regulation.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Quality of Compounded Sterile Preparations)

56. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondent compounded drugs that lacked quality and dispensed those drugs to patients in violation of Regulations sections 1735.1, subd. (a)(e), and 1735.2, subd. (g). The circumstances are that from approximately May 1, 2020 to June 2, 2020, Respondent compounded and dispensed 11 lots, consisting of 452 orders and 1,981 vials, to California patients, which lacked quality.

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THIRD CAUSE FOR DISCIPLINE

(Adulterated Preparations)

57. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs by violating Health and Safety Code sections 111250, 111255, and 111295, by compounding, selling, and dispensing adulterated drugs. The circumstances are that between approximately April 22, 2020 and June 8, 2020, Respondent compounded, dispensed and sold at least 11 lots, consisting of 452 orders and 1,981 vials, to California patients which were, or could have been, adulterated.

FOURTH CAUSE FOR DISCIPLINE

(Assignment of Unsupported Extended Beyond Use Date)

58. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondent violated Regulations 1735.2, subdivision (i). The circumstances are that between approximately April 22, 2020 and June 8, 2020, Respondent assigned extended beyond use dates to at least 11 lots, consisting of 452 orders and 1,981 vials, which were not supported by method suitability tests, container closure integrity tests, and stability studies.

FIFTH CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

59. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondent violated Regulations section 1761, subdivision (a). The circumstances are that Respondent dispensed at least three prescriptions issued by physician J.D., to patient M.G., which contained significant error, omission, irregularity, uncertainty, ambiguity, or alteration without contacting the prescriber to obtain the information need to validate the prescription.

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SIXTH CAUSE FOR DISCIPLINE

(Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

60. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (f), in that Respondent committed acts of moral turpitude, dishonesty, fraud, deceit, or corruption. The circumstances are as follows:

a. On or about July 8, 2020, Respondent stated in writing that it was aware that peptides it was compounding were not on the FDA's list of bulk drug substances, but continued to promote, compound, and furnish compounded preparations containing peptides into California without making the consumers, physicians, or patients aware of the unapproved status of these preparations.

b. On or about November 21, 2018, Respondent posted a public communication on its YouTube.com channel/account titled "CJC-1295/Ipamorelin, PT-141(Bremelanotide), BPC-157" which contained false, fraudulent, misleading, and deceptive statements and claims for the purpose or to induce the rendering of professional services or furnishing of products in connection with its professional practice and business.

SEVENTH CAUSE FOR DISCIPLINE

(Misleading and Deceptive Advertisements)

61. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 651, in that Respondent published misleading and deceptive advertising for its drug products on its YouTube.com channel/account. The circumstances are as set forth in paragraph 54, above.

FACTS – DECEMBER 18, 2020, INVESTIGATION REPORT

62. On or about October 6, 2020, Board Supervising Inspector C.A. reviewed an article published by National Public Radio (NPR) written by Tom Dreisbach titled "Web of 'Wellness' Doctors Promote Injections of Unproven Coronavirus Treatment." The article noted that Respondent sells "custom wellness medications" for weight loss and "aesthetic dermatology" and promotes thymosin alpha-1 on its Facebook.com page along with the hashtags "#coronavirus" and "#covid."

63. C.A. reviewed Respondent's Facebook.com page and noted advertisements with false and misleading statements such as that Taurine (a sulfur-containing amino acid) is indicated to treat congestive heart failure, mitochondrial disease, mitochondrial encephalopathy, lactic acidosis, hepatitis, cirrhosis, diabetes, arthritis, blood pressure, nausea from cancer treatment, and kidney damage caused by drugs.

64. On July 20, 2020, July 21, 2020, and July 27, 2020, Respondent promoted on its Facebook.com page a seminar by Dr. Gordon Crozier that Respondent's product "Quad Immune" (a combination of thymosin alpha-1, Zinc, Vitamin D and Vitamin B Complex with Vitamin C) supports the human immune response against viral infections and help regulate pro-inflammatory cytokine storms.

