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

In the Matter of the Accusation Against:

TAILORMADE COMPOUNDING LLC;
JEREMY STEVEN DELK, CEO,
Nonresident Pharmacy Permit No. NRP 1885
Nonresident Sterile Compounding Permit No. NSC 101012

Respondent.

Agency Case No. 7091

DECISION AND ORDER

The attached Stipulated Surrender of License Order 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 March 9, 2022.

It is so ORDERED on February 7, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Seung W. Oh, Pharm.D.
Board President

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

In the Matter of the Accusation Against**:** **TAILORMADE COMPOUNDING LLC; JEREMY STEVEN DELK, CEO** **200 Moore Drive** **Nicholasville, KY 40356** **Nonresident Pharmacy Permit No. NRP 1885** **Nonresident Sterile Compounding Permit No. NSC 101012** Respondent.	Case No. 7091 **STIPULATED SURRENDER OF LICENSE AND ORDER**

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 Joshua B. Eisenberg, Deputy Attorney General.

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2. Tailormade Compounding LLC; Jeremy Steven Delk, CEO (Respondent) is representing itself in this proceeding and has chosen not to exercise its right to be represented by counsel.

3. On or about April 6, 2017, the Board issued Nonresident Pharmacy Permit Number NRP 1885 to Tailormade Compounding LLC; with Jeremey Steven Delk as its Chief Executive Officer and 100% shareholder (Respondent). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 7091 and was cancelled on March 3, 2021.

4. On or about July 10, 2018, the Board issued Nonresident Sterile Compounding Permit No. NSC 101012 to Tailormade Compounding LLC; with Jeremey Steven Delk as its Chief Executive Officer and 100% shareholder (Respondent). The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 7091 and was cancelled on March 3, 2021.

JURISDICTION

5. Accusation No. 7091 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on November 18, 2021. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 7091 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, and understands the charges and allegations in Accusation No. 7091. Respondent also has carefully read, and understands the effects of this Stipulated Surrender of License and Order.

7. 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 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 court

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

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

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 7091, if proven at hearing, constitute cause for imposing discipline upon its Nonresident Pharmacy Permit Number NRP 1885 and Nonresident Sterile Compounding Permit Number NSC 101012.

10. 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 those charges constitute cause for discipline. Respondent hereby gives up its right to contest that cause for discipline exists based on those charges.

11. Respondent understands that by signing this stipulation, it enables the Board to issue an order accepting the surrender of its Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit without further process.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board. Respondent understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and surrender, 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 Surrender and Disciplinary Order 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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13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of License and Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

14. This Stipulated Surrender of License and Order 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 Surrender of License and Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. 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 Order:

ORDER

IT IS HEREBY ORDERED that Nonresident Pharmacy Permit Number NRP 1885 and Nonresident Sterile Compounding Permit Number NSC 101012 issued to Respondent Tailormade Compounding LLC; Jeremy Steven Delk, CEO, are surrendered and accepted by the Board. Respondent(s) understand and acknowledge that for purposes of Business and Professions Code section 4307, this stipulated surrender is the same as a revocation.

1. The surrender of Respondent's Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit and the acceptance of the surrendered licenses by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

2. Respondent shall lose all rights and privileges as a Nonresident Pharmacy and Nonresident Sterile Compounding permit holder in California as of the effective date of the Board's Decision and Order.

3. Respondent shall cause to be delivered to the Board its pocket licenses and, if issued, its wall certificates on or before the effective date of the Decision and Order.

4. If Respondent ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply

with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Accusation No. 7091 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.

5. Respondent shall pay the agency its costs of investigation and enforcement in the amount of $24,409.50 prior to issuance of a new or reinstated license.

6. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation, No. 7091 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

7. Respondent shall not apply for licensure or petition for reinstatement for three (3) years from the effective date of the Board's Decision and Order.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order. I understand the stipulation and the effect it will have on my Nonresident Pharmacy Permit, and Nonresident Sterile Compounding Permit. I am authorized to enter into this Stipulated Settlement on behalf of Tailormade Compounding LLC. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

_____
TAILORMADE COMPOUNDING LLC;
JEREMY STEVEN DELK, CEO
Respondent

with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Accusation No. 7091 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.

