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

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| In the Matter of the Accusation Against**:**<br><br>**NORTH AMERICAN CUSTOM LABORATORIES DBA FARMAKEIO**<br>**DANIEL DENEUI, CEO**<br>**JUSTIN GRAVES, VICE PRES.**<br>**MICHAEL COLE, TREAS.**<br>**CODY BOATMAN, MEMBER**<br>**ROBERT HARRIS, MEMBER**<br>**1736 N. Greenville Ave.**<br>**Richardson, TX 75081**<br><br>**Nonresident Pharmacy Permit No. NRP 2285**<br><br>Respondent. | Case No. 7870<br><br>**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 March 13, 2020, the Board of Pharmacy (Board) issued Nonresident Pharmacy Permit Number NRP 2285 to North American Custom Laboratories doing business as

(dba) Farmakeio, (Respondent Farmakeio). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2025, unless renewed.

## JURISDICTION

3. 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.

4. Section 118 of the Code states:

> (a) The withdrawal of an application for a license after it has been filed with a board in the department shall not, unless the board has consented in writing to such withdrawal, deprive the board of its authority to institute or continue a proceeding against the applicant for the denial of the license upon any ground provided by law or to enter an order denying the license upon any such ground.
>
> (b) The suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.
>
> (c) As used in this section, "board" includes an individual who is authorized by any provision of this code to issue, suspend, or revoke a license, and "license" includes "certificate," "registration," and "permit."

5. Section 4011 of the Code 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 & Saf. Code §§ 11000, *et seq*.]

6. Section 4300 of the Code states, in pertinent part:

> (a) Every license 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 . . .

7. Section 4300.1 of the Code states:

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

8. Section 4301 of the Codes states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct includes, but it 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.

. . . .

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

. . . .

9. 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.

10. Section 4129 of the Code states, in pertinent part:

(a) A facility registered as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California.

. . . .

**STATUTORY PROVISIONS**

11. Section 4022 of the Code states:

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

(a) Any drug that bears the legend: Caution: federal law prohibits dispensing without prescription, Rx only, or words of similar import.

(b) Any device that bears the statement: Caution: federal law restricts this device to sale by or on the order of a _____, Rx only, or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

12. Section 4129.2 of the Code states, in pertinent part:

(a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) as an outsourcing facility and has an address outside of the state but in the United States of America is a nonresident outsourcing facility. A

nonresident outsourcing facility shall not compound sterile drug products or nonsterile drug products for distribution or use into this state without an outsourcing license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferrable.

. . . .

13. Section 4169 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 11250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

. . . .

14. Section 4207 of the Code states:

(a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board mya request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

15. Section 111250 of the Health & Safety Code states that any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

16. Section 111255 of the Health and Safety Code states that any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

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17. Section 111295 of the Health & Safety Code states that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

18. Section 111550 of the Health & Safety Code states:

> No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:
>
> (a) It is one of the following:
>
> (1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).
>
> (2) A new biologic product for which a license has been issued as required by the federal Public Health Service Act (42 U.S.C. Sec. 262).
>
> (3) A device that is reported under Section 510(k) of the federal act (21 U.S.C. Sec. 360(k)), or is a device exempted pursuant to subsection (l) or (m) of Section 360 of Title 21 of the United States Code, or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under Section 515 of the federal act (21 U.S.C. Sec. 360e).
>
> (b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended. Any person who files a new drug or device application with the department shall submit, as part of the application, all of the following information
>
> (1)Full reports of investigations that have been made to show whether or not the new drug or device is safe for use and whether the new drug or device is effective in use under the conditions prescribed, recommended, or suggested in the labeling or advertising of the new drug or device.
>
> (2) A full list of the articles used as components of the new drug or device.
>
> (3) A full statement of the composition of the new drug or device.
>
> (4) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new drug, or in the case of a new device, a full statement of its composition, properties, and construction, and the principles of its operation.
>
> (5) Samples of the new drug or device and of the articles used as components of the drug or device as the department may require.
>
> (6) Specimens of the labeling and advertisements proposed to be used for the new drug or device.

19. Title 21 of the United States Code (21 U.S.C.) section 353a states, in pertinent part:

> . . . .

(b) Compounded drug

(1) Licensed pharmacist and licensed physician

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

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

(i) that –

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

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

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

. . . .

**COST RECOVERY**

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

**FACTUAL ALLEGATIONS**

21. On or about April 15, 2020, the Board received a nonresident sterile compounding license application for Respondent Farmakeio, but due to the ongoing Covid-19 pandemic, an onsite inspection of the pharmacy and related compounding spaces was postponed.

