ROB BONTA
Attorney General of California
DAVID E. BRICE
Supervising Deputy Attorney General
MABEL LEW
Deputy Attorney General
State Bar No. 158042
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-6104
Facsimile: (916) 327-8643
Attorneys for Complainant

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

In the Matter of the Statement of Issues Against**:** **OLYMPIA PHARMACY** **Applicant for Renewal of Non-Resident Sterile Compounding License No. NSC100818** Respondent.	Case No. 7384 **FIRST AMENDED STATEMENT OF ISSUES**

PARTIES

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

2. On or about December 15, 2015, the Board issued Non-Resident Sterile Compounding License Number NSC 100818 to OPS International Incorporated, doing business as Olympia Pharmacy (Respondent), with Marco Loleit, its 100% shareholder, as its Chief Executive Officer, Chief Financial Officer, Secretary and Treasurer. The Non-Resident Sterile Compounding License was in full force and effect at all times relevant to the charges brought

herein and will expire on November 1, 2022, unless renewed. Prior to its expiration, Respondent applied for the renewal of Nonresident Sterile Compounding License No. NSC 100818. On or about September 16, 2022, Respondent's application for renewal was denied.

3. On or about September 26, 2022, the Board received Respondent's timely appeal of the Board's denial of Respondent's Nonresident Sterile Compounding License No. NSC 100818.

JURISDICTION

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

5. Code section 4300, 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.

6. Code section 4300.1 states:

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

7. Code section 4301 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 includes, but is not limited to, any of the following:
>
> . . .
>
> (c) Gross negligence.
>
> . . .

(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 statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

. . .

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

. . .

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

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

9. Code section 4123 states:

Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.

10. Code section 4126.8 states:

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

11. Code section 4127.2 states, in pertinent part:

(a) A nonresident pharmacy shall not compound sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

. . .

(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.

. . .

(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. . . .

12. Code section 4129.1 states, in pertinent part:

(a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) and with an address in this state shall also be licensed by the board as an outsourcing facility before doing business within this state. The license shall be renewed annually and is not transferable.

(b) An outsourcing facility shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) An outsourcing facility license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) An outsourcing facility license shall not be issued or renewed until the board does all of the following:

(1) Prior to inspection, reviews a current copy of the outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the outsourcing facility's premises conducted in the prior 12 months.

(3) Prior to inspection, receives a list of all sterile drugs and nonsterile drugs compounded by the outsourcing facility as reported to the FDA in the last 12 months.

(e) An outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Notice within 24 hours of any recall notice issued by the outsourcing facility.

(3) A copy of any clinically related complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.

(4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to the outsourcing facility's products.

13. Code section 4129.2 states, in pertinent part:

(a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) as an outsourcing facility and has an address outside of this state but in the United States of America is a nonresident outsourcing facility. A nonresident outsourcing facility shall not compound sterile drug products or nonsterile drug products for distribution or use into this state without an outsourcing license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) 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.

14. Code section 4169 states, in pertinent part:

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

. . .

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

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

15. Code section 4307 states, in pertinent part:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer,

director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

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

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

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

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

HEALTH AND SAFETY CODE

16. California Health and Safety Code (Health & Saf. 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."

17. Health & Saf. Code, section 111255, states, "Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."

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

19. Health and Saf. Code, section 111330, states, "Any drug or device is misbranded if its labeling is false or misleading in any particular."

20. Health and Saf. Code, section 111335, states, "Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

21. Health and Saf. Code section 111430 states, "A drug or device is misbranded if it was manufactured in an establishment not duly registered with the Secretary of Health, Education, and Welfare of the United States."

22. Health and Saf. Code section 111440 states, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

23. Health and Saf. Code section 111445 states, "It is unlawful for any person to misbrand any drug or device."

24. Health and Saf. Code section 111445 states, "It is unlawful for any person to misbrand any drug or device."

CALIFORNIA REGULATIONS

25. California Code of Regulations, title 16 (CCR), section 1735.2 states, in pertinent part:

> . . .
>
> (e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:
>
> . . .
>
> (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.
>
> . . .

26. CCR section 1735.4 states, in pertinent part:

> (a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:
>
> (1) Name of the compounding pharmacy and dispensing pharmacy (if different). . . .

27. CCR section 1735.5, subdivision (a) states, in pertinent part:

> Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

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28. CCR section 1735.8 states, in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel. . . .

29. CCR section 1751.6, subdivision (e), states, in pertinent part:

Pharmacies that compound sterile drug preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(F) Proper hand hygiene, gowning and gloving technique. . . .

FEDERAL STATUTES AND REGULATIONS

30. United States Code Annotated, title 21 (21 USCA) section 321 states, in pertinent part:

. . .

(ff) The term "dietary supplement" –

(1) Means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) Means a product that –

(A)

(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or

(ii) complies with section 350(c)(1)(B)(ii) of this title

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does-

(A) Include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 262 of title 42 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and

(B) not include-

(i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be unlawful under this chapter.