65. In fact, Thymosin alpha-1, is not approved by the FDA, and there are only four studies that have been done, two in China in 2019 in Coronavirus and COVID-19 patients, and two in the United States, one looking at the prevention of COVID-19 and one looking at the treatment of COVID-19. Thymosin alpha-1 is not approved for use in the United States. The other substances in this product, Zinc, Vitamin D, and Vitamin B Complex with Vitamin C are vitamins and supplements and are not drug products.

66. Supervising Inspector C.A. also reviewed marketing material provided by Respondent regarding "Quad Immune" with several false or misleading statements such as that it was "Clinically proven in 80 studies with over 230,000 patients in 30 countries" that "Quad Immune…allows for your immune system to function at its optimal state…" and "that it "may counteract viral evasion of natural killer cell in infection."

67. On or about May 16, 2017, a compounding pharmacist, A.J.C., employed as a compounding pharmacist by Respondent provided a video presentation wherein A.J.C. promotes Sermorelin and other peptides and posted on Respondent's YouTube.com channel/account. In this presentation A.J.C. makes several false statements promoting Sermorelin and other Peptides and fails to note at any time that none of these products are FDA approved or legal to be compounded with in the United States.

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EIGHTH CAUSE FOR DISCIPLINE

(Use of Non-Compliant Bulk Drug Substance)

68. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code sections 4301, subdivisions (j) and (o), and 4342, for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondent violated 21 U.S.C. section 353a, subdivision (b)(1)(A)(i) by compounding and dispensing at least 371 prescriptions consisting of 2,675 mL and 529 vials of Thymosin alpha-1 to California patients that were compounded using a non-compliant bulk drug substances. The circumstances are that Respondent compounded Thymosin alpha-1 using ingredients that do not comply with the standards of an applicable USP-NF monograph, are not a component of a drug already approved by the FDA, and do not appear on a list developed by the FDA and codified by regulation.

NINTH CAUSE FOR DISCIPLINE

(Failure to Maintain Quality of Compounded Sterile Preparations)

69. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondent compounded drugs that lacked quality and dispensed those drugs to patients in violation of Regulations sections 1735.1, subd. (a)(e), and 1235.2, subd. (g). The circumstances are that from approximately February 3, 2020 to July 30, 2020, Respondent compounded and dispensed at least 371 prescriptions, consisting of 2,675 mL and 529 vials, of Thymosin alpha-1 to California patients which lacked quality.

TENTH CAUSE FOR DISCIPLINE

(Adulterated Preparations)

70. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondent violated Health and Safety Code sections 111250, 111255, and 111295, by compounding, selling, and dispensing adulterated drugs. The circumstances are that Respondent compounded at least 371 prescriptions, consisting

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of 2,675 mL and 529 vials, of Thymosin alpha-1 which were dispensed and sold to California patients which were, or could have been, adulterated.

ELEVENTH CAUSE FOR DISCIPLINE

(Assignment of Unsupported Beyond Use Date)

71. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondent violated Regulations 1735.2, subdivision (i), by assigning extended beyond use dates for at least 371 prescriptions, consisting of 2,675 mL and 529 vials, of Thymosin alpha-1 that were not supported by method suitability tests, container closure integrity tests, and stability studies.

TWELFTH CAUSE FOR DISCIPLINE

(Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

72. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (f), in that Respondent committed acts of moral turpitude, dishonesty, fraud, deceit, or corruption. The circumstances are as follows:

a. On or about May 16, 2017, Respondent posted a public communication on its YouTube.com channel/account which consisted of a presentation titled "Sermorelin & Peptides" which contained false, fraudulent, misleading, and deceptive statements and claims for the purpose or to induce the rendering of professional services or furnishing of products in connection with its professional practice and business.

b. On or about July 27, 2020, Respondent posted a public communication on its Facebook.com and LinkedIn.com accounts titled "Immune Presentation" given by Dr. G.C., which contained false, fraudulent, misleading, and deceptive statements and claims for the purpose or to induce the rendering of professional services or furnishing of products in connection with its professional practice and business.

