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

In the Matter of the Accusation Against:

INFUSERVE AMERICA INC.;
DAVID KAZARIAN, PRESIDENT/TREASURER/CHIEF FINANCIAL OFFICER/PHARMACIST IN CHARGE;
JOHN GRISE, VICE-PRESIDENT/SECRETARY,

Nonresident Pharmacy Permit No. NRP 928,

and

Nonresident Sterile Compounding Pharmacy Permit No. NSC 99521,

Respondents

Agency Case No. 7060

OAH No. 2021090538

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on January 19, 2022.

It is so ORDERED on December 20, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
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Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **INFUSERVE AMERICA INC.;** **DAVID KAZARIAN,** **PRESIDENT/TREASURER/CHIEF FINANCIAL OFFICER/PHARMACIST IN CHARGE** **JOHN GRISE, VICE-PRESIDENT/SECRETARY** **11880 28th Street, North, Suite 200** **Saint Petersburg, FL 33716-1006** **Nonresident Pharmacy Permit No. NRP 928** **Nonresident Sterile Compounding Pharmacy Permit No. NSC 99521** Respondent.	Case No. 7060 OAH No. 2021090538 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Kristina T. Jarvis, Deputy Attorney General.

2. Infuserve America Inc.; David Kazarian, President, Treasurer/Chief Financial Officer, and Pharmacist In Charge, and John Grise, Vice President and Secretary (Respondent) is represented in this proceeding by attorney Herbert L. Weinberg, whose address is: 1990 South Bundy Drive, Suite 777, Los Angeles, CA 90025.

3. On or about November 19, 2008, the Board of Pharmacy issued Nonresident Pharmacy Permit Number NRP 928 and Nonresident Sterile Compounding Pharmacy Permit Number NSC 99521 to Infuserve America Inc.; David Kazarian, President, Treasurer/Chief Financial Officer, and Pharmacist In Charge, and John Grise, Vice President and Secretary (Respondent). The Non-Resident Pharmacy Permit and the Non-Resident Sterile Compounding Pharmacy Permit were in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2022, unless renewed.

JURISDICTION

4. Accusation No. 7060 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on June 2, 2021. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 7060 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7060. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and

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court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent understands and agrees that the charges and allegations in Accusation No. 7060, if proven at a hearing, constitute cause for imposing discipline upon its Nonresident Pharmacy Permit and Nonresident Sterile Compounding Pharmacy Permit.

9. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest those charges.

10. Respondent agrees that its Nonresident Pharmacy Permit and Nonresident Sterile Compounding Pharmacy Permit are subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

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12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Nonresident Pharmacy Permit No. NRP 928 and Nonresident Sterile Compounding Pharmacy Permit Number NSC 99521 issued to Respondent Infuserve America Inc.; David Kazarian, President, Treasurer/Chief Financial Officer, and Pharmacist In Charge, and John Grise, Vice President and Secretary shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 7060, attached as exhibit A.

Cost Recovery. No later than 18 MONTHS from the effective date of the Decision, Respondent shall pay $18,462.00 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew their Nonresident Pharmacy Permit or Nonresident Sterile Compounding Pharmacy Permit until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

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Practice Restriction. Respondent has agreed and will continue to cease shipping any and all non-sterile to sterile compounding into the State of California unless the Board agrees to lift this restriction in writing.

Full Compliance. As a resolution of the charges in Accusation No. 7060, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Nonresident Pharmacy Permit No. NRP 928 and Nonresident Sterile Compounding Pharmacy Permit No. NSC 99521.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it will have on my Non-Resident Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

INFUSERVE AMERICA INC.;
DAVID KAZARIAN, PRESIDENT
Respondent

I have read and fully discussed with Respondent Infuserve America Inc.; David Kazarian, President the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____

HERBERT L. WEINBERG
Attorney for Respondent

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Practice Restriction. Respondent has agreed and will continue to cease shipping any and all non-sterile to sterile compounding into the State of California unless the Board agrees to lift this restriction in writing.