5. Respondent shall pay the agency its costs of investigation and enforcement in the amount of $24,409.50 prior to issuance of a new or reinstated license.

6. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation, No. 7091 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

7. Respondent shall not apply for licensure or petition for reinstatement for three (3) years from the effective date of the Board's Decision and Order.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order. I understand the stipulation and the effect it will have on my Nonresident Pharmacy Permit, and Nonresident Sterile Compounding Permit. I am authorized to enter into this Stipulated Settlement on behalf of Tailormade Compounding LLC. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12/28/21

TAILORMADE COMPOUNDING LLC;
JEREMY STEVEN DELK, CEO
Respondent

ENDORSEMENT

The foregoing Stipulated Surrender of License and Order 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
KAREN R. DENVIR
Supervising Deputy Attorney General

JOSHUA B. EISENBERG
Deputy Attorney General
Attorneys for Complainant

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ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 12/28/21

Respectfully submitted,

ROB BONTA
Attorney General of California
KAREN R. DENVIR
Supervising Deputy Attorney General

JOSHUA B. EISENBERG
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 7091

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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**:** **TAILORMADE COMPOUNDING LLC; JEREMY STEVEN DELK, CEO** **200 Moore Drive** **Nicholasville, KY 40356** **Nonresident Pharmacy Permit No. NRP 1885** **Nonresident Sterile Compounding Permit No. NSC 101012** Respondent.	Case No. 7091 **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.

Nonresident Pharmacy Permit

2. On or about April 6, 2017, the Board of Pharmacy issued Nonresident Pharmacy Permit Number NRP 1885 to Tailormade Compounding LLC; with Jeremy Steven Delk as its Chief Executive Officer and 100% shareholder (Respondent). The Nonresident Pharmacy Permit

was in full force and effect at all times relevant to the charges brought herein and was cancelled on March 3, 2021.

Nonresident Sterile Compounding Permit

3. On or about July 10, 2018, the Board of Pharmacy issued Nonresident Sterile Compounding Permit Number NSC 101012 to Tailormade Compounding LLC, with Jeremy Steven Delk as its Chief Executive Officer and 100% shareholder (Respondent). The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and was cancelled on March 3, 2021.

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 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.

STATUTORY PROVISIONS

7. Code section 651, subdivision (a) states:

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

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 or whose license has been issued by mistake. Unprofessional conduct includes, but is not limited to, any of the following:

…

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

…

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

…

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(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 4302 states:

The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee.

10. Code section 4307 states, in pertinent part:

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

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

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

. . .

11. Code section 4076 states, in pertinent part:

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

12. Code section 4129, subdivision (a), states, "A facility licensed 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."

13. Code section 4126.8 states:

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

14. Code section 4127.2, subdivision (a), states:

A nonresident pharmacy shall not compound sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by

the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

15. Code section 4129.2, subdivision (a), states:

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

16. Code section 4169, subdivision (a), 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.

17. Code section 4022 states, in pertinent part:

"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.

HEALTH AND SAFETY CODE

18. California 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.

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19. Health & 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.

20. Health and Safety Code, section 111330 states:

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

21. Health and Safety Code, section 111335 states:

Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

22. Health and Safety Code section 111445 states:

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

FEDERAL STATUTES

23. 21 U.S. Code section 321 states, in pertinent part:

(ff) The term "dietary supplement" –

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

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

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

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

(2) Means a product that –

(A)

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

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

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

(C) is labeled as a dietary supplement; and

(3) does-

(A) Include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 262 of title 42 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary[1] has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and

(B) not include-

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

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

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

24. 21 U.S. Code section 350 states, in pertinent part:

(c) Definitions

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

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

(B) which-

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

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

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[1] The term "Secretary" refers to the Secretary of Health and Human Services.