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THIRTEENTH CAUSE FOR DISCIPLINE

(Misleading and Deceptive Advertising)

73. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 651, in that Respondent published misleading and deceptive advertising for its drug products on its Facebook.com account, its LinkedIn.com account, and its YouTube.com channel/account. The circumstances are as set forth in paragraphs 51-55, above.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Quarantine until Sterility Testing is Confirmed)

74. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondent violated Regulations section 1751.7, subdivision (e), by failing to complete USP chapter <71> compliant testing to confirm the sterility of the end product for at least fifteen prescriptions for CJC-1296/Ipamorelin, Trimix, Thymosin alpha-1, Ipamorelin/Semorelin, and DSIP1000 that were dispensed to California patients between December 16, 2019 and July 22, 2020.

FIFTEENTH CAUSE FOR DISCIPLINE

(Out of State Discipline)

75. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (n), in that Respondent has been disciplined by other States in which it holds licensure. The circumstances are as follows:

76. On or about November 4, 2016, the Alabama State Board of Pharmacy issued a Notice of Emergency Suspension of License as to Sterile Compounding. On June 13, 2017, Respondent voluntarily surrendered its nonresident pharmacy license and paid $10,000 in costs. This disciplinary action was based on the following:

a. A FDA 483 warning letter issued on September 13, 2016, released after a 2016 FDA inspection, noted concerns over a lack of sterility assurance of compounded products.

b. A voluntary agreement to restrict practice of sterile compounding in the state of Florida, this agreement was reached and issued due to the September 13, 2016, FDA 483 letter.

c. A voluntary recall of all sterile human and veterinary products prepared between February 22, 2016, and September 14, 2016, this recall was issued as a result of the September 13, 2016, FDA 483 letter.

77. On or about July 18, 2017, the New Hampshire State Board of Pharmacy denied a renewal application for Respondent based on recent disciplinary action taken by other states. Specifically, for the uses set forth in paragraph 64, above, and as follows. Respondent explained that in February 2016, one of its compounding rooms tested positive for airborne mold, penicillium. In March 2016, the room tested positive for mold again, this time penicillium and another unspecified growth. At an unknown later date, the room tested positive a third time and was shut down. Approximately 25,000 patients were affected by contaminated products due to this airborne mold growth, but none of the patients reported adverse effects. Additionally, Respondent engaged in the process of lyophilization and producing pellets without a valid manufacturing 503-B permit.

78. On or about September 21, 2017, the Wisconsin State Board of Pharmacy issued a Reprimand to Respondent and ordered Respondent to pay $468.00 in costs. This was a reciprocal action to the disciplinary action taken by the Florida State Board of Pharmacy as set forth in paragraph 64, subdivision (B).

79. On or about October 26, 2017, the Idaho State Board of Pharmacy issued a Stipulation and Consent Order against Respondent and ordered Respondent to pay a $10,000 fine. The cause for discipline was that Respondent had dispensed approximately 29 controlled substance prescriptions to Idaho residents that were prescribed by non-Idaho licensed prescribers.

a. In a follow-up proceeding, the Idaho State Board of Pharmacy issued an amended Stipulation and Consent Order against Respondent and ordered Respondent to pay a $14,000 fine. The cause for discipline was that Respondent had dispensed an additional seven controlled substance prescriptions to Idaho residents that were issued by non-Idaho licensed prescribers in violation of the previous order.

80. On or about June 18, 2019, the Missouri State Board of Pharmacy placed Respondent's license on probation for three years. The cause for discipline was that from April

2014 to July 2016, Respondent shipped controlled substance prescriptions to 24 Missouri residents that were prescribed by non-Missouri licensed practitioners.