Except for purposes of paragraph (g) and section 350f of this title, a dietary supplement shall be deemed to be a food within the meaning of this chapter.

31. 21 USCA section 331 states, in pertinent part:

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded. . . .

32. 21 USCA section 350 states, in pertinent part:

. . .

(c) Definitions

(1) For purposes of this section, the term "food to which this section applies" means a food for humans which is a food for special dietary use-

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(A) which is or contains any natural or synthetic vitamin or mineral, and

(B) which-

(i) is intended for ingestion in table, capsule, powder, softgel, gelcap, or liquid form, or

(ii) if not intended for ingestion in such a form, is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

33. 21 USCA 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 Act [21 USCA §§ 301 et seq.] as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this Act [21 USCA §§ 301 et seq.] as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 721(a) [21 USCA § 379e(a)], or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 721(a) [21 USCA § 379e(a)]; or (5) if it is a new animal drug which is unsafe within the meaning of section 512 [21 USCA § 360b]; or (6) if it is an animal feed bearing or contaminating a new animal drug, and such animal feed is unsafe within the meaning of section 512 [21 USCA § 360f].

(b) Strength, quality, or purity differing from official compendium. If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. . . . Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the

Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia. . . .

34. 21 USCA section 352 states, in pertinent part:

A drug or device shall be deemed to be misbranded—

. . .

(o) Drugs or devices from nonregistered establishments. If it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 [21 USCA § 360], if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 801(s) [21 USCA § 381(s)], if it was not included in a list required by section 510(j) [21 USCA § 360(j)], if a notice or other information respecting it was not provided as required by such section or section 510(k) [21 USCA § 360(k)], or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 510(e) [21 USCA § 360(e)] as the Secretary by regulation requires. . . .

35. 21 USCA section 353a states, in pertinent part:

(a) In general. Sections 501(a)(2)(B), 502(f)(1), and 505 [21 USCA §§ 351(a)(2)(B), 352(f)(1), and 355] shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

(1) is by—

(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

(B) a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

(2)

(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

(i) the licensed pharmacist or licensed physician; and

(ii)

(I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

(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);

(ii) that are manufactured by an establishment that is registered under section 510 [21 USCA § 360] (including a foreign establishment that is registered under section 510(i) [21 USCA § 360(i)]); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(B) compounds the drug product using ingredients (other than bulk drug substances) that 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;

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(2) Definition. For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

(3) Drug product. A drug product may be compounded under subsection (a) only if—

(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) such drug product is compounded in a State—

(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

…

(e) "Compounding" defined. As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

36. 21 USCA section 353b states, in pertinent part:

(a) In general. Sections 502(f)(1), 505, and 582 [21 USCA §§ 352(f)(1), 355, and 360eee-1] shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met:

(1) Registration and reporting. The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (b).

(2) Bulk drug substances. The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless—

(A)
(i) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by—

(I) publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;

(II) providing a period of not less than 60 calendar days for comment on the notice; and

(III) publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or

(ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 506E [21 USCA § 356e] at the time of compounding, distribution, and dispensing;

(B) if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substances each comply with the monograph;

(C) the bulk drug substances are each manufactured by an establishment that is registered under section 510 [21 USCA § 360] (including a foreign establishment that is registered under section 510(i)) [21 USCA § 360(i)]; and

(D) the bulk drug substances are each accompanied by a valid certificate of analysis.

(3) Ingredients (other than bulk drug substances) If any ingredients (other than bulk drug substances) are used in compounding the drug, such ingredients comply with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph if any.

(4) Drugs withdrawn or removed because unsafe or not effective. The drug does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

(5) Essentially a copy of an approved drug. The drug is not essentially a copy of one or more approved drugs.

(6) Drugs presenting demonstrable difficulties for compounding. The drug—

(A) is not identified (directly or as part of a category of drugs) on a list published by the Secretary, through the process described in subsection (c), of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients; or

(B) is compounded in accordance with all applicable conditions identified on the list described in subparagraph (A) as conditions that are necessary to prevent the drug or category of drugs from presenting the demonstrable difficulties described in subparagraph (A).

(7) Elements to assure safe use. In the case of a drug that is compounded from a drug that is the subject of a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 505-1 [21 USCA § 355-1], or from a bulk drug substance that is a component of such drug, the outsourcing facility demonstrates to the Secretary prior to beginning compounding that such facility will utilize controls comparable to the controls applicable under the relevant risk evaluation and mitigation strategy.

(8) Prohibition on wholesaling. The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. This paragraph does not prohibit administration of a drug in a health care setting or dispensing a

drug pursuant to a prescription executed in accordance with section 503(b)(1) [21 USCA § 353(b)(1)].

(9) Fees. The drug is compounded in an outsourcing facility that has paid all fees owed by such facility pursuant to section 744K [21 USCA § 379j-62].

(10) Labeling of drugs.