25. 21 U.S. Code section 351 states, in pertinent part:

A drug or device shall be deemed to be adulterated –

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

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

(2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or

> (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act [21 USCS §§ 301 et seq.] as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or
>
> (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this Act [21 USCS §§ 301 et seq.] as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or

(3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 721(a) [21 USCS § 379e(a)], or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 721(a) [21 USCS § 379e(a)]; or (5) if it is a new animal drug which is unsafe within the meaning of section 512 [21 USCS § 360b]; or (6) if it is an animal feed bearing or contaminating a new animal drug, and such animal feed is unsafe within the meaning of section 512 [21 USCS § 360f].

(b) Strength, quality, or purity differing from official compendium. If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. . . . Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

. . .

26. 21 U.S. Code section 353a states, in pertinent part:

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

(1) is by—

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

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

(2)

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

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

(i) the licensed pharmacist or licensed physician; and

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

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

(b) Compounded drug

(1) Licensed pharmacist and licensed physician.

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

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

(i) that—

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

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

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

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

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

(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

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

…

27. 42 U.S. Code section 262(a)(1)(A) states:

(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

…

COST RECOVERY

28. Code section 125.3 provides, 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, with failure of the licentiate 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.

DEFINITIONS

29. 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 MTHFS 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 an 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.

30. A peptide is a compound consisting of two or more amino acids linked in a chain, the carboxyl group of each acid being joined to the amino group of the next by a bond of the type –OC-NH-.

FACTUAL ALLEGATIONS

Out of State Discipline

31. On or about October 20, 2020, the Board received a change of ownership application from Respondent. The ownership change date was tentatively scheduled for November 20, 2020,

pending Board approval. In the application, Respondent disclosed six out of state disciplinary orders, as follows:

A. Oregon State Board of Pharmacy Case #2017-0113

On or about October 9, 2017, the Oregon State Board of Pharmacy issued a $10,000 civil penalty to Respondent based on the pharmacy shipping medications into the state without a license. The civil penalty was stayed pending no further violations for three years.

B. Maryland State Board of Pharmacy Case # PI-17-245

On or about October 24, 2017, the Maryland State Board of Pharmacy issued a $1,000 fine to Respondent based on the pharmacy shipping medications, including sterile preparations, into the state without a license between January and March 2017.

C. Illinois Department of Financial and Professional Regulation, Division of Professional Regulation Case #2017-12116

On or about December 5, 2018, the Illinois Division of Professional Regulation issued a formal Reprimand against Respondent's nonresident pharmacy license as a reciprocal action to the October 24, 2017 disciplinary order issued by the Maryland State Board of Pharmacy.

D. Alabama State Board of Pharmacy Case #18-L-0013

On or about December 13, 2018, the Alabama State Board of Pharmacy issued a $5,000 fine against Respondent based on the pharmacy shipping medications into the state without a license between December 2016 and February 2017, and a as reciprocal action to the October 9, 2017 disciplinary order issued by the Oregon State Board of Pharmacy.

E. New Hampshire State Board of Pharmacy Notice of Apparent Liability

On or about February 21, 2019, the New Hampshire State Board of Pharmacy issued a $150 fine against Respondent based on its failure to disclose disciplinary orders issued by the Alabama State Board of Pharmacy and the Oregon State Board of Pharmacy on a license renewal application.

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F. Colorado State Board of Pharmacy Case #2020-3161

On or about November 12, 2020, the Colorado State Board of Pharmacy issued a $1,000 fine against Respondent based on the pharmacy's voluntary recall of tesamorelin products produced between June 6 and September 11, 2018 and the results of an FDA inspection conducted between August 20 and October 24, 2018.

Federal Drug Administration (FDA) Action

32. On or about October 24, 2018, the FDA issued an Inspectional Observation Form 483 to Respondent based on the FDA's inspection of Respondent's pharmacy between August 20 and October 24, 2018. FDA inspectors observed multiple violations of section 503A of the Food, Drug, and Cosmetic Act related to the production of sterile drug products prepared in a nonsterile environment and distribution of misbranded drugs. On or about April 1, 2020, the FDA issued a Warning Letter to Respondent based on the pharmacy failing to provide sufficient documentation correcting the violations observed during the August 20 through October 24, 2018 inspection.