81. On or about May 10, 2019, the Nebraska State Board of Pharmacy denied Respondent's nonresident pharmacy renewal application based on out of state disciplinary action taken in other states as follows:

a. On or about November 6, 2014, the Maine State Board of Pharmacy issued a warning letter and $750 fine to Respondent for failing to notify the Board of a change in its pharmacist-in-charge.

b. On or about June 9, 2015, the Arizona State Board of Pharmacy placed Respondent on probation for one year and issued a $9,000 civil penalty based on sterile compounding and recordkeeping violations identified during inspections by the FDA and the Arizona State Board of Pharmacy.

c. On or about September 27, 2016, the Florida State Board of Pharmacy temporarily restricted Respondent's sterile compounding license as set forth in paragraph 64, subdivision (b), above.

d. On or about October 3, 2016, the South Carolina State Board of Pharmacy temporarily restricted Respondent's permit and ordered Respondent to stop shipping compounded products into South Carolina.

e. On or about November 1, 2016, the Texas State Board of Pharmacy issued a Public Reprimand to Respondent as a reciprocal action to the November 6, 2014, action by the Arizona State Board of Pharmacy.

f. On or about July 18, 2017, the New Hampshire State Board of Pharmacy denied Respondent's renewal application as set forth in paragraph 65, above.

g. On or about October 26, 2017, the Idaho State Board of Pharmacy issued a disciplinary order against Respondent as set forth in paragraph 67, above.

h. On or about June 13, 2018, the Oklahoma State Board of Pharmacy issued a $52,525.00 fine to Respondent for acting as an illegal "pick-up station" and intermediary for another pharmacy and for compounding commercially available drugs.

i. On or about June 18, 2019, the Missouri State Board of Pharmacy issued a disciplinary order against Respondent as set forth in paragraph 68, above.

82. On or about December 27, 2019, the Nebraska State Board of Pharmacy issued an Agreed Settlement and placed Respondent's license on probation for three years.

FACTS – AUGUST 1, 2021, INVESTIGATION REPORT

83. Between on or about April 22, 2021 and June 29, 2021, Board Inspector Board Inspector L.F. conducted a sterile compounding renewal inspection of Respondent's NSC permit. Due to the COVID-19 pandemic, the inspection was conducted remotely consisting of reviewing records provided to L.F. by Respondent. L.F. discovered violations not only for the renewal of Respondent's NSC permit, which are set forth below in the Statement of Issues section, but also as to Respondent's NRP permit.

84. On or about September 29, 2020, Respondent was issued a written notice for compounding with bulk drug substances that did not have a USP monograph, were not components of drugs approved by the FDA, and did not appear on a list of bulk drug substances appropriate for compounding developed and codified in regulation by the FDA. Specifically, the written notice named BPC-157 and CJC-1295/Ipamorelin as drugs impermissibly compounded, dispensed, and shipped by Respondent.

85. BPC-157, CJC-1295/Ipamorelin, Thymosin Alpha-1 and Thymosin Beta-4, which are peptides, are not eligible for exemptions provided by section 503A of the Food Drug and Cosmetic Act.

86. BPC-157, CJC-1295/Ipamorelin, and Thymosin Alpha-1 are composed of 40 or fewer amino acids and are therefore considered a peptide or drug product.

87. Thymosin Beta-4 is composed of 43 amino acids and therefore is considered a protein and a biological product which requires approval of a biologics license application in order for any pharmacy to introduce it into interstate commerce. Thymosin Beta-4 is not an approved biological product.

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88. The investigation in this matter substantiated that Respondent continued to compound, dispense, and ship the products identified above, despite receiving the written notice that these products are not legal in the United States for compounding, dispensing, and shipping.

SIXTEENTH CAUSE FOR DISCIPLINE

(Use of a Non-Compliant Bulk Drug Substance)

89. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code sections 4301, subdivisions (j) and (o), and 4342, for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondent violated 21 U.S.C. section 353a, subdivision (b)(1)(A)(i), when it compounded non-compliant bulk drug substances as set forth below, and sold, dispensed, and shipped them to California patients. The drug products do not comply with the standards of an applicable USP-NF monograph, are not a component of a drug already approved by the FDA, and do not appear on a list developed by the FDA and codified by regulation.

a. After receiving a written notice on September 29, 2020, that BPC-157 was a non-compliant bulk drug substance, Respondent compounded and shipped at least 56 orders and 400 vials of BPC-157 to California consumers.

