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

In the Matter of the Third Amended Accusation Against: **EMPOWER CLINIC SERVICES LLC, DBA EMPOWER PHARMACY;** **ARTA SHAUN NOORIAN, MANAGER/ 100% SHAREHOLDER,** 7601 N. Sam Houston Pkwy W, Suite 100 Houston, TX 77064 **Nonresident Pharmacy Permit No. NRP 1834** **Nonresident Pharmacy Permit No. NRP 2567** **Nonresident Sterile Compounding Pharmacy Permit No. NSC 100984** **Nonresident Sterile Compounding Pharmacy Permit No. NSC 101695** Respondent.	Case No. 7117 **THIRD AMENDED ACCUSATION**

PARTIES

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

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2. On or about July 8, 2016, the Board issued Nonresident Sterile Compounding Permit Number NSC 100984 to Empower Clinic Services LLC dba Empower Pharmacy, with Arta Shaun Noorian (S.N.) as Manager/100% Shareholder, and Souchinda Nanthavoungdouangsy as Pharmacist-in-Charge (PIC)[1]. (Respondent). Following a change of location, on or about January 17, 2022, Respondent was issued Nonresident Sterile Compounding Permit number 101695. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2022, unless renewed.

3. On or about July 8, 2016, the Board issued Nonresident Pharmacy Permit Number NRP 1834 to Respondent, with S.N. as Manager/100% Shareholder, and Souchinda Nanthavoungdouangsy as Pharmacist-in-Charge (PIC). Following a change of location, on or about January 17, 2022, Respondent was issued Nonresident Pharmacy Permit number 2567. The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2022, unless renewed.

JURISDICTION

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

5. Code section 4300 states, in pertinent part:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in

[1] Souchinda Nanthavoungdouangsy was the Pharmacist-in-Charge (PIC)[1] between July 7, 2016 to October 7, 2019. Jordan Cuccia is the current PIC for Empower Pharmacy having started in that position on October 7, 2019.

its discretion may deem proper.

. . .

(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 4011 provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code § 11000 et seq.].

STATUTORY PROVISIONS

8. Code section 4301 states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . Unprofessional conduct shall include, but is not limited to, any of the following:

. . .

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

. . .

(j) The violation of any of the statutes of this state . . . 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.

. . .

9. Code section 4303, subdivision (b), states:

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

10. 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.

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

13. Code section 4127 states, in pertinent part:

. . .

(e) A pharmacy licensed pursuant to this section shall do all of the following:

. . .

(4) Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.

(f) Adverse effects reported or potentially attributable to a nonresident pharmacy's sterile compounded drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

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. 21 U.S. Code section 353b states, in pertinent part:

(a) Sections 352(f)(1), 355, and 360eee–1 of this title 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:

. . .

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

. . .

(8) Prohibition on wholesaling - The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug.

. . .

(10) Labeling of Drugs –

. . .

(A) Label

(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"…;

. . .

16. 42 U.S. Code 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; and

. . .

HEALTH AND SAFETY CODE SECTIONS

17. Health and Safety (Health & Saf.) Code section 111250 states that any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

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

19. Health & Saf. Code section 111330 states that any drug is misbranded if its labeling is false or misleading in any particular.

20. Health & Saf. code section 111395, subdivision (a) states that any drug is misbranded if it is an imitation of another drug.

21. Health & Saf. code section 111440 states that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

REGULATORY PROVISIONS

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

. . .

(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

. . .

(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.

23. CCR section 1735.2 states, in pertinent part:

(a) Except as specified in (b) and (c), no drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

. . .

(d) No pharmacy or pharmacist shall compound a drug preparation that:

. . .

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

(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.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,

(B) the chemical stability of any one ingredient in the compounded drug preparation,

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,

(E) for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and

(F) for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.

(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision; and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:

(i) the nature of the drug and its degradation mechanism,

(ii) the dosage form and its components,

(iii) the potential for microbial proliferation in the preparation,

(iv) the container in which it is packaged,

(v) the expected storage conditions, and

(vi) the intended duration of therapy.

Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,

(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,

(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

(D) The beyond use date assigned for sterility in section 1751.8.

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subdivision may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

24. 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:

. . .

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

25. CCR, 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[2] compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

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

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

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

[2] USP 71 Sterility Test is a culture test that requires at least two weeks of incubation to confirm sterility.

26. CCR, section 1735.3 states, in pertinent part:

(a) For each compounded drug preparation, pharmacy records shall include:

. . .

(2) A compounding log consisting of a single document containing all of the following:

. . .

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (*l*) shall apply.

27. CCR, section 1751.2 states, in pertinent part:

In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, a pharmacy that compounds sterile drug preparations shall include the following information on the label for each such preparation:

…

(b) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription…

28. CCR, section 1761 states, in pertinent part:

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

. . .

COST RECOVERY

29. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licensee 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, with failure of the licensee to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

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DRUG DESCRIPTION

30. *Ascor* is the brand name for an ascorbic acid (vitamin C) injection indicated for short term treatment of scurvy in patients for whom oral administration is not possible, insufficient, or contraindicated. Ascorbic acid injections are a dangerous drug pursuant to Code section 4022.

31. *Oxandrolone* is an anabolic steroid used for weight gain, for bone pain from osteoporosis and to prevent side effects from corticosteroids. Oxandrolone is sold under the Brand Names Anavar, Oxandrin, and Oxandrol. Oxandrolone is a dangerous drug pursuant to Code section 4022 and controlled substance pursuant to Health and Saf. Code 11056(f)(23).

FACTUAL ALLEGATIONS

Ascor Complaint

32. On or about March 8, 2019, the Board received a complaint that Respondent was compounding an ascorbic acid product, which is a copy of Ascor, a commercially available ascorbic acid injectable.

33. On or about April 26, 2019, the Board requested Respondent's compounding records for 90 days, starting on January 1, 2019.

34. Following the Board's request for Respondent's compounding records, on or about May 7, 2019, S.N. sent a letter to the Board stating that the ascorbic acid produced by Respondent is not considered a copy as Respondent's formulation for injection is tapioca sourced and if requested, contains a preservative, which Ascor does not. Respondent advised that this creates a "significant difference" versus the commercially available product (Ascor).

35. On or about July 22, 2019, the Board requested the name of the raw material, the name of the vendor that provides the raw material, a list of patients that Respondent has shipped to in California over the last year, and the medical justification for the need for each patient that received products in California.

36. On or about August 19, 2019, Respondent provided a spreadsheet with a list of names of their patients that received ascorbic acid.

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37. On or about May 13, 2020, the Board requested further records including all records of sales into California for any compounded sterile preparation containing ascorbic acid or sodium ascorbate between January 1, 2020, and May 1, 2020.

38. On or about May 20, 2020, Respondent provided records of sales into California from any compounded sterile preparation containing ascorbic acid or sodium ascorbate between January 1, 2020, through May 1, 2020.

39. On or about May 26, 2020, the Board requested additional information from Respondent including the following:

- Compounding records;
- Master formulation records (to include all data to support the assigned beyond-use-date (BUD);
- Copies of prescriptions;
- For any order sent as "office use" various documents from the prescriber or prescriber's agent, documents showing the deliver to the prescriber's office, and documents showing the dispensing pharmacist has a credible basis for concluding it is a reasonable quantity for office use;
- Copies of the Certificate of Analysis (CoA) for each Active Pharmaceutical Ingredient (API) used for lots 66096, 66415, 66596, 67583, 65302, and 67577;
- Documentation showing ascorbic acid was in short supply at the time of compounding and sale;
- The specific documented medical need made known to the pharmacist prior to compounding each order and prescription; and
- Documentation showing patient consultation and direction for administration for 7 prescriptions in which the pharmacist allowed an infusion diluted only in sterile water.

40. On or about June 2, 2020, Respondent provided copies of prescriptions, Compounding logs for lots 66096, 66415, 66596, 67583, 65302, and 67577 and data to support the BUD.

41. On or about July 22, 2020, the Board requested information regarding medical justification for the need of the specific ascorbic acid from Respondent.

42. On or about September 8, 2020, the Board was advised that the ascorbic acid sold by United Foods Corporation is not to be used as a Drug substance or Active Pharmaceutical Ingredient and was not approved as a human injectable. The Safety Data Sheet for ascorbic acid provided by United Foods Corporation stated "additive for use in food and pharmaceutical; feed additive".

43. On or about September 8, September 17, and September 25, 2020, Respondent was asked for the prescribing protocol for Naturopathic Doctors (ND) Harter and WDowin. Respondent was also asked to identify which lots used ascorbic acid non-corn tapioca source preservative free (30 ML), documentation to support the use of United Food Corporation's ascorbic acid for an injectable preparation, and Respondent's recall policy.

44. On or about October 1, 2020, Responded provided additional information regarding prescriptions and fill information, prescribing protocol, a statement that all of Respondents ascorbic acid API is sourced form Fagron, Inc. (a Registered API manufacturer for ascorbic acid USP[3]), a copy of Respondent's recall procedures, and a statement that Respondent had not received any Adverse Drug Reactions (ADRS) or complaints in the last three years regarding their ascorbic acid non-corn tapioca source preservative free (30ML).

45. On or about October 2, 2020, the Board emailed S.N. to confirm that Fagron was not the manufacture of any of the ascorbic acid. S.N. confirmed that Fagron, Inc. acted as a repackager and that United Food Corporation was the importer.

FIRST CAUSE FOR DISCIPLINE

(Unlawful Compounding of a Commercially Available Product)

46. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR, section 1735.2, subdivision (d)(3), in that between January 1, 2020, and May 1, 2020, Respondent compounded and furnished at least 354 orders and 2,043 vials of ascorbic acid PF (30 ml) 500mg/ml injectable, which were a copy or essentially a copy of McGuff pharmaceuticals Inc.'s Ascor®, a commercially available drug product, without a documented shortage and a documented medical need prior to compounding.

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[3] The suffix "USP" is to indicate that the product meets the standards of the U.S. Pharmacopeia (a collection of concise but detailed drug information) for the United States published annually by the United States Pharmacopeial Convention (usually also called the USP), a nonprofit organization that owns the trademark and also owns the copyright on the pharmacopeia itself. USP has no role in enforcing its standards; enforcement is the responsibility of the U.S. Food and Drug Administration (FDA) and other government authorities in the United States.