22. On or about March 28, 2022, Board inspector M.V. contacted Respondent Farmakeio's vice president J.G., who was also the Pharmacist-in-Charge (PIC), according to Board records, and requested pre-inspection documents to complete an onsite inspection of the pharmacy and compounding spaces for the non-resident sterile compounding license.

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23. Concurrently, on or about March 30, 2022, the Food and Drug Administration (FDA) released a MedWatch Alert on sterile products compounded by Farmakeio Superior Custom Compounding. The Board initiated an investigation of this alert.

24. On or about April 1, 2022, M.V. emailed J.G. and requested an unredacted copy of the FDA Form 483 that had prompted the FDA MedWatch. J.G. stated that he was working on a state board memo that would be provided "shortly."

25. On or about April 4, 2022, M.V, received a copy of Respondent Farmakeio's "Memo to the State Board of Pharmacies," which included several inaccessible document hyperlinks to documents submitted to the FDA as part of Respondent Farmakeio's official responses to the FDA Form 483.

26. On or about April 5, 2022, M.V. received the pre-inspection documents that had been requested from Respondent Farmakeio on March 28, 2022, related to the application for a nonresident compounding license. The pre-inspection documents included a list of compounded sterile preparations (CSP's) made at Farmakeio, which was relevant to the Board's investigation regarding the FDA MedWatch Alert.

27. The next day, on or about April 6, 2022, in response to the request for information related to the FDA MedWatch Alert, J.G. emailed M.V. and Supervising Board inspector C.A. a hyperlink with the following documents: Respondent Farmakeio's FDA Form 483, the cover letter to FDA, the FDA Form 483 responses, the signed HHE worksheet, the signed HHE worksheet Committee Review, and a Pall AcroPak brochure. In its responses to the FDA Form 483, Respondent Farmakeio identified a non-pharmaceutical grade filter, Pall Acropak 20 for sterile filtration of injectable solutions, specifically the Pall Acropak 20 with 0.8/0.2-micron Supor filter. After receiving this information, M.V. requested that J.G. provide a list of all prescriptions shipped to California by Respondent Farmakeio from April 1, 2020, to April 1, 2022, and for one copy of an executed compounding log for each sterile injectable preparation compounded at Farmakeio.

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28. On or about April 13, 2022, J.G. provided the first California dispensing report showing all prescriptions dispensed to California between April 1, 2020, to April 1, 2022, which showed no compounded sterile preparations had been shipped to California.

29. On or about April 14, 2022, J.G. told M.V. that Respondent Farmakeio did not compound any sterile injectables that could be shipped to California, and on April 19, 2022, M.V. received copies of unexecuted compounding logs for five injectables. Upon review, Board investigators discovered those logs were not in full compliance with regulations and the injectables could not be shipped to California.

30. On or about April 20, 2022, M.V. and C.A. had a virtual meeting with J.G. to discuss the requirements for assigning extended beyond-use dates to compounded sterile preparations including method suitability studies, container closure integrity testing, stability-indicating stability studies, and the use of peptides for compounding. C.A. also told J.G. that the five preparations for which compounding logs had been provided were not in full compliance with regulations and could not be shipped to California. And, M.V. told J.G. that non-sterile compounded oral preparations using peptide bulk drug substances could not be shipped to California because they failed to comply with Section 503a of the FDCA.

31. On or about April 21, 2022, J.G. told M.V. that he was no longer the PIC of Respondent Farmakeio as of November 2021, despite the fact that it was J.G. who had been in contact with M.V. since August 2020, and M.V. had always referred to him as PIC without being corrected by J.G. of his status.

32. On or about April 25, 2022, Board investigators M.V. and C.A. had a follow-up meeting with J.G. and PIC A.B. in which they discussed Respondent Farmakeio's sterile compounding license application and onsite inspection. J.G. said that Respondent Farmakeio's application was on hold, and that an onsite inspection was therefore unnecessary. At that meeting, C.A. told J.G. and PIC A.B. that the Board was investigating the possibility that compounded sterile preparations made at Respondent Farmakeio had been shipped into California.

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33. On or about May 10, 2022, M.V. requested the additional documents from Respondent Farmakeio, including complete patient profiles (from April 1, 2020), a copy of the prescriptions, the dispensing history, and shipping information for three patients, FF, JS, and EC, and individual reports showing all prescriptions ordered and dispensed between April 1, 2020, to May 10, 2022, by providers WC (DO), AL (FNP), JH (NP), and TT (DO).