b. After receiving a written notice on September 29, 2020, that CJC-1295/Ipamorelin was a non-compliant bulk drug substance, Respondent compounded and shipped at least 190 orders and 715 vials of CJC-1295/Ipamorelin to California consumers.

c. After receiving a written notice on September 29, 2020, that Thymosin Alpha-1 was a non-compliant bulk drug substance, Respondent compounded and shipped at least 471 orders and 3,449 vials of Thymosin Alpha-1 to California consumers.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Failure to Obtain Biologics License)

90. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondent violated 42 U.S.C. section 262, subdivision (a)(1)(A), in that between April 1, 2020 and June 30, 2020, Respondent compounded,

dispensed, and shipped at least 41 orders and 240 vials of Thymosin Beta, which is designated as a biological product by the FDA, into California without first obtaining a biologics application approval from the FDA.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Assignment of Unsupported Beyond Use Date)

91. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondent assigned beyond use dates that were unsupported by tests and studies in violation of Regulations section 1735.2, as follows:

a. Respondent violated Regulations section 1735.2, subdivision (i)(3)(B), assigning an extended beyond use date of 180 days to lot 01142021@82 for Sermorelin Kit 15 mg. ing., when container closure integrity tests had not been performed. This is a repeat violation from an inspection performed on July 21, 2020, that Respondent failed to correct.

b. Respondent violated Regulations section 1735.2, subdivision (i)(3)(C), assigning extended beyond use dates to five lots of compounded drugs, two lots of Thymosin Alpha-1, one lot of BPC-157, and two lots of CJC-1295/Ipamorelin without having stability studies.

NINETEENTH CAUSE FOR DISCIPLINE

(Failure to Quarantine until Sterility Testing is Confirmed)

92. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent violated laws and regulations governing pharmacy and regulating dangerous drugs by violating Regulations section 1751.7, subdivision (e), by dispensing compounded drug products to patients without completing USP chapter <71> compliant testing to confirm the sterility of the end product as follows:

a. Lot number CA-07142020@10 was released without USP Chapter <71> compliant testing. Respondent stated this was because the samples were sent to the wrong lab and correcting the problem would have caused delay.

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b. Lot numbers CA-08282020@11 and CA-09162020@17 for CJC/Ipamorelin, and lot numbers CA-09232020@8 and CA-9162020@20 for BPC-157 were released without USP chapter <71> testing. Respondent stated these lots were released prior to USP chapter <71> testing due to product demand and vendor issues.

c. Respondent admitted that multiple lots were shipped into California prior to USP Chapter <71> testing being completed due to customer service representatives selecting non-CA designations and verification checks failed to confirm regulatory compliance.

TWENTIETH CAUSE FOR DISCIPLINE

(Failure to Notify Board of Product Recall)

93. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent violated laws and regulations governing pharmacy and regulating dangerous drugs by violating Code sections 4127.2, subdivision (e)(3), by failing to notify the Board that Respondent had issued a recall of multiple lots of sterile compounded drugs including Thymosin Alpha-1, and Thymosin Beta-4, which had been dispensed to California patients prior to USP chapter <71> testing being completed.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Failure to Notify Patient of Recalled Sterile Compounded Drug)

94. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent violated laws and regulations governing pharmacy and regulating dangerous drugs by violating Code sections 4127.8, subdivision (2)(b)(1), by issuing a "call tag" recall requesting that the courier return and not deliver multiple lots of sterile compounded drugs including Thymosin Alpha-1, and Thymosin Beta-4, which had been dispensed to California patients prior to USP chapter <71> testing being completed. Respondent acknowledged that despite the "call tag," some or all of the products were delivered to patients and Respondent failed to notify the patients of this recall.

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TWENTY-SECOND CAUSE FOR DISCIPLINE

(Gross Negligence)

95. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (b), in that Respondent committed gross negligence when it knowingly dispensed and shipped sterile compounds into California that had not had USP chapter <71> testing as required by Regulations section 1751.7, subdivision (e)(1).