SECOND CAUSE FOR DISCIPLINE

(Failure to Quarantine Until End Product Testing is Complete)

47. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR, section 1751.7, subdivision (e)(1), in that between March 7, 2020, and April 23, 2020, Respondent furnished into California at least the following 4 batches, and at least 1,327 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml injectable without first confirming sterility with a USP chapter 71 compliant test:

Lot Numbers	Made On	BUD assigned	QA Analysis	Filled date(s)
66096	3/10/20	3/10/21	Sterility: 3/17/20 (scan RDI[4])	3/7/20, 552 vials
66415	3/17/20	3/17/21	Sterility: 3/23/20 (scan RDI)	4/1/20-4/2/20, 303 vials
66596	3/19/20	3/19/21	Sterility: 3/23/20 (scan RDI)	3/24/20-3/31/20, 296 vials
67577	4/7/20	4/7/21	Sterility: 4/13/20 (scan RDI)	4/20/20-4/23/20, 176 vials

THIRD CAUSE FOR DISCIPLINE

(**Assignment of Unsupported Beyond Use Date**)

48. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR, 1735.2, subdivision (i), in that between March 10, 2020, and April 23, 2020, Respondent compounded and assigned an extended BUD of approximately 365 days (1 year) to at least the following 6 batches and at least 1,758 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml injectable which were furnished into California, without the data required to support this extended BUD:

Lot Numbers	Made On	BUD assigned	QA Analysis
66096	3/10/20	3/10/21 365 days	Sterility: 3/17/20 (scan RDI) Potency: 3/17/20 Endotoxin: 3/18/20
66415	3/17/20	3/17/21 365 days	Sterility: 3/23/20 (scan RDI) Potency: 3/24/20 Endotoxin: 3/24/20
66596	3/19/20	3/19/21 365 days	Sterility: 3/23/20 (scan RDI) Potency: 3/23/20 Endotoxin: 3/23/20
67583	4/7/20	4/7/21 365 days	Sterility: 4/16/20 (scan RDI), 4/14/20 (71 test)-ARL

[4] Scan RDI is a rapid test alternative to the USP chapter 71 sterility test which uses fluorescent labeling and solid phase laser cytometry to identify viable microorganisms from filterable samples.

			Potency: 4/16/20 Endotoxin: 4/15/20
65302	2/25/20	2/24/21 365 days	Sterility: 3/3/20 (scan RDI), 4/10/20 (71 test)-ARL Potency: 3/4/20 Endotoxin: 3/4/20
67577	4/7/20	4/7/21 365 days	Sterility: 4/13/20 (scan RDI) Potency: 4/16/20 Endotoxin: 4/16/20

FOURTH CAUSE FOR DISCIPLINE

(**Failure to Maintain the Quality of a Compounded Sterile Preparation**)

49. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR, section 1735.1, subdivision (ae), in that between February 25, 2020, and April 7, 2020, Respondent compounded and furnished at least the following 6 lots and 1,758 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml injectable preparations, which lacked quality:

Lot numbers	Made on	Vials
66096	3/10/20	552 vials
66415	3/17/20	303 vials
66596	3/19/20	296 vials
67583	4/7/20	231 vials
65302	2/25/20	200 vials
67577	4/7/20	176 vials

FIFTH CAUSE FOR DISCIPLINE

(**Adulterated Preparations**)

50. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to Code section 4169, subdivision (a), in conjunction with Health & Saf. Code sections 111250 and 111295, in that between February 25, 2020, and April 7, 2020, Respondent compounded and furnished at least the following 6 lots and 1,758 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml injectable, which were adulterated:

Lot numbers	Made on	API used	Vials
66096	3/10/20	Fagron: 19H12-U01-001507	552 vials
66415	3/17/20	Fagron: 19H12-U01-001507	303 vials
66596	3/19/20	Fagron: 19H01-U07-001401	296 vials
67583	4/7/20	Fagron: 19C04-U08-005401	231 vials
65302	2/25/20	Fagron: 19H12-U01-001507	200 vials

67577	4/7/20	Fagron: 19H01-U07-001401	176 vials

SIXTH CAUSE FOR DISCIPLINE

(**Incomplete Compounding Logs**)

51. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR, section 1735.3, subdivision (a)(2)(F), in that between February 25, 2020, and April 7, 2020, Respondent compounded at least the following 6 lots and 1,758 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml injectable and failed to document the manufacturer of ascorbic acid:

Lot numbers	Made on	API used	Vials
66096	3/10/20	Fagron: 19H12-U01-001507	552 vials
66415	3/17/20	Fagron: 19H12-U01-001507	303 vials
66596	3/19/20	Fagron: 19H01-U07-001401	296 vials
67583	4/7/20	Fagron: 19C04-U08-005401	231 vials
65302	2/25/20	Fagron: 19H12-U01-001507	200 vials
67577	4/7/20	Fagron: 19H01-U07-001401	176 vials

SEVENTH CAUSE FOR DISCIPLINE

(**Failure to Receive Prescriber's Approval For the Use of a Compounded Drug Preparation**)

52. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR, section 1735.2, subdivision (a), in that between March 10, 2020, and May 1, 2020, Respondent compounded and dispensed at least the following 71 prescriptions and 1,754 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml injectable, a compounded sterile preparation, without the prescriber's approval for use of a compounded drug preparation:

Fill Date	Rx Number	Patient Last Name	Quantity Dispensed
3/10/2020	20383261	Masakayan	40
3/10/2020	20383278	McPeck	40
3/10/2020	20383297	Regan	40
3/10/2020	20383304	Proverdo	40
3/10/2020	20383313	Webster	40
3/17/2020	20401143	Ledford	24
3/17/2020	20401147	Hitch	60
3/17/2020	20401158	Yates	60
3/17/2020	20401078	Web	60
3/17/2020	20401084	Schoenneman	60
3/17/2020	20401085	Lortscher	60
3/17/2020	20401128	Pizzuti	48

3/17/2020	20401133	Hart	60
3/17/2020	20401140	Robinson	60
3/17/2020	20401154	Myers	60
3/27/2020	20427248	Mann	50
3/27/2020	20427251	Perey	50
3/27/2020	20427252	Kayaman	50
3/27/2020	20427256	Fields	50
3/27/2020	20427280	Lang	50
3/27/2020	20428146	Goungo	10
3/31/2020	20432619	Tate	20
3/31/2020	20435688	Cage	16
4/1/2020	20435859	Harmon	20
4/1/2020	20436126	Benkovsky	100
4/1/2020	20436137	Biddle	100
4/2/2020	20437528	Jones	14
4/2/2020	20437529	Walters	14
4/2/2020	20437534	Brennt	14
4/2/2020	20437544	McMenomy	14
4/2/2020	20437561	Ernst	14
4/2/2020	20437630	Lino	14
4/2/2020	20438249	Duggan	5
4/20/2020	20472942	Walker	20
4/21/2020	20477216	Agoulu, Jr.	8
4/22/2020	20478961	Nagaoka	10
4/22/2020	20478989	Nagaoka	10
4/22/2020	20479133	O'Hara	10
4/22/2020	20479139	Burke	10
4/22/2020	20479398	Brooks	10
4/22/2020	20479427	Gilliam	10
4/22/2020	20479447	Tuggle	10
4/22/2020	20479469	Charon	10
4/22/2020	20479477	Madenhauer	10
4/22/2020	20479501	Hellesvig	10
4/22/2020	20479512	West	10
4/22/2020	20479513	Cingolani	10
4/22/2020	20479515	Uribe	10
4/22/2020	20479140	Echeverria	10
4/23/2020	20480839	Light	6
4/28/2020	20491088	Perry	4
4/29/2020	20494647	Kavayiotidis	4
4/30/2020	20497136	Ramos	100
4/30/2020	20497159	LaValley	100
5/1/2020	20498827	Solovij	15

EIGHTH CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

53. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR, section 1761, subdivision (a), in that between March 31, 2020, and May 1, 2020, Respondent failed to obtain the information needed to validate the prescription, a protocol

for a Naturopathic Doctor (ND) to practice under a medical doctor (MD) or osteopathic doctor (DO) for at least at least the following 9 prescriptions and 135 vials:

Fill Date	Rx Number	Patient Last Name	Naturopathic Doctor (ND)	Quantity Dispensed	Lot
3/31/2020	20432619	Tate	Harter	20	66596
3/31/2020	20435688	Cage	Harter	16	66596
4/2/2020	20437528	Jones	WDowin	14	66415
4/2/2020	20437529	Walters	WDowin	14	66415
4/2/2020	20437534	Brennt	WDowin	14	66415
4/2/2020	20437544	McMenomy	WDowin	14	66415
4/2/2020	20437561	Ernst	WDowin	14	66415
4/2/2020	20437630	Lino	WDowin	14	66415
5/1/2020	20498827	Solovij	Harter	15	67583

NINTH CAUSE FOR DISCIPLINE

(Failure to Obtain Active Ingredient from a Supplier Registered with the FDA)

54. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR, section 1735.3, subdivision (c), in that Respondent used active ingredients received from an unknown manufacturer with an unattainable registration with the Food and Drug Administration (FDA) which was imported by United Food Corporation as a food additive for the following active ingredients:

Wholesaler Lot Information
Fagron: 19H12-U01-001507
Fagron: 19H01-U07-001410
Fagron: 20C04-U08-005401

TENTH CAUSE FOR DISCIPLINE

(Unlawful Compounding of a Commercially Available Product)

55. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.2, subdivision (d)(3), in that between January 1, 2020, and May 1, 2020, Respondent compounded and furnished at least 354 orders and 2,043 vials of ascorbic acid PF (30 ml) 500mg/ml injectable which were a copy or essentially a copy of McGuff pharmaceuticals Inc.'s Ascor®, a commercially available drug product, without a documented shortage and a documented medical need prior to compounding.