34. On or about May 12, 2022, J.G. provided a response that stated that Respondent Farmakeio did not ship sterile injectables into California, and that none of the requested prescriptions had been shipped to California. J.G. stated that the FF prescriptions had been shipped directly to Texas, the JS prescription had been shipped directly to the patient's home in Texas, and the EC prescriptions had been shipped directly to Illinois. J.G. did not provide the requested additional documents.

35. On or about May 23, 2022, M.V. sent a follow up email to PIC A.B. and J.G. again requesting the documents requested on May 10, 2022. M.V. also requested the shipping records mentioned by J.G. in order to validate Respondent Farmakeio's response. A third email was sent to PIC A.B. and J.G. requesting the additional documents on June 1, 2022. No response was received.

36. On or about June 6, 2022, Board investigator C.A. again requested the additional documents from Respondent Farmakeio along with complete patient profiles showing all prescriptions ordered and dispensed for 23 patients; copies of prescription hardcopies and labels for 29 patients; provider profiles for any-and-all prescriptions ordered and shipped to California for 22 providers; the California license number for Dr. KN; and any information showing a doctor/patient relationship between Dr. KN and patients UN and VN.

37. On June 17 and 20, 2022, M.V. received records from Respondent Farmakeio including FedEx confirmations for patient FF, EC, and JS, prescription hardcopies and labels for 29 prescription records, provider profiles for 22 providers, and patient profiles showing dispenses from April 1, 2020, to June 1, 2020, for 23 patients. The patient profiles were incomplete, including missing prescription orders.

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38. On or about June 28, 2022, M.V. emailed PIC A.B. requesting clarification of the inconsistencies found on the recent documents compared to both the original California dispensing report received from Respondent Farmakeio on April 13, 2022, and the FDA six-month log. Certain prescriptions ordered for California patients did not show up on the provided patient profiles, and compounded sterile preparations were found on the FDA six-month report that had been shipped to California. Also, in the provider profiles, Dr. DY's provider profile showed 19 prescriptions had been shipped to California from April 1, 2020, to April 1, 2022, but the California dispensing report previously provided only showed one prescription had been shipped to California by Dr. DY. Therefore, M.V. again requested that PIC A.B. provide complete unredacted copies of the patient profiles, provider reports showing any-and-all prescriptions ordered and shipped to California for the 22 providers noted, and any-and-all prescriptions shipped to California from April 1, 2020, to June 28, 2022. M.V. also requested acquisition records, copies of prescription orders, and shipping records for seven pellet orders that were shipped to California.

39. On July 1 and 12, 2022, Respondent Farmakeio provided M.V. with an updated California dispensing log from April 1, 2020, to June 6, 2022, along with copies for prescription orders and shipping records for 8 prescriptions, and Texas licensing information for Dr. GC and Dr. KN. Respondent Farmakeio also provided clarifications, additional responses, and explanations for questions M.V. requested on June 28, 2022.

40. On or about November 18, 2022, the FDA issued a warning letter to Respondent Farmakeio.

41. For her Board investigation, M.V. reviewed FedEx confirmation records of all preparations that were sent to clinics or medical offices. There were inconsistencies between statements made by J.G. and the records, including the location of where prescriptions had been sent. Also, FedEx confirmation records showed two additional prescriptions were found that did not appear on the initial California dispensing log sent by Respondent Farmakeio for April 1, 2020, to April 1, 2022.

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42. In M.V.'s review of 27 of the 29 prescription hardcopies and labels (including information sent from the FDA), she found that the intended shipping address for all except four prescriptions were to California addresses. Further investigation showed that from at least October 14, 2020, to at least April 6, 2022, Respondent Farmakeio compounded and furnished at least eight adulterated compounding drug preparations:

| Rx Number | Patient | Drug Name | Date Filled |
|---|---|---|---|
| 582142 | HP | Selank Acetate 7.5 mg/ml nasal spray | 10/14/2020 |
| 586383 | MSz | Semax Acetate 7.5 mg/ml nasal spray | 11/18/2020 |
| 592246 | WD | BPC-157 Acetate 500 mg capsules | 1/7/2021 |
| 593338 | JHu | MK-677 (Ibutamoren Mesylate) 25 mg capsules | 1/14/2021 |
| 607303 | CD | 5-Amino-1MQ 50 mg capsules | 4/26/2021 |
| 636937 | HY | LGD-4033 5 mg capsules | 11/2/2021 |
| 643901 | SB | 5-Amino-1MQ 50 mg capsules | 12/16/2021 |
| 654705 | RMu | LGD-4033 0.5 mg capsules | 2/25/2022 |
| 661977 | JBe | BPC-157 Acetate 500 mcg capsules | 4/1/2022 |
| 645943 | CGi | Selank Acetate 7.5 mg/ml nasal spray | 4/6/2022 |