Full Compliance. As a resolution of the charges in Accusation No. 7060, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Nonresident Pharmacy Permit No. NRP 928 and Nonresident Sterile Compounding Pharmacy Permit No. NSC 99521.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it will have on my Non-Resident Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 15-Nov-2021

INFUSERVE AMERICA INC.;
DAVID KAZARIAN, PRESIDENT
Respondent

I have read and fully discussed with Respondent Infuserve America Inc.; David Kazarian, President the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 11/15/2021

HERBERT L. WEINBERG
Attorney for Respondent

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 11/15/2021

Respectfully submitted,

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General

KRISTINA T. JARVIS
Deputy Attorney General
Attorneys for Complainant

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General

KRISTINA T. JARVIS
Deputy Attorney General
Attorneys for Complainant

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35660642.docx

Exhibit A

Accusation No. 7060

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Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **INFUSERVE AMERICA INC.; DAVID KAZARIAN, PRESIDENT/TREASURER/CHIEF FINANCIAL OFFICER/PHARMACIST IN CHARGE JOHN GRISE, VICE-PRESIDENT/SECRETARY 11880 28th Street, North, Suite 200 Saint Petersburg, FL 33716-1006** **Nonresident Pharmacy Permit No. NRP 928 Nonresident Sterile Compounding Pharmacy Permit No. NSC 99521** Respondent.	Case No. 7060 **ACCUSATION**

PARTIES

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

2. On or about November 19, 2008, the Board of Pharmacy issued Nonresident Pharmacy Permit Number NRP 928 and Nonresident Sterile Compounding Pharmacy Permit Number NSC 99521 to Infuserve America Inc.; David Kazarian, President, Treasurer/Chief Financial Officer, and Pharmacist In Charge, and John Grise, Vice President and Secretary

(Respondent). The Nonresident Pharmacy Permit and the Nonresident Sterile Compounding Pharmacy Permit were in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2021, unless renewed.

JURISDICTION

3. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 4300 of the Code 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 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.

5. Section 4300.1 of the Code states:

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

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STATUTORY PROVISIONS

6. Section 4301 of the Code states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

…

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

…

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

7. 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.

8. 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.

9. Section 4169, subdivision (a) of the Code 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.

UNITED STATES CODE

10. Title 21 of the United States Codes (U.S.C.), Section 353a, subdivision (b), which states in pertinent part,

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

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

…

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

…

HEALTH AND SAFETY CODE SECTIONS

11. Health and Safety Code section 111250 states:

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

12. Health and Safety Code section 111295 states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

13. Health and Safety Code section 111330 states:

Any drug or device is misbranded if its labeling is false or misleading in any particular.

14. Health and Safety Code section 111445 states:

It is unlawful for any person to misbrand any drug or device.

REGULATORY PROVISIONS

15. California Code of Regulations, Title 16, (Regulations) section 1735.1, subdivision (ae), states:

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

16. Regulations section 1735.2, subdivision (g), states:

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.

17. Regulations section 1735.3, subdivision (c), states:

Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA-registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals,

bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

18. Regulations section 1735.4, subdivision (a), states, in pertinent part:

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…

COST RECOVERY

19. 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.

DRUG DESCRIPTION

20. 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.

21. Sodium ascorbate is ascorbic acid combined with sodium. Sodium ascorbate is a dangerous drug pursuant to Code section 4022. Injectable forms of sodium ascorbate are not FDA approved to treat any disease or disorder.

22. Dexapanthenol is an alcohol derivative of panthothenic acid, a component of the B complex vitamins and an essential component of normal skin. Dexapanthenol is generally used as a topical cream. Dexapanthenol is a dangerous drug pursuant to Code section 4022. Injectable forms of Dexapanthenol are not FDA approved to treat any disease or disorder.

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23. Glutathione is a substance made from amino acids, and is produced naturally by the liver. Glutathione is generally consumed as a pill or tablet. Glutathione is a dangerous drug pursuant to Code section 4022. Injectable forms of Glutathione are not FDA approved to treat any disease or disorder.

24. Methylcobalamin (methyl vitamin B12) is the synthetic and active form of cobalamin (vitamin B12) that helps in synthesis of methionine and S-adenosylmethionine. Methylcobalamin is required for integrity of myelin, neuronal function, proper red blood cell formation and DNA synthesis. Cobalamin is an essential nutrient which is not synthesized in humans and therefore must be obtained by dietary intake or supplementation. Cobalamin is created by bacteria and can only be found naturally in animal products; however, synthetic forms are widely available as dietary supplements and added to many foods such as packaged cereals.