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ELEVENTH CAUSE FOR DISCIPLINE

(**Failure to Quarantine Until End Product Testing Is Complete**)

56. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1751.7, subdivision (e)(1), in that between March 7, 2020, and April 23, 2020, Respondent furnished into California at least the following 4 batches and at least 1,327 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml injectable without first confirming sterility with a USP chapter 71 compliant test:

Lot Numbers	Made On	BUD assigned	QA Analysis	Filled date(s)
66096	3/10/20	3/10/21	Sterility: 3/17/20 (scan RDI)	3/7/20, 552 vials
66415	3/17/20	3/17/21	Sterility: 3/23/20 (scan RDI)	4/1/20-4/2/20, 303 vials
66596	3/19/20	3/19/21	Sterility: 3/23/20 (scan RDI)	3/24/20-3/31/20, 296 vials
67577	4/7/20	4/7/21	Sterility: 4/13/20 (scan RDI)	4/20/20-4/23/20, 176 vials

TWELFTH CAUSE FOR DISCIPLINE

(**Assignment of Unsupported Beyond Use Date**)

57. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.2, subdivision (i), in that between March 10, 2020, and April 23, 2020, Respondent compounded and assigned an extended BUD of approximately 365 days (1 year) to at least the following 6 batches and at least 1,758 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml injectable which were furnished into California, without the data required to support the extended BUD:

Lot Numbers	Made On	BUD assigned	QA Analysis
66096	3/10/20	3/10/21 365 days	Sterility: 3/17/20 (scan RDI) Potency: 3/17/20 Endotoxin: 3/18/20
66415	3/17/20	3/17/21 365 days	Sterility: 3/23/20 (scan RDI) Potency: 3/24/20 Endotoxin: 3/24/20
66596	3/19/20	3/19/21 365 days	Sterility: 3/23/20 (scan RDI) Potency: 3/23/20 Endotoxin: 3/23/20
67583	4/7/20	4/7/21 365 days	Sterility: 4/16/20 (scan RDI), 4/14/20 (71 test)-ARL Potency: 4/16/20 Endotoxin: 4/15/20

65302	2/25/20	2/24/21 365 days	Sterility: 3/3/20 (scan RDI), 4/10/20 (71 test)-ARL Potency: 3/4/20 Endotoxin: 3/4/20
67577	4/7/20	4/7/21 365 days	Sterility: 4/13/20 (scan RDI) Potency: 4/16/20 Endotoxin: 4/16/20

THIRTEENTH CAUSE FOR DISCIPLINE

(**Failure to Maintain the Quality of a Compounded Sterile Preparation**)

58. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.1, subdivision (ae), in that between February 25, 2020, and April 7, 2020, Respondent compounded and furnished at least the following 6 lots and 1,758 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml injectable preparations, which lacked quality:

Lot numbers	Made on	Vials
66096	3/10/20	552 vials
66415	3/17/20	303 vials
66596	3/19/20	296 vials
67583	4/7/20	231 vials
65302	2/25/20	200 vials
67577	4/7/20	176 vials

FOURTEENTH CAUSE FOR DISCIPLINE

(**Adulterated Preparations**)

59. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to Code section 4169, subdivision (a), in conjunction with Health and Safety code sections 111250 and 111295, in that between February 25, 2020, and April 7, 2020, Respondent compounded and furnished at least the following 6 lots and 1,758 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml injectable which were adulterated:

Lot numbers	Made on	API used	Vials
66096	3/10/20	Fagron: 19H12-U01-001507	552 vials
66415	3/17/20	Fagron: 19H12-U01-001507	303 vials
66596	3/19/20	Fagron: 19H01-U07-001401	296 vials
67583	4/7/20	Fagron: 19C04-U08-005401	231 vials
65302	2/25/20	Fagron: 19H12-U01-001507	200 vials
67577	4/7/20	Fagron: 19H01-U07-001401	176 vials

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FIFTEENTH CAUSE FOR DISCIPLINE

(**Incomplete Compounding Logs**)

60. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.3, subdivision (a)(2)(F), in that between February 25, 2020, and April 7, 2020, Respondent compounded at least the following 6 lots and 1,758 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml injectable and failed to document the manufacturer of ascorbic acid:

Lot numbers	Made on	API used	Vials
66096	3/10/20	Fagron: 19H12-U01-001507	552 vials
66415	3/17/20	Fagron: 19H12-U01-001507	303 vials
66596	3/19/20	Fagron: 19H01-U07-001401	296 vials
67583	4/7/20	Fagron: 19C04-U08-005401	231 vials
65302	2/25/20	Fagron: 19H12-U01-001507	200 vials
67577	4/7/20	Fagron: 19H01-U07-001401	176 vials

SIXTEENTH CAUSE FOR DISCIPLINE

(**Failure to Receive Prescriber's Approval for the Use of a Compounded Drug Preparation**)

61. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.2, subdivision (a), in that between March 10, 2020, and May 1, 2020, Respondent compounded and dispensed at least the following 71 prescriptions and 1,754 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml injectable, a compounded sterile preparation, without the prescriber's approval for use of a compounded drug preparation:

Fill Date	Rx Number	Patient Last Name	Quantity Dispensed
3/10/2020	20383261	Masakayan	40
3/10/2020	20383278	McPeck	40
3/10/2020	20383297	Regan	40
3/10/2020	20383304	Proverdo	40
3/10/2020	20383313	Webster	40
3/17/2020	20401143	Ledford	24
3/17/2020	20401147	Hitch	60
3/17/2020	20401158	Yates	60
3/17/2020	20401078	Web	60
3/17/2020	20401084	Schoenneman	60
3/17/2020	20401085	Lortscher	60
3/17/2020	20401128	Pizzuti	48
3/17/2020	20401133	Hart	60
3/17/2020	20401140	Robinson	60
3/17/2020	20401154	Myers	60
3/27/2020	20427248	Mann	50
3/27/2020	20427251	Perey	50

3/27/2020	20427252	Kayaman	50
3/27/2020	20427256	Fields	50
3/27/2020	20427280	Lang	50
3/27/2020	20428146	Goungo	10
3/31/2020	20432619	Tate	20
3/31/2020	20435688	Cage	16
4/1/2020	20435859	Harmon	20
4/1/2020	20436126	Benkovsky	100
4/1/2020	20436137	Biddle	100
4/2/2020	20437528	Jones	14
4/2/2020	20437529	Walters	14
4/2/2020	20437534	Brennt	14
4/2/2020	20437544	McMenomy	14
4/2/2020	20437561	Ernst	14
4/2/2020	20437630	Lino	14
4/2/2020	20438249	Duggan	5
4/20/2020	20472942	Walker	20
4/21/2020	20477216	Agoulu, Jr.	8
4/22/2020	20478961	Nagaoka	10
4/22/2020	20478989	Nagaoka	10
4/22/2020	20479133	O'Hara	10
4/22/2020	20479139	Burke	10
4/22/2020	20479398	Brooks	10
4/22/2020	20479427	Gilliam	10
4/22/2020	20479447	Tuggle	10
4/22/2020	20479469	Charon	10
4/22/2020	20479477	Madenhauer	10
4/22/2020	20479501	Hellesvig	10
4/22/2020	20479512	West	10
4/22/2020	20479513	Cingolani	10
4/22/2020	20479515	Uribe	10
4/22/2020	20479140	Echeverria	10
4/23/2020	20480839	Light	6
4/28/2020	20491088	Perry	4
4/29/2020	20494647	Kavayiotidis	4
4/30/2020	20497136	Ramos	100
4/30/2020	20497159	LaValley	100
5/1/2020	20498827	Solovij	15

SEVENTEENTH CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

62. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1761, subdivision (a), in that between March 31, 2020, and May 1, 2020, Respondent failed to obtain the information needed to validate the prescription, a protocol for a naturopathic doctor (ND) to practice under a medical doctor (MD) or osteopathic doctor (DO) for at least the following 9 prescriptions and 135 vials:

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Fill Date	Rx Number	Patient Last Name	Naturopathic Doctor (ND)	Quantity Dispensed	Lot
3/31/2020	20432619	Tate	Harter	20	66596
3/31/2020	20435688	Cage	Harter	16	66596
4/2/2020	20437528	Jones	WDowin	14	66415
4/2/2020	20437529	Walters	WDowin	14	66415
4/2/2020	20437534	Brennt	WDowin	14	66415
4/2/2020	20437544	McMenomy	WDowin	14	66415
4/2/2020	20437561	Ernst	WDowin	14	66415
4/2/2020	20437630	Lino	WDowin	14	66415
5/1/2020	20498827	Solovij	Harter	15	67583

EIGHTEENTH CAUSE FOR DISCIPLINE

(**Failure to Obtain Active Ingredient from a Supplier Registered with the FDA**)

63. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.3, subdivision (c), in that Respondent used active ingredients received from an unknown manufacturer with an unattainable registration with the Food and Drug Administration (FDA) which was imported by United Food Corporation as a food additive for the following active ingredients:

Wholesaler Lot Information
Fagron: 19H12-Uo1-001507
Fagron: 19H01-U07-001410
Fagron: 20C04-U08-005401

N.S. Complaint

64. On or about July 7, 2020, the Board received a complaint from N.S. that a Oxandrolone prescription that was compounded by Respondent, did not work and that H.P., a pharmacist for Respondent, refused to provide the master match records and batch production records when requested.

65. On or about August 5, 2020, a Board Inspector requested various records relating to the N.S. prescription for Oxandrolone including, but not limited to, the batch record for the prescription including all lab work with raw data, and API testing results.

66. On or about August 10, 2020, S.N. provided the requested records to the Board Inspector. The prescription for Oxandrolone 15mg oral capsules was written on April 24, 2020, and was for 180 capsules. A note was entered on the prescription by E.G. that the lactose and corn free formulation was required for suspected patient sensitivities.

67. On or about August 18, 2020, the Board Inspector contacted the complainant regarding whether he was allergic to corn or lactose or had a suspected allergy, as noted on the prescription document provided by Respondent. N.S. confirmed he was not allergic to corn or lactose nor did he have a suspected allergy, and if that was in his record, it was an error.

68. On or about August 18, 2020, the Board Inspector requested additional records from Respondent, including the full patient profile for N.S., and the resume and training records for E.G., the employee who noted the suspected allergy on the prescription record.

69. On or about August 26, 2020, Respondent provided the resume and training records for E.G. The records revealed that E.G. was not a pharmacist and that E.G. was hired as a data entry technician.

70. On or about August 27, 2020, Respondent provided additional records including the full patient profile for N.S. that stated no known allergies.

71. None of the records for N.S. indicated that N.S. or his prescriber were alerted that there was a commercially available product for Oxandrolone oral capsules with no clinical difference from the medication provided by Respondent.

NINETEENTH CAUSE FOR DISCIPLINE

(Unlawful Compounding of a Commercially Available Product)

72. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.2, subdivision (d)(3), in that Respondent compounded and furnished a product to N.S. when the product was not justified by a specific medical need and a review of the information for the commercially available Oxandrolone tables showed no clinical difference to warrant the compounded product. The suspected allergy notation by E.G. was false and misleading and not documented by a pharmacist.

TWENTIETH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

73. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to Code section 4301, subdivision (g), in that E.G. knowingly made or signed a document that falsely

represented the existence or nonexistence of a state of facts as more thoroughly set forth in Paragraphs 65 - 71 above.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(**Unprofessional Conduct - Duties of a Pharmacist**)

74. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR section 1793.1, in that on or about April 24, 2020, a compounded product was dispensed to N.S. when the product was not justified by a specific medical need. The suspected allergy noted was false and misleading and not documented by a pharmacist as more thoroughly set for in paragraphs 65 - 71 above.