43. M.V. also reviewed the 22 provider profiles received and compared them to the prescriptions shipped to California from April 1, 2020, to April 1, 2022, and the two California dispensing reports. Four of the provider profiles did not match the two California dispensing reports. At least 22 pellets that had been shipped to California and noted on the provider profiles were not found on the first California dispensing report provided to Board investigators.

44. In her review of California-provider licensing information, M.V. discovered that GC's NP license was delinquent, Dr. KN MD license was canceled, and Dr. ST's MD license was surrendered.[1]

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[1] Those providers did have an active Texas license and were prescribing medications for California patients.

45. M.V. compared twenty-three patient profiles with both California dispensing reports received and the provider profiles, and specifically found that:

a. For patient MJ, at least two prescriptions were dispensed for this patient, but only one was found on the patient profile. The comment "not shipped to California" was found under the "drug name" column instead of the actual drug name (Testosterone/Triamcinolone 100/20mcg pellet). When asked, Respondent Farmakeio said that its records did not show that those two prescriptions were dispensed to MJ, nor were those prescriptions shipped to California.

b. For Patient EC, only one prescription appeared on the patient profile (Ivermectin) when it had been previously established that two other prescriptions were prescribed to EC, neither of which appeared on EC's patient profile as "not shipped to California." M.V. determined that if the initial California dispensing report was generated based on patients with a California address, both missing prescriptions should have been on the first California dispensing report and were not.

46. M.V. compared both California dispensing reports for the period between April 1, 2020, to April 1, 2022. She found the following differences noted on the second California dispensing report (received July 1, 2022) that were not on the first California dispensing report (received April 13, 2022):

a. 20 prescriptions for pellets for fifteen patients ordered by RC, NP

b. 7 prescriptions for pellets for four patients ordered by AD, MD

c. 4 prescriptions for pellets for two patients ordered by JH, NP

d. 1 prescription for an injectable solution (Lidocaine/Epinephrine) for one patient ordered by KS, MD

e. 12 prescriptions for pellets for four patients ordered by VT, MD

f. 29 prescriptions for pellets for eight patients ordered by DW

g. 18 prescriptions for pellets for five patients ordered by DY, MD

47. An email sent by Respondent Farmakeio on July 1, 2022, stated that the original California dispensing report was generated based on patients who had a California address, while

the second California dispensing report was based on orders shipped to California. M.V.'s request had been for all prescriptions shipped to California. The first California dispensing report should have shown most or all of the prescriptions on the FDA six-month log, but it did not.

48. Regarding the prescriptions and shipping records for pellets and testosterone injectable, Respondent Farmakeio provided five prescription hardcopies and four shipping records for testosterone/triamcinolone and estradiol pellets. One prescription hardcopy and shipping record for a testosterone 200 mg/ml injectable was provided. The shipping records for the pellets shows the pellets were delivered to the providers' offices in California. The shipping record for the testosterone injectable solution showed that the prescription was delivered to San Diego, California, but the full delivery address was missing. No acquisition records were provided for the pellets or the injectable solution.

49. Respondent Farmakeio also owns and manages an outsourcing facility "Farmakeio Outsourcing" that is not licensed by the Board, and therefore cannot compound drugs for California patients. Farmakeio Outsourcing manufactures testosterone, testosterone/triamcinolone, and estradiol pellets. Respondent Farmakeio had sent an email on July 12, 2022, which stated that none of the pellets shipped to California were compounded by Farmakeio Custom Compounding Pharmacy. Likewise the email stated that the one injectable testosterone solution prescription was also not compounded at Farmakeio Custom Compounding Pharmacy.

50. Board inspectors determined, after an extensive review of all documentation, that Respondent Farmakeio was not compliant with the Federal Food, Drug, and Cosmetic Act, and had sold its adulterated drugs via interstate commerce, a violation of pharmacy law.