Cobalamin can be converted by the liver to methylcobalamin, unless an individual has methenyltetrahydrofolate synthetase deficiency disorder. Methenyltetrahydrofolate synthetase deficiency is a rare neurodevelopmental disorder caused by mutations affecting the MTHFR gene and is generally diagnosed at birth or early infancy.

Cyanocobalamin is the only FDA approved commercially available injectable drug product indicated to treat deficiencies in inadequate absorption such as pernicious anemia.

Injectable Methylcobalamin is not FDA approved product to treat any disease or disorder.

There are many nonprescription oral dietary supplements with either cyanocobalamin or methylcobalamin meant to alleviate insufficient dietary intake.

GENERAL BACKGROUND INFORMATION

25. A dietary supplement is defined in 21 U.S. Code section 321, subdivision (ff). In pertinent part, a dietary supplement is a product that is intended to supplement the diet and includes vitamins, minerals, herbs or other botanicals, and amino acids. A dietary supplement is intended for ingestion and does not include products that are intended for injection either via intramuscular (IM), intravenous (IV), or subcutaneous routes.

26. Vitamins and minerals are defined in 21 U.S. Code section 350, which states, in pertinent part, that vitamins and minerals are a food for humans for special dietary use which is or

contains any natural or synthetic vitamin or mineral, and is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form.

27. In September 2018, the FDA released a draft guidance which included an example of an insanitary condition that could cause a drug to become contaminated and therefore legally be considered to be adulterated. That example was the use of ingredients that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents.

AUGUST 24, 2020, INVESTIGATION REPORT – BACKGROUND INFORMATION

28. On or about March 15, 2019, the Board received a complaint alleging Respondent was compounding an ascorbic acid product, which is a copy of a commercially available ascorbic acid injectable product.

29. Board Inspectors E.F. and C.A. conducted an investigation into this allegation.

30. Inspectors E.F. and C.A. determined that the source of raw materials being used by Respondents was a food grade active pharmaceutical ingredient (API). However, Respondents used this food grade API to compound a sterile injectable product.

31. Additionally, Respondents admitted to compounding with "Ascorbic Acid Powder" and records show Respondent used ascorbic acid USP (United States Pharmacopeia). Yet Respondent labeled the preparation "Sodium Ascorbate" but it was not "Sodium Ascorbate."

FIRST CAUSE FOR DISCIPLINE

(Misbranding Compounded Sterile Drug Preparations)

32. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), in that Respondent has violated statutes regulating dangerous drugs. The circumstances are that from approximately February 1, 2019, to March 30, 2019, Respondent violated Health and Safety Code sections 111330 and 111445 by compounding ascorbic acid but labeling the product as "Sodium Ascorbate 500 mg/ml."

SECOND CAUSE FOR DISCIPLINE

(Failing to Maintain Quality of Compounded Sterile Preparations)

33. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent has violated regulations governing the

practice of pharmacy. The circumstances are that from approximately February 1, 2019, to March 30, 2019, Respondent violated Regulations sections 1735.1, subdivision (ae), and 1735.2, subdivision (g), by compounding ascorbic acid with dietary grade materials for a sterile injectable drug product.

THIRD CAUSE FOR DISCIPLINE

(Adulterated Preparations)

34. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (j), in that Respondent has violated statutes regulating dangerous drugs. The circumstances are that Respondent violated Code section 4169, subdivision (a)(2), and Health and Safety Code sections 11250 and 11295 from approximately February 1, 2019, to March 30, 2019, by compounding ascorbic acid for injection using ungraded or dietary grade materials.

FOURTH CAUSE FOR DISCIPLINE

(Incorrectly Labeled Compounded Sterile Preparations)

35. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), in that Respondent has violated regulations governing the practice of pharmacy. The circumstances are that from approximately February 1, 2019, to March 30, 2019, Respondent violated Regulations section 1735.4, subdivision (a), by failing to provide the correct name of a drug preparation on the label. Respondent compounded with an ascorbic acid powder but labeled the drug preparation as "Sodium Ascorbate 500 mg/ml."

FEBRUARY 10, 2021, INVESTIGATION REPORT – BACKGROUND INFORMATION

36. On or about August 18, 2020, Board Inspector J.L. began a remote annual sterile compounding renewal inspection for Respondent's Nonresident Sterile Compounding Pharmacy Permit.