33. In light of the FDA's Warning Letter, and to ensure that only drug compounds that complied with the requirements of section 503A of the Food, Drug, and Cosmetic Act were being shipped into California, the Board initiated an investigation into Respondent's conduct. As part of the investigation, the Board's inspector requested disposition records of all drug compounds sent into California from 5/1/20 to 10/15/20.

34. A review of the disposition records for items shipped into California for the time period between 5/16/20 to 10/15/20 revealed that Thymosin Alpha and Thymosin Beta were still being used to compound drug products. Specifically, between at least 5/16/20 and 10/15/20, at least 466 Thymosin Alpha prescriptions with a total of 788 vials and 104 Thymosin Beta prescriptions with a total of 240 vials shipped into California. These products were dispensed after 5/15/20, which was the date that CEO Delk had stated Respondent Tailormade would no longer be dispensing non-FDA approved drugs.

35. The Board's investigation further revealed that, on or between 5/16/20 to 10/15/20, Respondent compounded with bulk drug substances which did not have a USP monograph, were not components of drugs approved by the Secretary, and did not appear on a list developed by the

Secretary. Specifically, the Board's investigation found at least 466 orders and 788 vials of Thymosin Alpha, which is considered a peptide by the FDA, were dispensed and shipped into California. Additionally, the investigation found at least 104 orders and 240 vials of Thymosin Beta, which is considered a biological product by the FDA, were dispensed and shipped into California.

36. Additionally, the investigation revealed that from at least 9/1/20 to 10/13/20, Respondent compounded and furnished drug preparations that were adulterated, specifically Thymosin Alpha. The investigation found this to be true for at least the following 6 lots, 165 orders, and 259 vials, in that the grade of the Thymosin Alpha powder used to compound could not be determined.

Drug	Date made	Lot #	Ingredients Used	Number of orders dispensed	Vials dispensed
Thymosin Alpha 3000 mcg/ml 5 ml	8/11/2020	08112020@2	Thymosin Alpha Powder (WOBPT106442-26) Lot # BPT106442026200313	10	12
Thymosin Alpha 3000 mcg/ml 5 ml	8/18/2020	08182020@3	Thymosin Alpha Powder (WOBPT106443-19) Lot # BPT106443019200402	32	43
Thymosin Alpha 3000 mcg/ml 5 ml	8/24/2020	08242020@8	Thymosin Alpha Powder (WOBPT106443-19) Lot # BPT106443019200402	22	35
Thymosin Alpha 3000 mcg/ml 5 ml	9/4/2020	09042020@2	Thymosin Alpha Powder (WOBPT106443-19) Lot # BPT106443019200402	27	40
Thymosin Alpha 3000 mcg/ml 5 ml	9/21/2020	09212020@20	Thymosin Alpha Powder	26	42

			(WOBPT106443-19) Lot # BPT106443019200402		
Thymosin Alpha 3000 mcg/ml 5 ml	9/28/2020	09282020@26	Thymosin Alpha Powder (WOBPT106443-19) Lot # BPT106443019200402	48	87
			Totals	165	259

United States District Court, Eastern District of Kentucky, Case No. 3:20-CR-00015-GFVT

37. On or about October 29, 2020, CEO Delk pled guilty to a violation of Title 21 United States Code sections 331, subdivision (t) and 353, subdivision (e), for the unlawful wholesale distribution of the prescription drug methylcobalamin. On or about October 29, 2020, Respondent pled guilty to a violation of Title 21 United States Code sections 331, subdivision (d) and 355, for the unlawful distribution of unapproved drugs into interstate commerce.

The underlying circumstances are that on or between October 25, 2018 and April 1, 2020, Respondent unlawfully distributed selective androgen receptor modulators ("SARMS") and other substances that the FDA had not approved for distribution in the United States. SARMS are synthetic chemicals designed to mimic the effects of testosterone and other anabolic steroids. Respondent also unlawfully distributed other unapproved new drugs, including BPC 157, Cerebrolysin, CJC 12995, DSIP, Epitalon, GW 501516, Ipamorelin, LGD-4033, LL-3, Melanotan II, MK 677, PEG-MGF, Selank, and Semax.