TWENTY-THIRD CAUSE FOR DISCIPLINE

(Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

96. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (f), in that Respondent committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption as follows:

a. Respondent knowingly dispensed and shipped sterile compounds into California that had not had USP chapter <71> testing as required by Regulations section 1751.7, subdivision (e)(1).

b. Respondent continued to dispense and ship BPC-157 and CJC-1295/Ipamorelin into California after receiving a written notice on September 29, 2020, that the bulk substances Respondent was using to compound did not have a USP monograph, were not components of drugs approved by the FDA, and did not appear on a list developed and codified in regulation by the FDA, and therefore did not qualify for the 21 U.S.C. 353a exemption.

STATEMENT OF ISSUES

97. Facts set forth in paragraphs 71 through 76, for the August 1, 2021, investigation report are incorporated herein by reference as though fully set forth.

98. This Statement of Issues is based on the August 1, 2021, Inspection report, and therefore the facts underlying the causes for denial are identical to the sixteenth through twenty-third causes for discipline, paragraphs 83 through 88.

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FIRST CAUSE FOR DENIAL

(Use of a Non-Compliant Bulk Drug Substance)

99. Respondent's application for renewal of its NSC permit is subject to denial pursuant to Code sections 4127.2, subdivision (c), and 4300, subdivision (c) for unprofessional conduct pursuant to Code sections 4301, subdivisions (j) and (o), and 4342, in that Respondent violated laws and regulations governing pharmacy and regulating dangerous drugs by violating 21 U.S.C. 353a, subdivision (b)(1)(A)(i), when it compounded non-compliant bulk drug substances as set forth below, and shipped, sold, and dispensed them to California patients. The drug products do not comply with the standards of an applicable USP-NF monograph, are not a component of a drug already approved by the FDA, and do not appear on a list developed by the FDA and codified by regulation.

a. After receiving a written notice on September 29, 2020, that BPC-157 was a non-compliant bulk drug substance, Respondent compounded and shipped at least 56 orders and 400 vials of BPC-157 to California consumers.

b. After receiving a written notice on September 29, 2020, that CJC-1295/Ipamorelin was a non-compliant bulk drug substance, Respondent compounded and shipped at least 190 orders and 715 vials of CJC-1295/Ipamorelin to California consumers.

c. After receiving a written notice on September 29, 2020, that Thymosin Alpha-1 was a non-compliant bulk drug substance, Respondent compounded and shipped at least 471 orders and 3,449 vials of Thymosin Alpha-1 to California consumers.

SECOND CAUSE FOR DENIAL

(Failure to Obtain Biologics License)

100. Respondent's application for renewal of its NSC permit is subject to denial for unprofessional conduct pursuant to Code sections 4127.2, subdivision (c), and 4300, subdivision (c), as defined by Code section 4301, subdivisions (j) and (o), in that Respondent violated laws and regulations governing pharmacy and regulating dangerous drugs by violating 42 U.S.C. section 262, subdivision (a)(1)(A), in that between April 1, 2020 and June 30, 2020, Respondent compounded, dispensed, and shipped at least 41 orders and 240 vials of Thymosin Beta, which is

designated as a biological product by the FDA, into California without first obtaining a biologics application approval from the FDA.

THIRD CAUSE FOR DENIAL

(Assignment of Unsupported Beyond Use Date)

101. Respondent's application for renewal of its NSC permit is subject to denial for unprofessional conduct pursuant to Code sections 4127.2, subdivision (c) and 4300, subdivision (c), as defined by Code section 4301, subdivisions (j) and (o), in that Respondent violated laws and regulations governing pharmacy and regulating dangerous drugs when it assigned beyond use dates that were unsupported by tests and studies in violation of Regulations section 1735.2, as follows:

a. Respondent violated Regulations section 1735.2, subdivision (i)(3)(B), assigning an extended beyond use date of 180 days to lot 01142021@82 for Sermorelin Kit 15 mg. inj., when container closure integrity tests had not been performed. This is a repeat violation from an inspection performed on July 21, 2020, that Respondent failed to correct.

b. Respondent violated Regulations section 1735.2, subdivision (i)(3)(C), assigning extended beyond use dates to five lots of compounded drugs, two lots of Thymosin Alpha-1, one lot of BPC-157, and two lots of CJC-1295/Ipamorelin without having stability studies.