(A) Label. The label of the drug includes—

(i) the statement "This is a compounded drug." or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

(ii) the name, address, and phone number of the applicable outsourcing facility; and

(iii) with respect to the drug—

(I) the lot or batch number;

(II) the established name of the drug;

(III) the dosage form and strength;

(IV) the statement of quantity or volume, as appropriate;

(V) the date that the drug was compounded;

(VI) the expiration date;

(VII) storage and handling instructions;

(VIII) the National Drug Code number, if available;

(IX) the statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only"; and

(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

(B) Container. The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include—

(i) the information described under subparagraph (A)(iii)(X), if there is not space on the label for such information;

(ii) the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088 (or any successor Internet Web site or phone number); and

(iii) directions for use, including, as appropriate, dosage and administration.

(C) Additional information. The label and labeling of the drug shall include any other information as determined necessary and specified in regulations promulgated by the Secretary.

(11) Outsourcing facility requirement. The drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section.

(b) Registration of outsourcing facilities and reporting of drugs.

. . .

(2) Drug reporting by outsourcing facilities.

(A) In general. Upon initially registering as an outsourcing facility, once during the month of June of each year, and once during the month of December of each year, each outsourcing facility that registers with the Secretary under paragraph (1) shall submit to the Secretary a report—

(i) identifying the drugs compounded by such outsourcing facility during the previous 6-month period; and

(ii) with respect to each drug identified under clause (i), providing the active ingredient, the source of such active ingredient, the National Drug Code number of the source drug or bulk active ingredient, if available, the strength of the active ingredient per unit, the dosage form and route of administration, the package description, the number of individual units produced, and the National Drug Code number of the final product, if assigned.

. . .

(4) Risk-based inspection frequency.

(A) In general. Outsourcing facilities—

(i) shall be subject to inspection pursuant to section 704 [21 USCA § 374]; and

(ii) shall not be eligible for the exemption under section 704(a)(2)(A) [21 USCA § 374(a)(2)(A)].

(B) Risk-based schedule. The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect outsourcing facilities in accordance with a risk-based schedule established by the Secretary.

(C) Risk factors. In establishing the risk-based schedule, the Secretary shall inspect outsourcing facilities according to the known safety risks of such outsourcing facilities, which shall be based on the following factors:

(i) The compliance history of the outsourcing facility.

(ii) The record, history, and nature of recalls linked to the outsourcing facility.

(iii) The inherent risk of the drugs compounded at the outsourcing facility.

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(iv) The inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has been inspected pursuant to section 704 [21 USCA § 374] within the last 4 years.

(v) Whether the outsourcing facility has registered under this paragraph as an entity that intends to compound a drug that appears on the list in effect under section 506E [21 USCA § 356e].

(vi) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(5) Adverse event reporting. Outsourcing facilities shall submit adverse event reports to the Secretary in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).

. . .

(d) Definitions. In this section:

(1) The term "compounding" includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

(2) The term "essentially a copy of an approved drug" means—

(A) a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 503(b) [21 USCA § 353(b)] and not subject to approval in an application submitted under section 505 [21 USCA § 355], unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 506E [21 USCA § 356e] at the time of compounding, distribution, and dispensing; or

(B) a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 503(b) [21 USCA § 353(b)] and not subject to approval in an application submitted under section 505 [21 USCA § 355], unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

(3) The term "approved drug" means a drug that is approved under section 505 [21 USCA § 355] and does not appear on the list described in subsection (a)(4) of

drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective. . . .

37. Code of Federal Regulations, title 21 (CFR), section 1302.03 states, in pertinent part:

(a) Each commercial container of a controlled substance (except for a controlled substance excepted by the Administrator pursuant to § 1308.31 of this chapter) shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. Each such commercial container, if it otherwise has no label, must bear a label complying with the requirement of this part.

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(b) Each manufacturer shall print upon the labeling of each controlled substance distributed by him the symbol designating the schedule in which such controlled substance is listed.

(c) The following symbols shall designate the schedule corresponding thereto:

Schedule	
Schedule I	CI or C-I.
Schedule II	CII or C-II.
Schedule III	CIII or C-III.
Schedule IV	CIV or C-IV.
Schedule V	CV or C-V.

The word "schedule" need not be used. No distinction need be made between narcotic and nonnarcotic substances. . . .

DEFINITIONS

38. **Aseptic process simulations** (APS), also known as media fill, are studies conducted on the aseptic filling process, which is simulated to the actual production procedure where the product is replaced with growth media.

39. **Food Chemical Codex (FCC)**. The FCC and associated Reference Materials enables you to verify the identity, quality, and purity of the food ingredients you buy and sell, which help to ensure the overall safety and integrity of the food ingredient supply chain. An FCC standard can be used to characterize ingredients used in food. Monographs in the FCC consist of tests and specifications for identification, assay and impurities, as well as other tests that help describe the purity and quality of the ingredient. FCC standards are reviewed and approved by independent experts.

40. **Lyophilization** is a low temperature dehydration process where the product is frozen, the pressure lowered, and ice removed by sublimation. Lyophilization allows for ease of storage, shipping, and reconstitution to the product's original form for injection.