TWENTY-SECOND CAUSE FOR DISCIPLINE

(**Erroneous or Uncertain Prescription**)

75. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR section 1716, subdivision (a), in that Respondent compounded and dispensed a prescription that falsely represented a state of facts by issuing the Oxandrolone prescription to N.S. when the product was not justified by a specific medical need as the suspected allergy noted was false and misleading and not documented by a pharmacist as more thoroughly set for in Paragraph 65 - 71 above.

Annual Sterile Compounding Renewal Inspection, June 15, 2020

76. On or about June 15, 2020, the Board conducted a remote annual pharmacy sterile compounding renewal inspection for Respondent. Following the remote inspection, five written notices and two corrections were issued and reviewed with S.N.

77. The written notices are as follows:

a. The Labels of many products did not contain the generic names and the weights associated with them including, but not limited to, LIPO, LIPO-B, Arousal Cream, and T3/T4 (Lio/levo), in violation of CCR 1735.4(a)(2).

b. Respondent was advised that a review of records produced by Respondent showed the following products produced were essentially a copy of commercially available products: bacteriostatic water, human chorionic gonadotropin (HCG) injection, tadalafil tablets,

sildenafil tablets, cyanocolbalamin, ascorbic acid, doxycycline monohydrate, doxycycline hyclate and fish oil in violation of CCR 1735.2(d)(3).

c. Respondent delivered over 5000 units of misbranded product to California consumers from September 3, 2019, through February 27, 2020, in violation of Health & Saf. Code section 111440.

d. Several products including Progesterone, tadalafil, sildenafil, DHEA, and melatonin bore the term slow release or sustained release on the label when there was no scientific data to support these claims in violation of Health & Saf. Code section 111330.

e. The glutathione injection from lot number 65517 was made with an ungraded API rendering it adulterated in violation of Health & Saf. Code section 111295.

78. The June 15, 2020, Order of Correction listed the following violations of Pharmacy Law:

a. Respondent was advised that the training records provided did not show the pharmacist and pharmacy technician had training every 12 months in that the last training provided was January 2019 in violation of CCR 1751.6(e)(2) in conjunction with CCR 1751.6(e)(1)((B)C)(D)(G)(H).

b. Respondent was advised that competencies provided for the pharmacist and the pharmacy technician were not completed every six months consistently and that both employees engaged in non-sterile to sterile compounding in violation of CCR 1751.7(b)(2).

79. On or about June 18, 2020, the Board received an email from S.N. with the correction responses attached.

80. On or about June 28, 2020, the Board emailed S.N. regarding his responses to the violations.

81. On or about June 29, 2020, S.N. stated that his attorneys advised him he did not have to respond to the written notices.

82. Following a clarification email by the Board, on or about June 29, 2020, S.N. replied that Respondent disagreed that the five issues on the June 15, 2020, Written Notice were actually violations.

TWENTY-THIRD CAUSE FOR DISCIPLINE

(**Compounding Limitations and Requirements**)

83. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR section 1735.4, subdivision (a)(2), in that Respondent between September 3, 2019, and February 27, 2020, sent over 4000 doses of medication into California without the generic name on the label as follows:

Labeled as	**Number of Rx's**	**Units sold**
Arousal 1 (A/EM/P/SC/T/L-ARG) (30 ML)	8	9
Arousal 2(A/EM/P/SC/T) (30 ML)	4	5
Arousal 3(A/EM/P/SC/L-ARG) (30 ML)	2	2
Arousal 4 (A/EM/P/SC) (30 ML) (30 ML)	2	2
BI-EST	2	85
BI-EST (30 ML)	49	60
BI-EST (50/50) (30 ML)	13	16
BI-EST (50/50) VAG W/APPL	1	1
BI-EST (E2:80/E3:20)/PROGEST/TESTO (30 ML)	2	2
BI-EST/PROGEST/TESTO (30 ML)	2	2
BI-EST/PROGESTERONE (30 ML)	18	31
BI-EST/TESTOSTERONE (30 ML)	3	6
BI-MIX (LYO)	17	19
LIPO (10 ML)	32	45
LIPO (30 ML)	144	375
LIPO-B (10 ML)	157	305
LIPO-B (30 ML)	309	483
LIPO-C (10 ML)	132	228
LIPO-C (30 ML)	932	1,817
SUPER BI-MIX (LYO)	20	32
SUPER QUAD-MIX (LYO)	40	62
SUPER TRI-MIX (LYO)	95	119
TRI-MIX (LYO)	314	375
Grand Total	**2,296**	**4,081**

TWENTY-FOURTH CAUSE FOR DISCIPLINE

(**Misbranding of Compounded Preparations**)

84. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to Code section 4169, subdivision (a), in conjunction with Health and Saf. Code sections 111395 and 111440, in that between September 3, 2019, and February 27, 2020, Respondent delivered misbranded drugs that were imitations of commercially available drugs by selling and delivering over 10,000 vials of HCG and over 14,000 vials of bacteriostatic water to California patients as follows:

Drug/strength	Number of Rx's	Units sold
BACTERIOSTATIC WATER (12 ML)	2,393	9
BACTERIOSTATIC WATER (30 ML)	17	5
BACTERIOSTATIC WATER (6 ML)	5,299	2
HCG 500 IU	50	1,090
HCG (LYO) 12,000 IU	2,464	3,524
HCG (LYO) 50,000 IU	115	150
HCG (LYO) 6,000 IU	3,138	6,410
Grand Total	**13,476**	**25,812**

TWENTY-FIFTH CAUSE FOR DISCIPLINE

(Compounding of a Commercially Available Product)

85. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR section 1735.2, subdivision (d)(3), in that between September 3, 2019, and February 27, 2020, Respondent sent imitations of commercially available drugs by delivering over 10,000 vials of HCG and over 14,000 vials of bacteriostatic water to California patients without any documented specific medical need as more thoroughly set forth in Paragraph 84 above.

TWENTY-SIXTH CAUSE FOR DISCIPLINE

(Unlawful Sale of Misbranded Drugs)

86. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to Code section 4169, subdivision (a) in conjunction with Health and Safety Code sections 111330 and 111440, in that between September 3, 2019, and February 27, 2020, Respondent delivered misbranded drugs that were imitations of commercially available drugs by selling and delivering over 110,000 doses labeled as slow release to California consumers as follows:

Row Labels	Number of Rx's	Units sold
DHEA SLOW RELEASE	263	22,620
DHEA/PREGNENOLONE SLOW RELEASE	41	3,660
LIOTHYRONINE SODIUM SLOW RELEASE	117	10,804
MELATONIN SLOW RELEASE	9	425
PHENTERMINE HCL SLOW RELEASE	27	1,080
PHENTERMINE HCL SLOW RELEASE HTP COMPLEX	11	420
PREGNENOLONE SLOW RELEASE	190	16,295
PROGESTERONE SLOW RELEASE	422	18,680
PROGESTERONE SLOW RELEASE (CLEAR CAPSULE)	1	30
SILDENAFIL SLOW RELEASE	183	4,479
T3/T4 (LIO/LEVO) SODIUM SLOW RELEASE	1	90

TADALAFIL SLOW RELEASE	909	40,467
Grand Total	**2,174**	**119,050**

TWENTY-SEVENTH CAUSE FOR DISCIPLINE

(**Failure to Maintain the Quality of a Compounded Sterile Preparation**)

87. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to Code section 4169, subdivision (a), in conjunction with Health and Safety Code sections 111250 and 111295, and CCR sections 1735.1(ae) and 1735.2(g), in that between February 27, 2020, and March 4, 2020, Respondent furnished glutathione 200mg/ml injection, with preservative compounded using a raw material, Shandong Glutathione (L) reduced lot B200117, which was ungraded, therefore adulterating the compounded sterile preparation of at least the following two batches:

Date	Lot Number	API 17, page 1	Vials Made
February 27, 2020	65517	Shandon Juncheng Lot B200117	1,800
March 4, 2020	65787	Shandon Juncheng Lot B200117	1,800

TWENTY-EIGHTH CAUSE FOR DISCIPLINE

(**Use of Non-Compliant End Product Testing**)

88. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR section 1751.7, subdivision (e)(1), in that Respondent compounded and released glutathione 200mg/ml injection, with preservative without first confirming sterility with a USP 71 compliant test on at least batches as more thoroughly set forth in Paragraph 87 above.

TWENTY-NINTH CAUSE FOR DISCIPLINE

(**Compounding Limitations and Requirements**)

89. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR section 1735.4, subdivision (a)(2), in that Respondent between September 3, 2019, and February 27, 2020, sent over 4000 doses of medication into California without the generic name on the label as more thoroughly set forth in Paragraph 83 above.

THIRTIETH CAUSE FOR DISCIPLINE

(**Misbranding of Compounded Preparations**)

90. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to Code section 4169, subdivision (a), in conjunction with Health and Safety Code sections 111395 and

111440, in that between September 3, 2019, and February 27, 2020, Respondent delivered misbranded drugs that were imitations of commercially available drugs by selling and delivering over 10,000 vials of HCG and over 14,000 vials of bacteriostatic water to California patients as more thoroughly set forth in Paragraph 84 above.

THIRTY-FIRST CAUSE FOR DISCIPLINE

(Compounding of a Commercially Available Product)

91. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR section 1735.2, subdivision (d)(3), in that between September 3, 2019, and February 27, 2020, Respondent sent imitations of commercially available drugs by delivering over 10,000 vials of HCG and over 14,000 vials of bacteriostatic water to California patients without any documented specific medical need as more thoroughly set forth in Paragraph 84 above.

THIRTY-SECOND CAUSE FOR DISCIPLINE

(Unlawful Sale of Misbranded Drugs)

92. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to Code section 4169, subdivision (a), in conjunction with Health and Safety Code sections 111330 and 111440, in that between September 3, 2019, and February 27, 2020, Respondent delivered misbranded drugs that were imitations of commercially available drugs by selling and delivering over 110,000 doses labeled as slow release to California consumers as more thoroughly set forth in Paragraph 86 above.