FOURTH CAUSE FOR DENIAL

(Failure to Quarantine until Sterility Testing is Confirmed)

102. Respondent's application for renewal of its NSC permit is subject to denial for unprofessional conduct pursuant to Code sections 4127.2, subdivision (c) and 4300, subdivision (c), as defined by Code section 4301, subdivisions (j) and (o), in that Respondent violated laws and regulations governing pharmacy and regulating dangerous drugs by violating Regulations section 1751.7, subdivision (e), by dispensing compounded drug products to patients without completing USP chapter <71> compliant testing to confirm the sterility of the end product as follows:

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a. Lot number CA-07142020@10 was released without USP Chapter <71> compliant testing. Respondent stated this was because the samples were sent to the wrong lab and correcting the problem would have caused delay.

b. Lot numbers CA-08282020@11 and CA-09162020@17 for CJC/Ipamorelin, and lot numbers CA-09232020@8 and CA-9162020@20 for BPC-157 were released without USP chapter <71> testing. Respondent stated these lots were released prior to USP chapter <71> testing due to product demand and vendor issues.

c. Respondent admitted that multiple lots were shipped into California, to patients residing in California prior to USP Chapter <71> testing being completed due to customer service representatives selecting non-CA designations and verification checks failed to confirm regulatory compliance.

FIFTH CAUSE FOR DENIAL

(Failure to Notify Board of Product Recall)

103. Respondent's application for renewal of its NSC permit is subject to denial for unprofessional conduct pursuant to Code sections 4127.2, subdivision (c) and 4300, subdivision (c), as defined by Code section 4301, subdivisions (j) and (o), in that Respondent violated laws and regulations governing pharmacy and regulating dangerous drugs by violating Code sections 4127.2, subdivision (e)(3), by failing to notify the Board it had issued a recall of multiple lots of sterile compounded drugs including Thymosin Alpha-1, and Thymosin Beta-4, which had been dispensed to California patients prior to USP chapter <71> testing being completed.

SIXTH CAUSE FOR DENIAL

(Failure to Notify Patient of Recalled Sterile Compounded Drug)

104. Respondent's application for renewal of its NSC permit is subject to denial for unprofessional conduct pursuant to Code sections 4127.2, subdivision (c) and 4300, subdivision (c), as defined by Code section 4301, subdivisions (j) and (o), in that Respondent violated Code sections 4127.8, subdivision (2)(b)(1), by issuing recall known as a "call tag" requesting that the courier return and not deliver multiple lots of sterile compounded drugs including Thymosin Alpha-1, and Thymosin Beta-4, which had been dispensed to California patients prior to USP

chapter <71> testing being completed. Respondent acknowledged that despite the "call tag," some or all of the products were delivered to patients and Respondent failed to notify the patients of this recall.

SEVENTH CAUSE FOR DENIAL

(Gross Negligence)

105. Respondent's application for renewal of its NSC permit is subject to denial for unprofessional conduct pursuant to Code sections 4127.2, subdivision (c) and 4300, subdivision (c), as defined by Code section 4301, subdivision (b), in that Respondent committed gross negligence when it knowingly dispensed and shipped sterile compounds into California that had not had USP chapter <71> testing as required by Regulations section 1751.7, subdivision (e)(1).

EIGHTH CAUSE FOR DENIAL

(Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

106. Respondent's application for renewal of its NSC permit is subject to denial for unprofessional conduct pursuant to Code sections 4127.2, subdivision (c) and 4300, subdivision (c), as defined by Code section 4301, subdivision (f), in that Respondent committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption as follows:

a. Respondent knowingly dispensed and shipped sterile compounds into California that had not had USP chapter <71> testing as required by Regulations section 1751.7, subdivision (e)(1).

b. Respondent continued to dispense and ship BPC-157 and CJC-1295/Ipamorelin into California after receiving a written notice on September 29, 2020, that the bulk substances Respondent was using to compound did not have a USP monograph, were not components of drugs approved by the FDA, and did not appear on a list developed and codified in regulation by the FDA, and therefore did not qualify for the 21 U.S.C. section 353a exemption.