41. **Methionine** is a sulfur-containing essential amino acid that is a constituent of most proteins.

42. **Out-of-Specification Investigation**. A required element of the Quality Assurance Plan required as described in CCR section 1735.8 in response to a product test result outside its specification limits. A written procedure, i.e., SOP, must exist that describes the methodology for performing an OOS investigation. OOS investigations must be documented.

43. **Settle Plates**, also known as sedimentation plates or settling plates, are used in the pharmaceutical industry for semi-quantitative determination of microbial contamination in the air. The plate is typically a petri dish containing an agar medium. The plate is opened and exposed over a given period of time, allowing microbe-bearing particles to deposit onto the plate. The number of microbe bearing particles deposited onto the agar surface of the plate over the period of exposure is ascertained by incubating the plate and counting the number of microbial colonies (colony-forming units, [CFUs]).

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

45. **USP-NF** is the United States Pharmacopeia-National Formulary, a comprehensive source for over 5,000 quality standards for medicines, active pharmaceutical ingredients (API), and inactive ingredients.

46. **USP Monographs**. USP-NF publishes monographs that articulate the quality expectations for medicines approved by the U.S. Food and Drug Administration (US FDA), including the medication identity, strength, purity and performance. Monographs also describe the tests to validate that a medicine and its ingredients meet USP-NF criteria.

DRUG DESCRIPTIONS

47. **Ascorbic acid injection** (brand name *Acor*®) is indicated for short term treatment of scurvy in patients for whom oral administration is not possible, insufficient, or contraindicated. It is a dangerous drug within the meaning of Code section 4022.

48. **Biotin injection,** compounded by Respondent, is a dangerous drug within the meaning of Code section 4022. There is no FDA approved indication for this drug.

49. **Benzocaine/Lidocaine/Tetracaine (BLT), Formula ID #7409,** compounded by Respondent, is a non-sterile drug preparation for topical application.

50. **Butylated hydroxytoluene (BHT)** is a synthetic organic chemical compounding which inhibits oxidation of unsaturated organic compounds. It is often used in food, cosmetics, and pharmaceutical applications to prevent oxidation.

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51. **Formula ID #6924**, non-sterile preparations, compounded by Respondent, is comprised of minoxidil/ fluocinolone/retinoic acid 5/0.01/0.01%.

52. **Olympia Vita-Complex Injection**, compounded by Respondent, contains thiamine hydrochloride (vitamin B1), niacinamide (vitamin B3), riboflavin (vitamin B2), dexpanthenol (vitamin B5), pyridoxine hydrochloride (vitamin B6), benzyl alcohol, and SWFI. It is a dangerous drug within the meaning of Code section 4022. There is no FDA approved indication for this drug.

53. **Sermorelin Acetate injection**, compounded by Respondent, is a human growth hormone-releasing hormone (GHRH or GRF) used for diagnostic evaluation of pituitary function and also for increasing growth in children. It is a dangerous drug pursuant to Code section 4022.

54. **Testosterone Cypionate injection** (Respondent's tradename Ultratest), compounded by Respondent, comes only in the form of an injectable solution given into a muscle. It is used to treat symptoms of hypogonadism in males (a condition where males do not produce enough of the sex hormone testosterone). It is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (f)(30), and a dangerous drug pursuant to Code section 4022.

STATEMENT OF FACTS

55. On or about August 1 and 2, 2022, Inspector J.F. conducted an on-site, annual, nonresident sterile compounding renewal inspection of Respondent's facility in Orlando, Florida. Inspector J.F. requested, and Respondent provided, numerous documents for evaluation. At the conclusion of the inspection and upon review of Respondent's documentation, Inspector J.F. found multiple violations of Pharmacy Law, many of which constituted cause for denial of Respondent's application to renew its nonresident sterile compounding license. On or about September 19, 2022, Inspector J.F. issued another Written Notice to Respondent, notifying Respondent of the following violations:

Written Notice #1

56. Inspector J.F. found that Respondent failed to follow its own SOPs. Specifically, Respondent's *Policy on Current Good Documentation Practices* states, in pertinent part, "Never sign a task that is not completed". Respondent's quality associate, L.S., admitted to Inspector

J.F. that he documented for a future date of August 2, 2022, that dispositioned passive viable air plates were sampled on July 27, 2022, and passed with 0 CFU counts. Respondent's *Policy on Current Good Documentation Practices*, also states, in pertinent part, "Never sign or initial anyone else's name or initials". L.S. admitted to Inspector J.F. that it was his practice to document the samplers' initials on Respondent's environmental monitoring form without personally performing the sampling.