**FIRST CAUSE FOR DISCIPLINE**

**(Subverting or Attempting to Subvert an Investigation)**

51. Respondent Farmakeio is subject to disciplinary action under Code section 4301, subdivision (q), for violating Code section 4207, subdivision (d), in that it failed to supply records as requested an/or supplied incomplete or edited records that were to be used for the purposes of

investigating unlicensed activity, as more particularly set forth in paragraphs 24-27, 28-39, 41-43, and 45-49 above, and incorporated herein by reference.

**SECOND CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct - Shipping Pellets to California)**

52. Respondent is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), in that Respondent Farmakeio shipped approximately 92 prescriptions for compounded or manufactured hormonal pellets to California that were obtained from their outsourcing facility Farmakeio Outsourcing LLC, which is not licensed in California, as more particularly set forth in paragraphs 26, 28, 32, 37-39, 41-43, and 45-49 above, and incorporated herein by reference.

**THIRD CAUSE FOR DISCIPLINE**

**(Adulterated Preparations)**

53. Respondent Farmakeio is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) for violating Health and Safety Code sections 111250, and 111295, as related to Code section 4169, subdivision (a), in that from at least October 14, 2020, to at least April 6, 2022, Respondent Farmakeio compounded and furnished at least ten compounded drug preparations, which were adulterated, as more specifically set for the paragraphs 23-30, and 32-50 above, and incorporated here by reference.

**FOURTH CAUSE FOR DISCIPLINE**

**(Use of a Non-Compliant Bulk Drug Substance)**

54. Respondent Farmakeio is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) for violating Health and Safety Code section 111550, as related to 21 U.S. Code section 353a, subdivision (b)(1)(A)(i), in that from October 14, 2020, to at least April 6, 2022, at least ten compounding drug preparations were not compounded within the allowance of Section 503A of the Federal Food, Drug, and Cosmetic Act and were not a new drug approved by the Food and Drug Administration, as more specifically set for the paragraphs 21-50 above, and incorporated here by reference.

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## OTHER MATTERS

55. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit No. NRP 2285 issued to North American Custom Laboratories dba Farmakeio, it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy Permit No. NRP 2285 is placed on probation or until Nonresident Pharmacy Permit No. NRP 2285 is reinstated if it is revoked.

56. Pursuant to Code section 4307, is discipline is imposed on Nonresident Pharmacy Permit No. NRP 2285 issued to North American Custom Laboratories dba Farmakeio while Justin Graves, Daniel Deneui, Michal Cole, Cody Boatman, or Robert Harris has been a member, shareholder, officer, director, or manager and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Justin Graves, Daniel Deneui, Michal Cole, Cody Boatman, or Robert Harris shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy Permit No. NRP 2285 is placed on probation or until Nonresident Pharmacy Permit No. NRP 2285 is reinstated if it is revoked.

## 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 2285, issued to North American Custom Laboratories dba Farmakeio;

2. Prohibiting Chief Executive Officer Daniel Deneui from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy Permit Number NRP 2285 is placed on probation or until Nonresident Pharmacy Permit Number NRP 2285 is reinstated if Nonresident Pharmacy Permit Number NRP 2285 issued to North American Custom Laboratories dba Farmakeio is revoked;

3. Prohibiting Treasurer Michael Cole from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy Permit Number NRP 2285 is placed on probation or until Nonresident Pharmacy

Permit Number NRP 2285 is reinstated if Nonresident Pharmacy Permit Number NRP 2285 issued to North American Custom Laboratories dba Farmakeio is revoked;

4. Prohibiting Member Cody Boatman from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy Permit Number NRP 2285 is placed on probation or until Nonresident Pharmacy Permit Number NRP 2285 is reinstated if Nonresident Pharmacy Permit Number NRP 2285 issued to North American Custom Laboratories dba Farmakeio is revoked;

5. Prohibiting Member Robert Harris from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy Permit Number NRP 2285 is placed on probation or until Nonresident Pharmacy Permit Number NRP 2285 is reinstated if Nonresident Pharmacy Permit Number NRP 2285 issued to North American Custom Laboratories dba Farmakeio is revoked;

6. Prohibiting Vice President Justin Graves from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy Permit Number NRP 2285 is placed on probation or until Nonresident Pharmacy Permit Number NRP 2285 is reinstated if Nonresident Pharmacy Permit Number NRP 2285 issued to North American Custom Laboratories dba Farmakeio is revoked;

7. Ordering North American Custom Laboratories dba Farmakeio to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and, if placed on probation, the costs of probation monitoring; and,

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

DATED: 10/17/2024

Sodergren, Anne@DCA Digitally signed by Sodergren, Anne@DCA Date: 2024.10.17 05:55:55 -07'00'

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

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