THIRTY-THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain the Quality of a Compounded Sterile Preparation)

93. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to Code section 4169, subdivision (a), in conjunction with Health and Safety Code sections 111250 and 111295, and CCR sections 1735.1(ae) and 1735.2(g), in that between February 27, 2020, and March 4, 2020, Respondent furnished glutathione 200mg/ml injection, with preservative compounded using a raw material, Shandong Glutathione (L) reduced lot B200117, which was ungraded, therefore adulterating the compounded sterile preparation as more thoroughly set forth in Paragraphs 77 and 87 above.

THIRTY-FOURTH CAUSE FOR DISCIPLINE

(Use of Non-Compliant End Product Testing)

94. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR section 1751.7, subdivision (e)(1), in that Respondent compounded and released glutathione 200mg/ml injection, with preservative without first confirming sterility with a USP 71 compliant test on at least batches as more thoroughly set forth in Paragraphs 77 and 87 above.

THIRTY-FIFTH CAUSE FOR DISCIPLINE

(Out of State Discipline)

95. Respondent's Nonresident Pharmacy Permit pharmacy permit is subject to discipline under Code section 4301, subdivision (n), in that Respondent was disciplined as a pharmacy by an out of state agency as follows: On or about May 12, 2021, in the case entitled *In the Matter of: Nonresident Pharmacy License of Empower Pharmacy*, Case No. 2018-123, the Iowa Board of Pharmacy Examiners (Iowa Board) issued a disciplinary Order in which Respondent was placed on probation for a period of three (3) years under various conditions, ordered to pay a civil penalty in the amount of $25,000 dollars, ordered to undergo at least one on-site inspection and ordered to pay fees associated with the disciplinary hearing. The circumstances are that in 2017 and 2018, Respondent shipped HCG injectable preparations that were essentially copies of commercially available products to Iowa patients. None of the prescriptions had any patient specific documentation as to why the FDA-approved HCG injectables could not be used.

CDPH Complaint

96. On or about March 4, 2021, the Board was notified of a hospitalization of a patient (Patient MV) who developed *Pseudomonas fluorescens* sepsis requiring hospitalization after injections of compounded preparations from three pharmacies, including Respondent.

97. The Patient received vitamin infusions at Age Management Institute in Santa Barbara, CA (Santa Barbara Clinic) that used medications from two compounding pharmacies, including Respondent.

98. Patient MV received Vitamin C, B complex, MgC12 and Zn as an infusion, Glutathione IVP and possibly B12IVP.

99. On or about March 22, 2021, Board inspectors conducted an inspection at the Santa Barbara Clinic and reviewed various records and documentation that revealed that the ascorbic acid used by the clinic was from Respondent when McGuff Pharmaceuticals Inc. had an FDA approved Ascorbic acid product called Ascor available.

100. On or about March 23, 2021, Board inspectors returned to the Santa Barbara clinic and issued an inspection report and official receipt for the following records:

(a) Incident file from MV;
(b) Fume hood log;
(c) Empower UV purchase report;
(d) Empower invoices;
(e) Log of scrips from Archway Apothecary LLC;
(f) Statement from SB;
(g) Email from Empower clarifying lot # of drugs used to compound for M.V.

101. On or about March 23, 2021, the Board received various documents from Respondent including the following:

(a) Sales between January 1, 2020, through March 8, 2021, into California;

(b) Adverse reaction received from lot 72635, Glutathione preserved (30ml) from patient JN (Rx 2094846);

(c) Five (5) complaints received from California patients or providers between January 1, 2020, and March 8, 2021.

102. On or about April 30, 2021, the Board received additional documents from Respondent including the following:

(a) Ascorbic acid PF batch records;
(b) Glutathione PF batch records;
(c) Glutathione PS batch records;
(d) Licenses held
(e) Log of prescriptions for Bacteriostatic water, HCG 500 IU, and HCG (LYO);
(f) Patient profiles for four (4) patients;
(g) Raw material documents;
(h) Copies of the front and back of various prescriptions;
(i) Data to support assigned BUD;

103. A review of the prescription log for Bacteriostatic water showed that there was no shortage at the time of compounding or dispensing.

104. A review of the prescription log for HCG 500 IU showed that there was no shortage at the time of compounding or dispensing and that it was a biological that cannot be compounded.

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105. A review of the prescription log for HCG (LYO) showed that there was no shortage at the time of compounding or dispensing and that it was a biological and cannot be compounded.

106. The prescription records also showed that Respondent continued to make bacteriostatic water and HCG even after receiving a written notice on June 15, 2020, for making essentially a copy of a commercially available drug.

107. A review of the raw material documentation from Respondent showed no COA from the manufacturer provided or who the manufacturer was for 5 lots of Ascorbic Acid and 5 lots for Glutathione.

108. S.N. was unable to provide the information on the manufacturer of the active ingredient used to compound the ascorbic acid PF 500mg/ml after being asked to do so by the Board.

109. The data used by Respondent to support the assigned BUD showed that sterility was with a 14 day USP 71 test and no validation for Scan RDI.

THIRTY-SIXTH CAUSE FOR DISCIPLINE

(Failure to Report Adverse Effect Potentially Attributable to a Sterile Compounded Drug Product)

110. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to Code section 4127.2, subdivision (f), in that Respondent failed to report to the Board within 12 hours and immediately report to the MedWatch program of the federal Food and Drug Administration a reported adverse effect or potentially attributable adverse effect from a compounded drug it manufactured as more thoroughly set forth in paragraph 101 above.

THIRTY-SEVENTH CAUSE FOR DISCIPLINE

(Failure to Advise the Board of Received Complaints)

111. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to Code section 4127.2, subdivision (e)(4), in that Respondent failed to advise the Board of complaints received from a provider, pharmacy or patient in California as more thoroughly set forth in paragraph 101 above.

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THIRTY-EIGHTH CAUSE FOR DISCIPLINE

(Unlawful Compounding of a Commercially Available Product)

112. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR, section 1735.2, subdivision (d)(3), in that between April 1, 2020, and April 15, 2021, Respondent compounded and furnished at least 18,730 orders and 52,979 vials of human chorionic gonadotropin and at least 42,482 orders and 77,856 vials of bacteriostatic water to California patients which were a copy or essentially a copy of a commercially available drug without a documented shortage and a documented medical need prior to compounding as follows:

Drug	# of prescriptions sold	Number of vials
Bacteriostatic Water (12 ML) 0.009	2,314	4,529
Bacteriostatic Water (12 ML) 0.015	4,423	8,659
Bacteriostatic Water (30 ML) 0.009	45	64
Bacteriostatic Water (6 ML) 0.009	12,932	23,504
Bacteriostatic Water (6 ML) 0.015	22,768	41,100
HCG 500 IU	908	23,660
HCG (LYO) 12,000 IU	7,663	10,858
HCG (LYO) 50,000 IU	285	377
HCG (LYO) 6,000 IU	9,874	18,084

THIRTY-NINTH CAUSE FOR DISCIPLINE

(Unlawful Sale of Misbranded Drugs)

113. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to Code section 4169, subdivision (a) in conjunction with Health and Safety Code sections 111395 and 111440, in that between April 1, 2020, and April 15, 2021, Respondent delivered misbranded drugs that were imitations of commercially available drugs by selling and furnishing at least 18,730 orders and 52,979 vials of human chorionic gonadotropin and at least 42,482 orders and 77,856 vials of bacteriostatic water to California consumers as follows:

Drug	# of prescriptions sold	Number of vials
Bacteriostatic Water (12 ML) 0.009	2,314	4,529
Bacteriostatic Water (12 ML) 0.015	4,423	8,659
Bacteriostatic Water (30 ML) 0.009	45	64
Bacteriostatic Water (6 ML) 0.009	12,932	23,504
Bacteriostatic Water (6 ML) 0.015	22,768	41,100
HCG 500 IU	908	23,660
HCG (LYO) 12,000 IU	7,663	10,858
HCG (LYO) 50,000 IU	285	377
HCG (LYO) 6,000 IU	9,874	18,084

FORTIETH CAUSE FOR DISCIPLINE

(**Unlicensed Manufacturing of a Biologic**)

114. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to 42 U.S. Code section 262, subdivision (a)(1)(A), in that between April 1, 2020, and April 15, 2021, Respondent shipped at least 18,730 orders and 52,979 vials of human chorionic gonadotropin, a biological, into California, without the Biologics License to introduce or deliver it into interstate commerce.

FORTY-FIRST CAUSE FOR DISCIPLINE

(**Use of Non-Compliant end Product Testing**)

Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR, section 1751.7, subdivision (e)(1), in that between November 18, 2019, and February 25, 2021, Respondent furnished into California at least 9 batches and at least 2,385 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml; 4 batches and at least 385 vials of Glutathione PF (30 ml) 200mg/ml; and 5 batches and at least 1,144 vials of Glutathione Preserved (30 ml) 200mg/ml without first confirming sterility with a USP chapter 71 compliant test as follows:

Ascorbic acid PF (30 ml) 500mg/ml

Lot Number	Date made	BUD assigned	Vials Shipped	Prescriptions sold	Notes
65302	2/25/21	2/24/21	200	5	Scan RDI used 3/3/20
66096	3/10/21	3/10/21	552	10	Scan RDI used 3/17/20
66415	3/17/21	3/17/21	323	11	Scan RDI used 3/23/20
66596	3/19/21	3/17/21	296	8	Scan RDI used 3/23/20
66770	3/24/20	3/24/21	221	9	Scan RDI used 4/1/20
67577	4/7/20	4/7/21	176	17	Scan RDI used 4/13/20
67583	4/8/20	4/7/21	241	7	Scan RDI used 4/15/20
68865	4/30/20	4/30/21	200	4	Scan RDI used 5/6/20
71070	6/10/20	6/10/21	176	8	Scan RDI used 6/17/20

Glutathione PF (30 ml) 200mg/.ml

Lot Number	Date made	BUD assigned	Vials Shipped	Prescriptions sold	Notes
60583	11/18/19	5/6/20	141	34	Scan RDI used 11/25/19
61583	12/11/19	6/8/20	79	24	Scan RDI used 12/18/19
63195	7/13/20	7/13/20	94	20	Scan RDI used 1/21/20
64804	2/18/20	8/17/20	71	17	Scan RDI used 2/25/20

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Glutathione Preserved (30 ml) 200mg/ml

Lot Number	Date made	BUD assigned	Vials Shipped	Prescriptions sold	Notes
61886	12/16/19	6/13/20	248	74	Scan RDI used 12/26/19
64068	1/29/20	7/27/20	153	52	Scan RDI used 2/6/20
64470	2/6/20	8/4/20	329	78	Scan RDI used 2/17/20
64590	2/10/20	8/8/20	146	55	Scan RDI used 2/19/20
65172	2/20/20	8/18/20	268	87	Scan RDI used 2/27/20