57. Inspector J.F. found that Respondent did not follow its own SOPs for conducting and reviewing aseptic processing simulations. For example, Respondent's *Aseptic Process Simulation 2* (APS2) procedure required mixing the final completed volume on the stir plate for no less than 60 minutes. On March 10, 2022, Lot APS2-A10-22 was mixed for 40 minutes. The procedure further required filtration time "of no less than 2 hours". On March 10, 2022, the total filtration time for Lot APS2-A10-22 was 22 minutes. The procedure required completion of the filling process prior to lyophilization. The filling for Lot APS2-A10-22 was documented as completed at 18:13 hours, yet lyophilization was documented as having started at 18:00 hours, thirteen minutes before filling was completed. On April 1, 2022, the lot was verified to conform to the finished product specification for quality assurance release and adhere to cGMP requirements.

58. Respondent's APS2 procedure required six filling personnel. On March 17, 2022, only five filling personnel participated in filling for Lot APS2-B017-22. Respondent's procedure also required no less than two hours for filtration. On March 17, 2022, the total filtration time was documented at 30 minutes. On April 6, 2022, the lot was verified to conform to the finished product specification for quality assurance release and adhere to cGMP requirements.

59. Inspector J.F. notified Respondent that the act set forth in paragraphs 56 through 58 were in violation of CCR section 1735.5, subdivision (a).

Written Notice #2

60. Inspector J.F. found that Respondent's SOP, *Shipping of Compounded Preparations,* requires, in pertinent part, that "Temperature sensitive compounded preparations must be maintained at a temperature of <8C for the entire duration of the transit." The labeled

requirement for frozen products, however, is to store frozen (-10C to -25C/-13º to 14ºF). The three different box sizes used by Respondent were not adequately described in Respondent's procedures. Respondent's 2021 study of its use of Nordic ice packs for shipping lacked sufficient information. The date the study was performed, the materials and equipment used, and the configuration employed were not fully documented. The study concluded in part, "These products are more than enough to preserve the efficacy of all medications that require room temperature or cold delivery demands." The study did not support adequate temperature control for frozen product. This is a repeat violation. Inspector J.F. notified Respondent that it was in violation of Code section 4126.8.

Written Notice #3

61. Inspector J.F. found that Respondent used secondary packaging for its "Vitamindrip" kit, consisting of a box containing three vials, each containing a different sterile product compounded by Respondent. One vial contained ascorbic acid 30mL, the second vial contained Olympia mineral blend 30mL, and the third vial contained VitaComplex 30mL. The kit is labeled as "Hydration Injection, USP". Inspector J.F. found that there is not, and never was, a United States Pharmacopeia (USP) monograph for "Hydration Injection". Inspector J.F. notified Respondent that it was in violation of Code section 4169, subdivision (a)(3).

Written Notice #4

62. Inspector J.F. found that labels on Respondent's compounded products identified the pharmacy as "Olympia Pharmaceuticals." However, the licensee's registered name is "Olympia Pharmacy". For example, the primary label on released lot# F24020-22 for Biotin 0.05% listed the name of the producing pharmacy as "Olympia Pharmaceuticals". Inspector J.F. notified Respondent that it was in violation of CCR section 1735.4, subdivision (a)(1).

Written Notice #5

63. On or about July 20, 2022, in its formal response to a *Written Notice* generated by the Board on July 6, 2022, Respondent provided written assurance to the Board that as of September 2, 2021, its updated *Batch Release* policy required two signatures for each batch released. One signature would be from a member of its quality assurance unit and a second from

a pharmacist. Respondent assured the Board that this measure was taken to ensure that its batches are approved for release only after ensuring that all required specifications are met. Inspector J.F. found that batch records for phenylephrine, lmg/mL, Lot #'s D24A26-22, D24B26-22, and D24C26-22, released on or about June 27, 2022, had one signature only on the batch release documentation. The final release for those batches was missing a pharmacist's signature. Inspector J.F. notified Respondent that it was in violation of Code section 4301, subdivision (g).

Written Notices #s 6, 15, 19

64. On or about April 26, 2022, Respondent was notified of a customer's complaint describing a patient's anaphylaxis and subsequent hospitalization after an IM[1] injection of a drug compounded by Respondent. Respondent was informed that the patient had a sulfa allergy. Respondent determined that its customer should have advised the patient that the product was not appropriate for her to take because it contained methionine. Respondent stated that methionine was known to be related to sulfa allergies. In its final impact assessment related to the complaint, Respondent documented that "This was a one-time incident caused by a customer error. . . Not an unexpected adverse event, methionine known to cause potential reactions to persons allergic to sulfur. Methionine is listed as an ingredient on the product label." Methionine does not contain any sulfonamide group or sulfites. On or about August 7, 2022, Respondent submitted to the Board a written statement that there had been no adverse events regarding its compounded sterile products in the last twelve months. Inspector J.F. documented in his October 19, 2021, inspection report that he had reminded Respondent of the requirements of mandatory reporting, including the reporting of adverse events, recalls, and complaints. Inspector J.F. notified Respondent that the acts were in violation of Code sections 4301, subdivision (g), 4127.2, subdivision (f), and 4301, subdivision (c).