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NINTH CAUSE FOR DENIAL

(Pending Disciplinary Action)

107. Respondent's application for renewal of its NSC permit is subject to denial pursuant to Code section 4302 and Code section 4307, due to the pending disciplinary action set forth in paragraphs 34 through 96, above. The circumstances are as follows:

a. Pursuant to Code section 4302, if the Accusation results in discipline against Respondent, Wells Pharmacy Network LLC, then shareholders OB Joyful Dynasty Trust, The Colleen Stacy Shapiro 2010 Trust, The Shapiro Family D III Trust, and Rachel Ellyn McKim, as well as officers and managers Kristopher Jay Fishman, Jarrett Todd Bostwick, and William Edward McMillen shall be prohibited from owning 10% or more of any other pharmacy.

b. Pursuant to Code section 4307, if the Accusation results in discipline against Respondent, then Wells Pharmacy Network LLC, then shareholders OB Joyful Dynasty Trust, The Colleen Stacy Shapiro 2010 Trust, The Shapiro Family D III Trust, Nemomon LLC, Rachel Ellyn McKim, and Shirley Ann Eis, as well as officers and managers Kristopher Jay Fishman, Jarrett Todd Bostwick, and William Edward McMillen shall be prohibited from owning or managing any pharmacy.

DISCIPLINARY CONSIDERATIONS

108. On or about February 28, 2019, the Board issued citation number CI 2017 80725 with a $500.00 fine to Respondent's NRP license for violating Code section 4301, subdivision (n), unprofessional conduct, out of state disciplinary action in that the Oklahoma State Board of Pharmacy fined Respondent $52,525.00 and ordered it not to compound a product that is commercially available or a copy of an available FDA-approved drug product for delivery to Oklahoma residents or entities located in Oklahoma. The underlying facts are that Respondent sent prescriptions to a pharmacy clinic without an exemption under Oklahoma law allowing for pickup there by patients, refilled patients' prescriptions too soon, and compounded commercially-available products without justification. Respondent paid the fine and the citation is now final.

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OTHER MATTERS

109. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 1333 or on Nonresident Sterile Compounding Pharmacy Permit Number NSC 99845 issued to Wells Pharmacy Network LLC dba Wells Pharmacy Network LLC, then Wells Pharmacy Network LLC and Nemomon LLC 24% shareholder, The Colleen Stacy Shapiro 2010 Trust, 14% shareholder, OB Joyful Dynasty Trust, 9% shareholder, The Shapiro Family D III Trust, 8% shareholder, Jarrett Todd Bostwick, 8% shareholder, Rachel Ellyn McKim, 8% shareholder, and Howard Brown, Pharmacist in Charge, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five (5) years if either or both of the pharmacy permits are placed on probation; or, 2) if either or both of the pharmacy permits are revoked, the prohibition shall continue until either of the permits are 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 1333, issued to Wells Pharmacy Network LLC dba Wells Pharmacy LLC;

2. Revoking or suspending Nonresident Sterile Compounding Pharmacy Permit Number NSC 99845, issued to Wells Pharmacy Network LLC dba Wells Pharmacy LLC,;

3. Prohibiting Wells Pharmacy Network LLC dba Wells Pharmacy LLC from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

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

5. Prohibiting The Colleen Stacy Shapiro 2010 Trust from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

6. Prohibiting OB Joyful Dynasty Trust from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

7. Prohibiting The Shapiro Family D III Trust from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

8. Prohibiting Jarrett Todd Bostwick from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

9. Prohibiting Rachel Ellyn McKim from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

10. Prohibiting Howard Brown from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

11. Ordering Wells Pharmacy Network LLC dba Wells Pharmacy Network 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,

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

DATED: 12/4/2023

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2023.12.04 15:17:12 -08'00'

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

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