FORTY-SECOND CAUSE FOR DISCIPLINE

(**Failure to Maintain the Quality of a Compounded Sterile Preparation**)

115. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to Code section 4169, subdivision (a), in conjunction with Health and Safety Code sections 111250 and 111295, and CCR sections 1735.1(ae) and 1735.2(g), in that between November 18, 2019, and February 25, 2021, Respondent furnished at least 9 batches and at least 2,385 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml; 4 batches and at least 385 vials of Glutathione PF (30 ml) 200mg/ml; and 5 batches and at least 1,144 vials of Glutathione Preserved (30 ml) 200mg/ml using a raw material, which was ungraded, or food graded, therefore adulterating the compounded sterile preparation as follows:

Ascorbic acid PF (30 ml) 500mg/ml

Lot Number	Date made	BUD assigned	API	Vials Shipped	Prescriptions sold
65302	2/25/21	2/24/21	Fagron lot 19H12-U01-001507	200	5
66096	3/10/21	3/10/21	Fagron lot 19H12-U01-001507	552	10
66415	3/17/21	3/17/21	Fagron lot 19H12-U01-001507	323	11
66596	3/19/21	3/17/21	Fagron lot 19H01-U01-001410	296	8
66770	3/24/20	3/24/21	Fagron lot 19H01-U01-001410	221	9
67577	4/7/20	4/7/21	Fagron lot 20C04-U08-005401	176	17
67583	4/8/20	4/7/21	Fagron lot 20C04-U08-005401	241	7
68865	4/30/20	4/30/21	Fagron lot 20C04-U08-005401	200	4
71070	6/10/20	6/10/21	Fagron lot 20A14-U02-004451	176	8

Glutathione PF (30 ml) 200mg/.ml

Lot Number	Date made	BUD assigned	API	Vials Shipped	Prescriptions dispensed
60583	11/18/19	5/6/20	Medisca lot 163561/A	141	34
61583	12/11/19	6/8/20	Shandong Jincheng lot B190753	79	24
63195	7/13/20	7/13/20	Shandong Jincheng lot B190852	94	20
64804	2/18/20	8/17/20	Shandong Jincheng lot B200117	71	17

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Glutathione Preserved (30 ml) 200mg/ml

Lot Number	Date made	BUD assigned	API	Vials Shipped	Prescriptions dispensed
61886	12/16/19	6/13/20	Shandong Jincheng lot B190753	248	74
64068	1/29/20	7/27/20	Shandong Jincheng lot B190852	153	52
64470	2/6/20	8/4/20	Shandong Jincheng lot B200117	329	78
64590	2/10/20	8/8/20	Shandong Jincheng lot B200117	146	55
65172	2/20/20	8/18/20	Shandong Jincheng lot B200117	268	87

FORTY-THIRD CAUSE FOR DISCIPLINE

(**Incomplete Compounding Logs**)

116. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR, section 1735.3, subdivision (a)(2)(F), in that between November 18, 2019, and February 25, 2021, Respondent compounded Ascorbic acid PF (30 ml) 500mg/ml injectable, and Glutathione PF (30 ml) 200mg/ml and failed to document the manufacturer of ascorbic acid as follows:

Ascorbic acid PF (30 ml) 500mg/ml

Lot Number	Date made	Amount made	BUD assigned	API	Vials Shipped	Prescriptions sold
65302	2/25/21	1,731 vials	2/24/21	Fagron lot 19H12-U01-001507	200	5
66096	3/10/21	1,716 vials	3/10/21	Fagron lot 19H12-U01-001507	552	10
66415	3/17/21	1,716 vials	3/17/21	Fagron lot 19H12-U01-001507	323	11
66596	3/19/21	3,393 vials	3/17/21	Fagron lot 19H01-U01-001410	296	8
66770	3/24/20	2,563 vials	3/24/21	Fagron lot 19H01-U01-001410	221	9
67577	4/7/20	1,695 vials	4/7/21	Fagron lot 20C04-U08-005401	176	17
67583	4/8/20	1,558 vials	4/7/21	Fagron lot 20C04-U08-005401	241	7
68865	4/30/20	1,690 vials	4/30/21	Fagron lot 20C04-U08-005401	200	4
71070	6/10/20	3,377 vials	6/10/21	Fagron lot 20A14-U02-004451	176	8
74211	8/4/20	3,387 vials	8/4/21	Fagron lot 20D15-U10-006141	285	10

Glutathione PF (30 ml) 200mg/.ml

Lot Number	Date made	Amount made	BUD assigned	API	Vials Shipped	Prescriptions dispensed
60583	11/18/19	1,431 vials	5/6/20	Medisca lot 163561/A	141	34

FORTY-FOURTH CAUSE FOR DISCIPLINE

(**Failure to Obtain Active Ingredient from a Supplier Registered with the FDA**)

117. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR, section 1735.3, subdivision (c), in that Respondent used active ingredients received from a manufacturer with an unattainable registration with the Food and Drug Administration (FDA) as follows:

Ascorbic acid PF (30 ml) 500mg/ml

Lot Number	Date made	BUD assigned	API	Vials Shipped	Prescriptions sold
65302	2/25/21	2/24/21	Fagron lot 19H12-U01-001507	200	5
66096	3/10/21	3/10/21	Fagron lot 19H12-U01-001507	552	10
66415	3/17/21	3/17/21	Fagron lot 19H12-U01-001507	323	11
66596	3/19/21	3/17/21	Fagron lot 19H01-U01-001410	296	8
66770	3/24/20	3/24/21	Fagron lot 19H01-U01-001410	221	9
67577	4/7/20	4/7/21	Fagron lot 20C04-U08-005401	176	17
67583	4/8/20	4/7/21	Fagron lot 20C04-U08-005401	241	7
68865	4/30/20	4/30/21	Fagron lot 20C04-U08-005401	200	4
71070	6/10/20	6/10/21	Fagron lot 20A14-U02-004451	176	8
74211	8/4/20	8/4/21	Fagron lot 20D15-U10-006141	285	10

Glutathione PF (30 ml) 200mg/.ml

Lot Number	Date made	BUD assigned	API	Vials Shipped	Prescriptions dispensed	Notes
60583	11/18/19	5/6/20	Medisca lot 163561/A	141	34	Scan RDI used 11/25/19

FORTY-FIFTH CAUSE FOR DISCIPLINE

(**Failure to Have Data to Support Assigned Beyond Use Date**)

118. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR, 1735.2, subdivision (i), in that between November 18, 2019, and February 25, 2021, Respondent compounded and assigned an extended BUD of approximately 365 days (1 year) to at least 9 batches and at least 2,385 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml; 4 batches and at least 385 vials of Glutathione PF (30 ml) 200mg/ml; and 5 batches and at least 1,144 vials of Glutathione Preserved (30 ml) 200mg/ml which were furnished into California, without the data required to support this extended BUD:

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Ascorbic acid PF (30 ml) 500mg/ml

Lot Number	Date made	BUD assigned	API	Vials Shipped	Prescriptions sold
65302	2/25/21	2/24/21	Fagron lot 19H12-U01-001507	200	5
66096	3/10/21	3/10/21	Fagron lot 19H12-U01-001507	552	10
66415	3/17/21	3/17/21	Fagron lot 19H12-U01-001507	323	11
66596	3/19/21	3/17/21	Fagron lot 19H01-U01-001410	296	8
66770	3/24/20	3/24/21	Fagron lot 19H01-U01-001410	221	9
67577	4/7/20	4/7/21	Fagron lot 20C04-U08-005401	176	17
67583	4/8/20	4/7/21	Fagron lot 20C04-U08-005401	241	7
68865	4/30/20	4/30/21	Fagron lot 20C04-U08-005401	200	4
71070	6/10/20	6/10/21	Fagron lot 20A14-U02-004451	176	8

Glutathione PF (30 ml) 200mg/.ml

Lot Number	Date made	BUD assigned	API	Vials Shipped	Prescriptions dispensed
60583	11/18/19	5/6/20	Medisca lot 163561/A	141	34
61583	12/11/19	6/8/20	Shandong Jincheng lot B190753	79	24
63195	7/13/20	7/13/20	Shandong Jincheng lot B190852	94	20
64804	2/18/20	8/17/20	Shandong Jincheng lot B200117	71	17

Glutathione Preserved (30 ml) 200mg/ml

Lot Number	Date made	BUD assigned	API	Vials Shipped	Prescriptions dispensed
61886	12/16/19	6/13/20	Shandong Jincheng lot B190753	248	74
64068	1/29/20	7/27/20	Shandong Jincheng lot B190852	153	52
64470	2/6/20	8/4/20	Shandong Jincheng lot B200117	329	78
64590	2/10/20	8/8/20	Shandong Jincheng lot B200117	146	55
65172	2/20/20	8/18/20	Shandong Jincheng lot B200117	268	87

FORTY-SIXTH CAUSE FOR DISCIPLINE

(Failure to Report Adverse Effect Potentially Attributable to a Sterile Compounded Drug Product)

119. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to Code section 4127.2, subdivision (f), in that Respondent failed to report to the Board within 12 hours and immediately report to the MedWatch program of the federal Food and Drug Administration a reported adverse effect or potentially attributable adverse effect from a compounded drug it manufactured as more thoroughly set forth in paragraph 101 above.

FORTY-SEVENTH CAUSE FOR DISCIPLINE

(Failure to Advise the Board of Received Complaints)

120. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to Code section 4127.2, subdivision (e)(4), in that Respondent failed to advise the Board of complaints

received from a provider, pharmacy or patient in California as more thoroughly set forth in paragraph 101 above.