Written Notice #7

65. Inspector J.F. found that Respondent's lyophilized product, Sermorelin 9mg., was labeled as a multi-dose vial. Inspector J.F. also found antimicrobial effectiveness testing had not

[1] An intramuscular (IM) injection is a technique used to deliver a medication deep into the muscles. This allows the medication to be absorbed into the bloodstream quickly.

been completed as part of stability testing, which considers the possible diluent(s) used. Sermorelin is not directly formulated with a preservative, and it is unknown whether this product has inherent antimicrobial effectiveness properties making it suitable for multi-dose label claims. Respondent's label does not specify the required diluent(s) for use. Respondent only completed method suitability for its multi-dose product, SB4. Preservative effectiveness had not been demonstrated, and test results were pending. This is a repeat violation. Inspector J.F. notified Respondent that it was in violation of CCR section 1751.2, subdivision (b).

Written Notice #8

66. Respondent holds a Food and Drug Administration (FDA) 503B registration for an outsourcing facility. Inspector J.F. found that Respondent's Storage Instructions leaflets, as well as other informational material, that generally accompany Respondent's product shipments into California, represent that Respondent is "A 503B Outsourcing Facility". Respondent does not hold a license as a nonresident outsourcing facility in the State of California. This is a repeat violation. Inspector J.F. notified Respondent that it was in violation of Code section 4129.2, subdivision (a).

Written Notice #10

67. Inspector J.F. found that Respondent's testosterone injection, Lot #J24014, compounded on October 14, 2021, with a BUD of October 14, 2022, failed to include a controlled substance designation on the label. Inspector J.F. notified Respondent that it was in violation of Code section 4301, subdivision (j).

Written Notice #11

68. Inspector J.F. found that on or about April 26, 2022, Respondent recalled all lots produced prior to March 1, 2022. Respondent's SOP, *Recall of Compounded Product,* states, in pertinent part, that, "the states that received the products from the affected lots must be notified immediately or within 12 hours of product being deemed as a recall, whichever is sooner." The initial recall notification provided to the Board did not include the recall of all products. Inspector J.F. notified Respondent that it was in violation of Code section 4127.2, subdivision (e)(3).

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Written Notice #12

69. Respondent had a Central Fill agreement with Mint Pharmacy and Skin Clinic, (NRP 1968), located at 1201 US HWY 1 STE# 305C, North Palm Beach, Florida. On or about June 8, 2022, Mint pharmacy changed its location to 7960 Central Industrial Dr. STE 120, West Palm Beach, Florida (NRP 2728). On or about June 8, 2022, Respondent began shipping compounded products to 7960 Central Industrial Dr. STE 120, West Palm Beach, Florida (new location). On or about June 20, 2022, Respondent began shipping compounded sterile products for injection to the new location. A new Central Fill agreement was not executed until August 2, 2022, during the Board's onsite inspection. The Board was not notified within 30 days of commencing central fill activities with NRP 2728. This is a repeat violation. Inspector J.F. notified Respondent that it was in violation of Code section 4123.

Written Notice #13

70. Inspector J.F. concluded that Respondent's quality assurance plan was inadequate in that he found that not all integral units produced by Respondent in its aseptic process simulation were properly incubated. Inspector J.F. found that media fill lots APS2-A10-22 and APS2-B017-22 failed to incubate a total of 72 vials for 14 days. Samples were prematurely sent to the contract lab for growth promotion testing. Inspector J.F. notified Respondent that it was in violation of CCR section 1735.8, subdivision (b).

Written Notices #s 14 and 16

71. Inspector J.F. found that the inactive ingredient "BHT" was not listed on the master formula for compounding formula ID# 7409 for Benzocaine/Lidocaine/Tetracaine (BLT) 20/4/5, a cream. The equipment required for trituration, mixing, pouring, and measuring was not defined in Respondent's master formula. Quality reviews were not described and adequacy of mixing was not documented.

72. Customer complaint CC-2022-011 documented a complaint of product separation for BLT, Lot #210130. The compounding technician for that product acknowledged that separation was "caused by not leaving mix spin for a while." The product was not recalled from other customers who received the same batch. Inspector J.F. found that other steps for compounding

formula ID #7409 were also not followed as required. Specifically, BHT, pluronic acid and polysorbate were required ingredients for formula ID #7409, but were not added. Inspector J.F. reviewed Respondent's March 15, 2022, compounding of formula ID# 7409, and confirmed that there were no changes to the master formula's essential compounding steps and no preventative action was taken to prevent reoccurrence of inadequate mixing. This is a repeat violation.

73. Inspector J.F. found that the master formulation and compounding logs for compounding formula ID #6924, lots K210219, K210202, compounded on November 29, 2021, and November 2, 2021, respectively, for minoxidil/fluocinolone/retinoic acid 5/0.01/0.01% called for the addition of vitamin E liquid, which was not added. Further, the final packaging requirements were not described and the final packout quantity for lot K210202 was unclear. Lastly, the labels did not include the compounding date.

74. Inspector J.F. found that the master formulation for Sermorelin 9mg formula ID# 5679 calls for 18 grams of API; however, the pharmacy routinely added a 10% overage without documenting an explanation for doing so.