Additionally, CEO Delk knowingly and unlawfully engaged in wholesale distribution of a prescription drug without licensing Respondent as a wholesale distributor with the Kentucky State Board of Pharmacy. Between October 23, 2018 through May 14, 2020, Respondent sent 112 vials of Methylcobalamin 10 mg/ml 10 mL to a California physician who operated an anti-aging/wellness clinic. The physician made bulk order of Methylcobalamin 10 mg/ml 10 mL rather than sending individualized, patient-specific prescriptions to Respondent. When the FDA and the Kentucky State Board of Pharmacy inspected Respondent between August 20 and October 24, 2018, CEO Delk took steps to hide records of Respondent's wholesale distributions of Methylcobalamin, as well as other records.

Supplemental Investigation

38. In or about early March of 2020, the Board was notified that Ryan Smith, a company leader for Respondent, gave an online presentation on the "Best Peptides for COVID-19 Prevention." In that presentation, Smith told a group of health care providers that Respondent had several drugs that they could "sort of market to your patients" during the pandemic. In the presentation, Smith repeated the falsehood that Thymosin Alpha-1 is "FDA approved," and he recommended the drug to his audience as a treatment for Lyme disease, "general anti-aging," and COVID-19.

39. On or about October 20, 2020, the Board received a change of ownership application from Respondent. The documents provided revealed that day-to-day staff would continue to be employed under the new ownership, the current PIC would remain PIC under the new ownership, and that the new ownership would operate as TMC Acquisition, LLC, dba Tailor Made Compounding with Dale Boden as Board Chair, Kenneth S. Berryman as Director, and Ross Jordan as Secretary.

40. On or about November 19, 2020, the Board's inspector accessed Respondent's "Peptide guide" via an internet search. The Peptide guide listed a number of peptides that were accompanied by a description that included the uses and protocol used for treatment with each compound. The Peptide guide contained dishonest and deceptive information for each of the following compounds: 1) BPC-157, 2) CJC-1295, 3) iRGD, 4) Bremelanotide PT 141, 5) Thymosin Beta 4.

41. On or about November 19, 2020, the Board's inspector accessed Respondent's "Peptide Catalog" via an internet search. The Peptide Catalog listed a number of peptides that were accompanied by a description that included the uses and protocol used for treatment with each compound. The Peptide Catalog contained dishonest and deceptive information for each of the following compounds: 1) BPC-157, 2) CJC-1295, 3) PT-141, 4) Thymosin Alpha-1, 5) Thymosin Beta.

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FIRST CAUSE FOR DISCIPLINE

(Substantially Related Conviction)

42. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (l), in that on or about October 29, 2020, Respondent pled guilty to one count of violating Title 21 United States Code sections 331, subdivision (d), and 355, and CEO Delk pled guilty to one count of violating Title 21 United States Code sections 331, subdivision (t), and 353, subdivision (e), as set forth above in paragraph 37.

SECOND CAUSE FOR DISCIPLINE

(Violation of Federal Law Regulating Controlled Substances and Dangerous Drugs)

43. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), in that Respondent violated federal law, as follows:

As set forth in paragraphs 37 and 42 above, between October 25, 2018 and April 1, 2020, Respondent Tailormade engaged in the unlawful distribution of selective androgen receptor modulators and other substances that the FDA had not approved for distribution in the United States.

THIRD CAUSE FOR DISCIPLINE

(Violation of Pharmacy Law: Unlawful Distribution)

44. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that on or between October 25, 2018 and April 1, 2020, Respondent engaged in the unlawful distribution of selective androgen receptor modulators and other substances that the FDA had not approved for distribution in the United States, as set forth above in paragraph 37 and 42.

FOURTH CAUSE FOR DISCIPLINE

(Out of State Discipline)

45. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (n), that Respondent was subject to disciplinary action in six other states, as set forth above in paragraph 31.