37. Inspector J.L. focused on a time period from May 18, 2020 through September 16, 2020, thereby avoiding overlap with the prior investigation; however, similar violations were found.

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FIFTH CAUSE FOR DISCIPLINE

(Failing to Maintain Quality of Compounded Sterile Preparations)

38. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent has violated regulations governing the practice of pharmacy. The circumstances are that from approximately May 28, 2020, to September 16, 2020, Respondent violated Regulations sections 1735.1, subdivision (ae), and 1735.2, subdivision (g), by compounding and selling Dexparthenol[1], Glutathione[2], Methylcobalamin[3], Sodium Ascorbate[4], and a Vitamin Syringe[5] into the State of California, all of which lacked quality.

SIXTH CAUSE FOR DISCIPLINE

(Adulterated Preparations)

39. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (j), in that Respondent has violated statutes regulating dangerous drugs. The circumstances are that Respondent violated Code section 4169, subdivision (a)(2), and Health and Safety Code sections 11250 and 11295 from approximately May 28, 2020 to September 16, 2020, by compounding and selling into California the following drug products with dietary, ungraded and excipient graded raw materials: dexpanthenol, glutathione, methylcobalamin, sodium ascorbate, and a vitamin syringe with the same lot numbers set forth in paragraph 37.

SEVENTH CAUSE FOR DISCIPLINE

(Failing to Report to the Board)

40. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), in that Respondent violated Code section 4127.2, subdivisions (e) and (f), by failing to report to the Board any complaint received from a provider, pharmacy, or patient in California, or to report adverse effects reported to the Respondent or potentially attributable to

[1] Lot numbers: 28May2020-006CA, 05Aug2020-007CA.
[2] Lot numbers: 11Aug2020-006, 12Aug2020-004CA, 18May2020-018CA
[3] ~~Lot numbers: 06Jul~~2020-003, 08Jul2020-009, 03Aug2020-003, 05Aug2020-009, 16Sep2020-006.
[4] Lot numbers: 06Jul2020-005, 08Jul2020-007, 03Aug2020-001, 05Aug2020-004, 16Sep2020-009.
[5] Lot number RX100 1037607

their sterile compounded drug product. The circumstances are that on or about May 18, 2020, Respondent received a complaint from California physician E.L. stating patient D.A. had suffered burning when administered glutathione on May 18, 2020. Respondent failed to report this adverse reaction to the Board or to the FDA's MedWatch program.

EIGHTH CAUSE FOR DISCIPLINE

(Failing to Obtain Ingredients from an FDA Registered Supplier)

41. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), in that Respondent violated Regulations section 1735.3, subdivision (c), and 21 U.S.C. section 353a, subdivision (b)(1)(A)(ii), by obtaining dexpanthenol and ascorbic acid from suppliers Hangzhou Xinfu Science and Technology (HXST) and United Foods, which are not suppliers registered with the FDA.

OTHER MATTERS

42. Pursuant to section 4307 of the Code, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 928 or on Nonresident Sterile Compounding Pharmacy Permit Number NSC 99521 issued to Infuserve America Inc.; David Kazarian, President, Treasurer/Chief Financial Officer, and Pharmacist In Charge, and John Grise, Vice President and Secretary, then Infuserve America Inc.; David Kazarian, President, Treasurer/Chief Financial Officer, and Pharmacist In Charge, and John Grise, Vice President and Secretary, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five (5) years if either or both of the pharmacy permits are placed on probation; or, 2) if either or both of the pharmacy permits are revoked, the prohibition shall continue until either of the permits are reinstated.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Nonresident Pharmacy Permit Number NRP 928, issued to Infuserve America Inc.; David Kazarian, President, Treasurer/Chief Financial Officer, and Pharmacist In Charge, and John Grise, Vice President and Secretary;

2. Revoking or suspending Nonresident Sterile Compounding Pharmacy Permit Number NSC 99521, issued to Infuserve America Inc.; David Kazarian, President, Treasurer/Chief Financial Officer, and Pharmacist In Charge, and John Grise, Vice President and Secretary;

3. Prohibiting Infuserve America Inc. from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

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

5. Prohibiting John Grise 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. Ordering Infuserve America Inc. 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,

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

DATED: 6/2/2021

Signature on File

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

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