75. Inspector J.F. notified Respondent that the acts set forth in paragraphs 71 through 74 above were in violation of Code section 4169, subdivision (a)(2) and CCR section 1735.2, subdivision (c).

Written Notice #17

76. Inspector J.F. found that Respondent's SOPs addressing hand hygiene did not require persistent activity hand sanitizer and that Respondent did not have a related competency assessment. Respondent's competency assessment for hand hygiene also did not evaluate operators for use of a nail pick to remove debris or the application of a waterless surgical scrub with persistent activity. Inspector J.F. notified Respondent that it was in violation of CCR section 1751.6, subdivision (e)(1)(F).

FIRST CAUSE FOR DENIAL OF APPLICATION

(Failure to Maintain Written Policies and Procedures for Compounding)

77. 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, subdivision (o). Specifically, Respondent failed to follow its written policies and procedures, in violation of CCR section 1735.5, subdivision (a), as follows:

a. Respondent's employee, L.S., admitted that he signed that a specific task was completed at a specific date when, in fact that task had not been completed on that date, contrary to Respondent's SOPs, as set forth in paragraph 56, above.

b. Respondent's employee, L.S., admitted that he entered initials of other employees on environmental monitoring forms without personally performing the task for which the initials were entered, contrary to Respondent's SOPs, as set forth in paragraph 56, above.

c. On or about April 1, 2022, Respondent verified that Lot APS-A10-22 met Respondent's finished product specifications for quality assurance when, in fact, Respondent's specifications had not been followed, as set forth in paragraph 57, above.

d. On or about April 6, 2022, Respondent verified that Lot APS-B017-22 met Respondent's finished product specifications for quality assurance when, in fact, Respondent's specifications had not been followed, as set forth in paragraph 58 above.

SECOND CAUSE FOR DENIAL OF APPLICATION

(Failure to Maintain United States Pharmacopeia-National Formulary Compounding Standards)

78. 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, subdivision (o). 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 paragraph 60, above. To wit:

a. Respondent's labels for packaging and shipping procedures for compounded sterile products requiring frozen storage conditions indicating that the compound is to be stored frozen (-10C to -25C/-13º to 14ºF) is incongruent with Respondent's procedure, which states that temperature sensitive compounded preparations must be maintained at a temperature of <8C for the entire duration of the transit.

b. Respondent failed to describe adequately box sizes for shipping.

c. Respondent failed to ensure adequate temperature control for shipped frozen product.

THIRD CAUSE FOR DENIAL OF APPLICATION

(Omission of Licensee's Name on Label)

79. 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, subdivision (o). Specifically, as set forth above in paragraph 62, Respondent's drug product labels identified the pharmacy as "Olympia Pharmaceuticals", when, in fact, Respondent's licensed name is "Olympia Pharmacy", in violation of CCR 1735.4, subdivision (a)(1).

FOURTH CAUSE FOR DENIAL OF APPLICATION

(False Certification/Documentation of Facts)

80. Respondent's application for renewal is subject to denial pursuant to Code section 4301, subdivision (g), 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. As set forth above in paragraph 63, Respondent released compounded sterile drug product without a pharmacist's final signature, contrary to its assurances to the Board that its compounded sterile drug batches would be reviewed and signed by a member of its Quality Unit as well as a pharmacist prior to release.

b. As set forth above in paragraph 64, Respondent stated to the Board that it had no adverse events regarding its compounded sterile products. In fact, on or about April 26, 2022, Respondent was notified of a customer's complaint describing anaphylaxis and subsequent hospitalization after use of a drug compounded by Respondent.

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FIFTH CAUSE FOR DENIAL OF APPLICATION

(Labeling Requirements – Inappropriate Instructions for Storage, Handling, Administration)

81. 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, subdivision and (o). Specifically, as set forth above in paragraph 65, Respondent failed to demonstrate that multi-dose vials used for Sermorelin and SB4 were suitable for multi-dose label claims, in violation of CCR 1751.2, subdivision (b).

SIXTH CAUSE FOR DENIAL OF APPLICATION

(Unlicensed Activity - Outsourcing)

82. 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, subdivision (o). Specifically, as set forth above in paragraph 66, Respondent represented to California consumers that it is a 503B outsourcing facility. Respondent does not hold a license as a non-resident outsourcing facility in the State of California, in violation of Code section 4129.2, subdivision (a).

SEVENTH CAUSE FOR DENIAL OF APPLICATION

(Improper Labeling of a Controlled Substance)

83. 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, subdivision (o). Specifically, as set forth above in paragraph 72, Respondent failed to label testosterone as a controlled substance, in violation of 21 CFR 1302.03.

EIGHTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Provide Board with Timely Notice of Recall)

84. 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, subdivision (o). Specifically, as set forth above in

paragraph 68, Respondent failed to provide the Board within twelve hours of its notice of recall for a sterile drug product that it compounded and shipped into California, in violation of Code section 4127.2, subdivision (e)(3).

NINTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Provide Board with Notice of Contract to Compound Drug for Parenteral Therapy)

85. 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, subdivision (o). Specifically, as set forth above in paragraph 69, Respondent failed to notify the Board, within 30 days of commencing compounding a drug for another pharmacy for parenteral therapy, of its contract with that pharmacy to do so, in violation of Code section 4123.

TENTH CAUSE FOR DENIAL OF APPLICATION

(Quality Assurance Plan – Written Procedures)

86. 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, subdivision (o). Respondent failed to ensure the adequacy of its compounding processes, in violation of CCR section 1735.8, subdivision (b). Specifically, as set forth above in paragraph 70, Respondent failed to adequately incubate for aseptic conditions and failed to have a pre-defined set of compounding instructions for its aseptic process simulation.

ELEVENTH CAUSE FOR DENIAL OF APPLICATION

(Written Master Formula)

87. 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, subdivision (o). Specifically, Respondent failed to prepare a written master formula adequate for compounding, in violation of CCR section 1735.2, subdivision (e), as follows:

a. As set forth above in paragraph 71, Respondent's master formulation for compound formula ID #7409 for BLT 20/4/5 was inadequate, to wit:

i. "BHT" was not listed on the master formula.

ii. Equipment required for trituration, mixing, pouring, and measuring was not defined in its SOPs.

iii. Quality reviews were not described.

iv. Adequacy of mixing was not documented.

b. As set forth above in paragraph 73, Respondent's master formulation for compound formula ID #6924, lot #K210219, compounded on or about November 29, 2021, and lot #K210202, compounded on or about November 2, 2021, was inadequate, to wit:

i. The addition of vitamin E liquid was not added, contrary to the mixing directions.

ii. The final packout quantity could not be determined for lot K210202.

iii. The labels were missing the compounding date.

c. As set forth above in paragraph 74, Respondent's master formulation for compound formula Sermorelin 9 mg. formula, ID# 5679 called for 18 grams of Active Pharmaceutical Ingredient (API); however, the pharmacy routinely added a 10% overage without documenting an explanation for doing so.

TWELFTH CAUSE FOR DENIAL OF APPLICATION

(Adverse Effects Reporting)

88. 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, subdivision (o). Specifically, as set forth in paragraph 64, above, Respondent failed to notify the Board within twelve hours of an adverse drug reaction for anaphylaxis of a patient resulting from use of a drug compounded by Respondent, in violation of Code section 4127.2, subdivision (f).

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THIRTEENTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Maintain Quality of Compounded Sterile Preparations)

89. 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, subdivision (o), in that Respondent violated pharmacy law. Specifically, Respondent violated CCR section 1735.2, subdivision (g), in that, as set forth in paragraph 75, above, Respondent compounded Lot #210130, a BLT cream preparation, which Respondent knew to have a compounding error and for which compounding steps were unclear, resulting in separation.

FOURTEENTH CAUSE FOR DENIAL OF APPLICATION

(Adulterated Preparation)

90. 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, subdivision (o), in that Respondent violated statutes regulating dangerous drugs and pharmacy law. Specifically, as set forth in paragraph 75, above, Respondent compounded and furnished Lot #210130, a BLT cream preparation, which was, or may have been, contaminated with filth, putrid, or decomposed substances, and was therefore adulterated pursuant to Health & Saf. Code sections 111250, 111255, and/or 21 USCA 351, subdivision (a), in violation of Code section 4169, subdivision (a)(2), Health & Saf. Code section 111295, and 21 USCA section 331, subdivision (a).

FIFTEENTH CAUSE FOR DENIAL OF APPLICATION

(Training and Evaluation of Compounding Staff – Hand Hygiene)

91. 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 (o). Specifically, as set forth above in paragraph 76, Respondent failed to include proper hand hygiene in its SOPs/written program of training and its evaluation of the hand hygiene of staff, in violation of CCR section 1751.6, subdivision (e)(1)(F).

SIXTEENTH CAUSE FOR DENIAL OF APPLICATION

(Gross Negligence)

92. 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, subdivision (c). Specifically, Respondent committed gross negligence when it erroneously concluded that methionine caused a customer's anaphylactic reaction, as set forth in paragraph 64, above.

SEVENTEENTH CAUSE FOR DENIAL OF APPLICATION

(Compounding and Furnishing Misbranded Drugs)

93. 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, subdivision (o). Specifically, Respondent violated Code section 4169, subdivision (a), and Health & Safety Code sections 111330, 111335, and 111445, in that it sold or transferred dangerous drugs that it knew, or should have known were misbranded, in that it failed to meet predefined specifications, failed to follow USP-NF compounding standards, failed to meet labeling requirements, lacked sterility assurance, failed to maintain quality of its CSPs, and compounded adulterated CSPs, and as set forth above in paragraphs 77-79, 81, 83, 86, 87, 89, 90, and 91.

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. Denying the renewal application of Olympia Pharmacy for a Non-Resident Sterile Compounding License; and,

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

DATED: 12/16/2022

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2022.12.16 12:30:15 -08'00'

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

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