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FIFTH CAUSE FOR DISCIPLINE

(Violation of Pharmacy Law: Use of a Non-Compliant Bulk Drug Substance)

46. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent was not compliant with 21 U.S. Code section 353a, subdivision (b)(1)(A)(i), as set forth above in paragraph 35.

SIXTH CAUSE FOR DISCIPLINE

(Violation of Pharmacy Law: Adulterated Preparations)

47. Respondent is subject to disciplinary action under Code section 4301, subdivision (o) in that Respondent violated Code section 4169, subdivision (a), and Health and Safety Code section 111295, as set forth above in paragraph 36.

SEVENTH CAUSE FOR DISCIPLINE

(Act of Dishonesty)

48. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (f), in that on or about April 23, 2020, CEO Delk stated in writing that Respondent had ceased compounding any product not appearing on United States Pharmacopeia (USP) or National Formulary (NF), FDA Approved, or the Bulk substance list (including products that had been nominated on the aforementioned list) and that on 5/15/20 they would cease dispensing those products. This statement was dishonest, as more particularly set forth above in paragraph 35.

EIGHTH CAUSE FOR DISCIPLINE

(Violation of Pharmacy Law: Unlicensed Activity)

49. Respondent is subject to disciplinary action under Code section 4301, subdivision (o), in that Respondent violated Code section 4127.2, subdivision (a), as follows: On or about 1/1/19, Respondent issued membership interests to Nina Alava as a representative of Integrated Medical Holdings Incorporated and Brett Smith as the sole owner of RMS Biomedical Consulting LLC. After 1/1/19, Respondent's ownership was comprised as follows: Delk Enterprises, Inc. – 47.5%, Integrative Medical Holdings, Inc. – 47.5%, and RMS Biomedical Consulting, Inc. – 5%.

However, Respondent never notified the Board of this change in ownership, and Jeremy Delk retained functional control of the company.

NINTH CAUSE FOR DISCIPLINE

(Act of Dishonesty)

50. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (f), in that Respondent posted public communications that contained dishonest, fraudulent, and deceptive statements, and claims as described more fully in paragraphs 40-41, above.

TENTH CAUSE FOR DISCIPLINE

(Violation of Pharmacy Law: Unlawful Advertising)

51. Respondent is subject to disciplinary action under Code section 4301, subdivision (o) in that Respondent violated Code section 651, subdivision (a) and Health and Safety Code section 110390. Specifically, Respondent disseminated public communication containing a false, fraudulent, misleading, or deceptive statement, or claim, as set forth above in paragraphs 40-41.

ELEVENTH CAUSE FOR DISCIPLINE

(Violation of Pharmacy Law: No Biologics License)

52. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o) in that Respondent violated 42 U.S.C. section 262, subdivision (a)(1)(A). Specifically, between at least 5/16/20 and 10/15/20, Respondent shipped at least 104 orders and 240 vials of Thymosin Beta into California without the Biologics License Application to introduce or deliver it into interstate commerce, as set forth above in paragraphs 34-35.

OTHER MATTERS

53. Pursuant to Code section 4307, if Nonresident Pharmacy Permit Number NRP 1185 or Nonresident Sterile Compounding Permit Number NSC 101012, issued to Tailormade Compounding LLC is suspended, revoked, or placed on probation, and Jeremy Steven Delk, while acting as the manager, administrator, owner, member, officer, director, associate, or partner, had knowledge of or knowingly participate in any conduct for which Nonresident

Pharmacy Permit Number NRP 1185 or Nonresident Sterile Compounding Permit Number NSC 101012 was revoked, suspended, or placed on probation, Jeremy Steven Delk shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

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 1885, issued to Tailormade Compounding LLC; Jeremy Steven Delk, CEO;

2. Revoking or suspending Nonresident Sterile Compounding Permit Number NSC 101012, issued to Tailormade Compounding LLC; Jeremy Steven Delk, CEO;

3. Prohibiting Jeremy Steven Delk 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. Ordering Tailormade Compounding LLC to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 11/11/2021

Signature on File

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

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