FORTY-EIGHTH CAUSE FOR DISCIPLINE

(Unlawful Compounding of a Commercially Available Product)

121. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.2, subdivision (d)(3), in that between April 1, 2020, and April 15, 2021, Respondent compounded and furnished at least 18,730 orders and 52,979 vials of human chorionic gonadotropin and at least 42,482 orders and 77,856 vials of bacteriostatic water to California patients which were a copy or essentially a copy of a commercially available drug without a documented shortage and a documented medical need prior to compounding as follows:

Drug	# of prescriptions sold	Number of vials
Bacteriostatic Water (12 ML) 0.009	2,314	4,529
Bacteriostatic Water (12 ML) 0.015	4,423	8,659
Bacteriostatic Water (30 ML) 0.009	45	64
Bacteriostatic Water (6 ML) 0.009	12,932	23,504
Bacteriostatic Water (6 ML) 0.015	22,768	41,100
HCG 500 IU	908	23,660
HCG (LYO) 12,000 IU	7,663	10,858
HCG (LYO) 50,000 IU	285	377
HCG (LYO) 6,000 IU	9,874	18,084

FORTY-NINTH CAUSE FOR DISCIPLINE

(Unlawful Sale of Misbranded Drugs)

122. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to Code section 4169, subdivision (a) in conjunction with Health and Safety Code sections 111395 and 111440, in that between April 1, 2020, and April 15, 2021, Respondent delivered misbranded drugs that were imitations of commercially available drugs by selling and furnished at least 18,730 orders and 52,979 vials of human chorionic gonadotropin and at least 42,482 orders and 77,856 vials of bacteriostatic water to California consumers as follows:

Drug	# of prescriptions sold	Number of vials
Bacteriostatic Water (12 ML) 0.009	2,314	4,529
Bacteriostatic Water (12 ML) 0.015	4,423	8,659
Bacteriostatic Water (30 ML) 0.009	45	64
Bacteriostatic Water (6 ML) 0.009	12,932	23,504
Bacteriostatic Water (6 ML) 0.015	22,768	41,100

HCG 500 IU	908	23,660
HCG (LYO) 12,000 IU	7,663	10,858
HCG (LYO) 50,000 IU	285	377
HCG (LYO) 6,000 IU	9,874	18,084

FIFTIETH CAUSE FOR DISCIPLINE

(**Unlicensed Manufacturing of a Biologic**)

123. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to 42 U.S. Code section 262, subdivision (a)(1)(A), in that between April 1, 2020, and April 15, 2021, Respondent shipped at least 18,730 orders and 52,979 vials of human chorionic gonadotropin, a biological, into California, without the Biologics License to introduce or deliver it into interstate commerce.

FIFTY-FIRST CAUSE FOR DISCIPLINE

(**Use of Non-Compliant end Product Testing**)

124. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1751.7, subdivision (e)(1), in that between November 18, 2019, and February 25, 2021, Respondent furnished into California at least 9 batches and at least 2,385 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml; 4 batches and at least 385 vials of Glutathione PF (30 ml) 200mg/ml; and 5 batches and at least 1,144 vials of Glutathione Preserved (30 ml) 200mg/ml without first confirming sterility with a USP chapter 71 compliant test as follows:

Ascorbic acid PF (30 ml) 500mg/ml

Lot Number	Date made	BUD assigned	Vials Shipped	Prescriptions sold	Notes
65302	2/25/21	2/24/21	200	5	Scan RDI used 3/3/20
66096	3/10/21	3/10/21	552	10	Scan RDI used 3/17/20
66415	3/17/21	3/17/21	323	11	Scan RDI used 3/23/20
66596	3/19/21	3/17/21	296	8	Scan RDI used 3/23/20
66770	3/24/20	3/24/21	221	9	Scan RDI used 4/1/20
67577	4/7/20	4/7/21	176	17	Scan RDI used 4/13/20
67583	4/8/20	4/7/21	241	7	Scan RDI used 4/15/20
68865	4/30/20	4/30/21	200	4	Scan RDI used 5/6/20
71070	6/10/20	6/10/21	176	8	Scan RDI used 6/17/20

Glutathione PF (30 ml) 200mg/.ml

Lot Number	Date made	BUD assigned	Vials Shipped	Prescriptions sold	Notes
60583	11/18/19	5/6/20	141	34	Scan RDI used 11/25/19
61583	12/11/19	6/8/20	79	24	Scan RDI used 12/18/19
63195	7/13/20	7/13/20	94	20	Scan RDI used 1/21/20

64804	2/18/20	8/17/20	71	17	Scan RDI used 2/25/20

Glutathione Preserved (30 ml) 200mg/ml

Lot Number	Date made	BUD assigned	Vials Shipped	Prescriptions sold	Notes
61886	12/16/19	6/13/20	248	74	Scan RDI used 12/26/19
64068	1/29/20	7/27/20	153	52	Scan RDI used 2/6/20
64470	2/6/20	8/4/20	329	78	Scan RDI used 2/17/20
64590	2/10/20	8/8/20	146	55	Scan RDI used 2/19/20
65172	2/20/20	8/18/20	268	87	Scan RDI used 2/27/20

FIFTY-SECOND CAUSE FOR DISCIPLINE

(**Failure to Maintain the Quality of a Compounded Sterile Preparation**)

125. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to Code section 4169, subdivision (a), in conjunction with Health and Safety Code sections 111250 and 111295, and CCR sections 1735.1(ae) and 1735.2(g), in that between November 18, 2019, and February 25, 2021, Respondent furnished at least 9 batches and at least 2,385 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml; 4 batches and at least 385 vials of Glutathione PF (30 ml) 200mg/ml; and 5 batches and at least 1,144 vials of Glutathione Preserved (30 ml) 200mg/ml using a raw material, which was ungraded, or food graded, therefore adulterating the compounded sterile preparation as follows:

Ascorbic acid PF (30 ml) 500mg/ml

Lot Number	Date made	BUD assigned	API	Vials Shipped	Prescriptions sold
65302	2/25/21	2/24/21	Fagron lot 19H12-U01-001507	200	5
66096	3/10/21	3/10/21	Fagron lot 19H12-U01-001507	552	10
66415	3/17/21	3/17/21	Fagron lot 19H12-U01-001507	323	11
66596	3/19/21	3/17/21	Fagron lot 19H01-U01-001410	296	8
66770	3/24/20	3/24/21	Fagron lot 19H01-U01-001410	221	9
67577	4/7/20	4/7/21	Fagron lot 20C04-U08-005401	176	17
67583	4/8/20	4/7/21	Fagron lot 20C04-U08-005401	241	7
68865	4/30/20	4/30/21	Fagron lot 20C04-U08-005401	200	4
71070	6/10/20	6/10/21	Fagron lot 20A14-U02-004451	176	8

Glutathione PF (30 ml) 200mg/.ml

Lot Number	Date made	BUD assigned	API	Vials Shipped	Prescriptions dispensed
60583	11/18/19	5/6/20	Medisca lot 163561/A	141	34
61583	12/11/19	6/8/20	Shandong Jincheng lot B190753	79	24
63195	7/13/20	7/13/20	Shandong Jincheng lot B190852	94	20
64804	2/18/20	8/17/20	Shandong Jincheng lot B200117	71	17

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Glutathione Preserved (30 ml) 200mg/ml

Lot Number	Date made	BUD assigned	API	Vials Shipped	Prescriptions dispensed
61886	12/16/19	6/13/20	Shandong Jincheng lot B190753	248	74
64068	1/29/20	7/27/20	Shandong Jincheng lot B190852	153	52
64470	2/6/20	8/4/20	Shandong Jincheng lot B200117	329	78
64590	2/10/20	8/8/20	Shandong Jincheng lot B200117	146	55
65172	2/20/20	8/18/20	Shandong Jincheng lot B200117	268	87

FIFTY-FOURTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Logs)

126. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.3, subdivision (a)(2)(F), in that between August 4, 2020, and March 19, 2021, Respondent compounded at least the following 11 lots and 2,811 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml injectable and Glutathione PF (30 ml) 200mg/ml and failed to document the manufacturer of ascorbic acid:

Ascorbic Acid PF 500mg/ml 30ml

Lot number	**Made on**	**Amount Made**	**BUD**	**API used**	**Vials Shipped**	**Prescriptions Sold**
65302	2/25/21	1,731 vials	2/24/21	Fagron: 19H12-U01-001507	200	5
66096	3/10/21	1,716 vials	3/10/21	Fagron: 19H12-U01-001507	552	10
66415	3/17/21	1,716 vials	3/17/21	Fagron: 19H01-U07-001507	323	11
66596	3/19/21	3,393 vials	3/17/21	Fagron: 19H01-U01-001410	296	8
66770	3/24/20	2,563 vials	3/24/21	Fagron: 19H01-U01-001410	221	9
67577	4/7/20	1,695 vials	4/7/21	Fagron: 20C04-U08-005401	176	17
67583	4/8/20	1,558 vials	4/7/21	Fagron: 20C04-U08-005401	241	7
68865	4/30/20	1,690 vials	4/30/21	Fagron: 20C04-U08-005401	200	4
71070	6/10/20	3,377 vials	6/10/21	Fagron: 20A14-U02-004451	176	8
74211	8/4/20	3,387 vials	8/4/21	Fagron: 20D15-U10-006141	285	10

Glutathione PF 200mg/ml 30ml

Lot number	**Made on**	**Amount Made**	**BUD**	**API used**	**Vials Shipped**	**Prescriptions Sold**
60583	11/18/19	1,431 vials	5/6/20	Medisca lot 163561/A	141	34

FIFTY-FIFTH CAUSE FOR DISCIPLINE

(**Failure to Obtain Active Ingredient from a Supplier Registered With the FDA**)

127. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.3, subdivision (c), in that Respondent used active ingredients received from an unknown manufacturer with an unattainable registration with the Food and Drug Administration (FDA) for the following active ingredients:

Ascorbic Acid PF 500mg/ml 30ml

Lot number	Date Made	BUD	API used	Vials Shipped	Prescriptions Sold
65302	2/25/21	2/24/21	Fagron: 19H12-U01-001507	200	5
66096	3/10/21	3/10/21	Fagron: 19H12-U01-001507	552	10
66415	3/17/21	3/17/21	Fagron: 19H01-U07-001507	323	11
66596	3/19/21	3/17/21	Fagron: 19H01-U01-001410	296	8
66770	3/24/20	3/24/21	Fagron: 19H01-U01-001410	221	9
67577	4/7/20	4/7/21	Fagron: 20C04-U08-005401	176	17
67583	4/8/20	4/7/21	Fagron: 20C04-U08-005401	241	7
68865	4/30/20	4/30/21	Fagron: 20C04-U08-005401	200	4
71070	6/10/20	6/10/21	Fagron: 20A14-U02-004451	176	8
74211	8/4/20	8/4/21	Fagron: 20D15-U10-006141	285	10

Glutathione PF 200mg/ml 30ml

Lot number	Made on	BUD	API used	Vials Shipped	Prescriptions Sold
60583	2/25/21	2/24/21	Medisca lot 163561/A	200	5

FIFTY-SIXTH CAUSE FOR DISCIPLINE

(**Assignment of Unsupported Beyond Use Date**)

128. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, 1735.2, subdivision (i), in that between November 18, 2019, and June 10, 2021, Respondent compounded and assigned an extended BUD of approximately 365 days (1 year) to at least the following 18 batches and at least 3,914 vials of non-sterile to sterile ascorbic acid PF (30 ml) 500mg/ml injectable, Glutathione PF (30 ml) 200mg/ml, and Glutathione Preserved (30 ml) 200/mg/ml which were furnished into California, without the data required to support this extended BUD:

Ascorbic Acid PF 500mg/ml 30ml

Lot number	Date Made	BUD	API used	Vials Shipped	Prescriptions Sold
65302	2/25/21	2/24/21	Fagron: 19H12-U01-001507	200	5
66096	3/10/21	3/10/21	Fagron: 19H12-U01-001507	552	10

66415	3/17/21	3/17/21	Fagron: 19H01-U07-001507	323	11
66596	3/19/21	3/17/21	Fagron: 19H01-U01-001410	296	8
66770	3/24/20	3/24/21	Fagron: 19H01-U01-001410	221	9
67577	4/7/20	4/7/21	Fagron: 20C04-U08-005401	176	17
67583	4/8/20	4/7/21	Fagron: 20C04-U08-005401	241	7
68865	4/30/20	4/30/21	Fagron: 20C04-U08-005401	200	4
71070	6/10/20	6/10/21	Fagron: 20A14-U02-004451	176	8

Glutathione PF 200mg/ml 30ml

Lot number	Made on	BUD	API used	Vials Shipped	Prescriptions Dispensed
60583	11/18/19	5/6/20	Medisca lot 163561/A	141	34
61583	12/11/19	6/8/20	Shandong Jincheng lot B190753	79	24
63195	7/13/20	7/13/20	Shandong Jincheng lot B190852	94	20
64804	2/18/20	8/17/20	Shandong Jincheng lot B200117	71	17

Glutathione Preserved 200mg/ml 30ml

Lot number	Made on	BUD	API used	Vials Shipped	Prescriptions Dispensed
61886	12/16/19	6/13/20	Shandong Jincheng lot B190753	248	74
64068	1/29/20	7/27/20	Shandong Jincheng lot B190852	153	52
64470	2/6/20	8/4/20	Shandong Jincheng lot B200117	329	78
64590	2/10/20	8/8/20	Shandong Jincheng lot B200117	146	55
65172	2/20/20	8/18/20	Shandong Jincheng lot B200117	268	87

June 15, 2021, Complaint

129. On or about June 15, 2021, the Board received a complaint that Respondent was compounding human chorionic gonadotropin (HCG) illegally, was sending office use orders of HCG to clinics disguised as patient specific prescriptions, and did not have a biologics[5] license.

130. On or about July 6, 2021, the Board requested Respondent provide records of all HCG compounded and sold into California between April 1, 2021, and July 6, 2021, as well as all the bacteriostatic water prescriptions which accompanied the HCG prescriptions.

131. On or about July 8, 2021, Responded provided the relevant records to the Board.

FIFTY-SEVENTH CAUSE FOR DISCIPLINE

(Unlawful Compounding of a Commercially Available Product)

132. Respondent's Nonresident Sterile Compounding Permit is subject to discipline pursuant to CCR, section 1735.2, subdivision (d)(3), in that between April 1, 2021, and June 16, 2021, Respondent furnished to California patients over 29,000 vials of HCG and over 10,000

[5] On or about March 23, 2020, the Federal Regulations required a biologics license to compound HCG.

which were a copy or essentially a copy of a commercially available product without a documented shortage and a documented medical need.

FIFTY-EIGHTH CAUSE FOR DISCIPLINE

(Unlawful Compounding of a Commercially Available Product)

133. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.2, subdivision (d)(3), in that between April 1, 2021, and June 16, 2021, Respondent furnished to California patients over 29,000 vials of HCG and over 10,000 which were a copy or essentially a copy of a commercially available product without a documented shortage and a documented medical need.

MATTERS IN AGGRAVATION

134. On or about April 22, 2019, the Board conducted its annual sterile compounding renewal inspection for Respondent. Following the remote inspection, two corrections were issued as follows:

a. During the inspection, it was discovered that products were labeled sustained release although there was no data to support the claim in violation of Health & Saf. Code section 111330; and

b. During the inspection it was discovered that products sent to California did not have correct and adequate instructions for storage and expiration in violation of CCR 1751.2(b).

135. On or about February 12, 2020, through March 6, 2020, Respondent's compounding facility was inspected by the Food and Drug Administration (FDA). The inspection identified the following violations:

a. Respondent failed to maintain adequate environmental controls during sterile drug production;

b. Respondent failed to establish validated hold-times for sterilized bulk drug products to mitigate the risk of contamination of finished drug products;

c. Respondent failed to adequately write and follow quality control procedures;

d. Respondent compounded drugs that are essentially a copy of one or more

approved drugs including, but not limited to, Human Chorionic Gonadotropin, Menotropins Injection, Leuprolide Acetate Injection, and Pyridoxine HCL Injection;

e. Respondent's containers at its outsourcing drug facility did not include the required information; and

f. Respondent's outsourcing facility did not submit adverse event reports as required.

136. On or about October 15, 2021, Respondent was issued a Warning Letter by the FDA following its March 6, 2020, inspection, and consideration of Respondent's March 27, 2020, response. The Warning Letter advised Respondent that drug products produced at its facility failed to meet the conditions of Section 503B as follows: Some of Respondent's drug products did not include the required adverse event reporting language; Respondent failed to submit a complete report to the FDA in December 2019 and June 2020; Respondent did not submit adverse event reports to the FDA in accordance with content and format requirements; and Respondent compounded a drug product that was sole by an different entity. Respondent was also found to be marketing products without an FDA-approved application on file for drug products that Respondent compounded; and Respondent had misbranded drug products. The warning letter advised that while some of its corrective actions taken by Respondent regarding the violations appeared adequate, multiple violations were not addressed, including the following:

a. Respondent's Standard Operating Procedure failed to adequately address adverse event reporting;

b. Respondent was wholesaling drugs that it compounded in violation of 503B(a)(8) of the FDCA[6] [21 U.S.C. §353b(a)(8)] which states that the "drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug".

c. Respondent's compounding facility contained drug products intended for dispensing to patients pursuant to a prescription that included the statement "For office use only" which would violation 503B(a)(10) of the FDCA [21 U.S.C. §353b(a)(10)].

[6] Federal Food, Drug and Cosmetic Act (FDCA)

d. Respondent's facility compounded Pyridoxine HCL 100mg/ml injection using the bulk drug substance Pyridoxine, a component of an approved drug product. Respondent was again advised that for a compounded drug product to qualify for the exemptions under section 503B, it must not be essentially a copy of one or more approved drugs (section 503B(a)(5) of the FDCA [21 U.S.C. § 353b(a)(5)]).

e. Respondent's facility was observed by the FDA investigator to produce biological products and that federal law does not provide a legal pathway for marketing biological products that have been prepared outside the scope of an approved biologics license application.

137. On or about June 15, 2020, Respondent was given a written notice regarding its compounding of HCG and bacteriostatic water, which were copies or essentially copies of a commercially available product without a documented shortage and a documented medical need. Respondent made no effort to discontinue the compounding and furnishing of HCG and bacteriostatic water into the State of California and continued to do so until June 16, 2021, as more thoroughly described in paragraphs 130 through 133 above.

OTHER MATTERS

138. On or about June 13, 2018, in the case entitled *In the Matter of the Complaint Against Empower Pharmacy (99-7594)*, Case No. 1510, the Oklahoma Board of Pharmacy (Oklahoma Board) issued a $37,200 fine against Respondent based on its dispensing of 372 HCG injectable preparations in commercially available quantities or essentially copies of commercially available FDA-approved drugs. The Agreed Order, deferred discipline for a period of two years during which time Respondent was placed on probation to ensure continued compliance with Oklahoma Board of Pharmacy Rules.

139. On or about July 2, 2019, in the case entitled *In the Matter of the License of: Empower Pharmacy*, Case No. BOP 18-053, Respondent entered into a Stipulation and Consent Order with the Idaho State Board of Pharmacy (Idaho Board) due to Respondent's dispensing of 14 prescriptions to Idaho residents that were prescribed by a prescriber not licensed to practice medicine in Idaho. As a result, Respondent was issued a $15,000 fine, ordered to verify that all prescribers issuing prescriptions to Idaho residents have the required prescriber license and

controlled substance registrations, and ordered to designate a representative to whom the Idaho Board may direct communications and inquiries.

140. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 1834 or on Nonresident Sterile Compounding Pharmacy Permit Number NSC 100984 issued to Empower Clinic Services LLC dba Empower Pharmacy; Arta Shaun Noorian, Manager/100% Shareholder; Souchinda Nanthayoungdouangsy, Pharmacist-in-Charge; and Jordan Cuccia, Pharmacist-in-Charge, then Empower Clinic Services LLC dba Empower Pharmacy; Arta Shaun Noorian, Manager/100% Shareholder; Souchinda Nanthayoungdouangsy, Pharmacist-in-Charge; and Jordan Cuccia, 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 Sterile Compounding Permit Number NSC 101695, issued to Empower Clinic Services LLC dba Empower Pharmacy; Arta Shaun Noorian, Manager/100% Shareholder; Souchinda Nanthayoungdouangsy, Pharmacist-in-Charge; and Jordan Cuccia, Pharmacist-in-Charge;

2. Revoking or suspending Nonresident Sterile Compounding Permit Number NSC 100984, issued to Empower Clinic Services LLC dba Empower Pharmacy; Arta Shaun Noorian, Manager/100% Shareholder; Souchinda Nanthayoungdouangsy, Pharmacist-in-Charge; and Jordan Cuccia, Pharmacist-in-Charge;

3. Revoking or suspending Nonresident Pharmacy Permit Number NRP 2567, issued to Empower Clinic Services LLC dba Empower Pharmacy; Arta Shaun Noorian, Manager/100% Shareholder; Souchinda Nanthayoungdouangsy, Pharmacist-in-Charge; and Jordan Cuccia, Pharmacist-in-Charge;

4. Revoking or suspending Nonresident Pharmacy Permit Number NRP 1834, issued to Empower Clinic Services LLC dba Empower Pharmacy; Arta Shaun Noorian, Manager/100% Shareholder; Souchinda Nanthayoungdouangsy, Pharmacist-in-Charge; and Jordan Cuccia, Pharmacist-in-Charge;

5. Prohibiting Empower Clinic Services LLC dba Empower Pharmacy 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 Arta Shaun Noorian 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. Ordering Empower Clinic Services LLC dba Empower Pharmacy to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 5/18/2022

Signature on File

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

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