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

In the Matter of the Accusation Against:

RIGHT VALUE DRUG STORE, LLC
dba CARIE BOYD'S PRESCRIPTION SHOP,
Non-Resident Outsourcing Facility Permit No. NSF 126

and

RIGHT VALUE DRUG STORE, LLC
dba CARIE BOYDS PRESCRIPTION SHOP,
Non-Resident Outsourcing Facility Permit No. NSF 109,

Respondents

Agency Case No. 6694

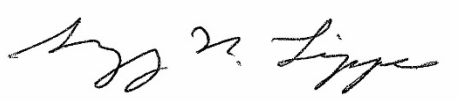
DECISION AND ORDER

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 February 11, 2021.

It is so ORDERED on January 12, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Greg Lippe
Board President

XAVIER BECERRA
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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**:** **RIGHT VALUE DRUG STORE, LLC dba CARIE BOYD'S PRESCRIPTION SHOP** **122 Grapevine Hwy** **Hurst, TX 76054** **APOTHECARY HEALTH SOLUTIONS LLC, owner** **RICHARD EARL APPLING, President** **Non-Resident Outsourcing Facility Permit No.: NSF 126** **and** **RIGHT VALUE DRUG STORE, INC dba CARIE BOYDS PRESCRIPTION SHOP** **122 Grapevine Hwy** **Hurst, TX 76054** **RICHARD EARL APPLING, owner and president** **Non-Resident Outsourcing Facility Permit No.: NSF 109** Respondents.	Case No. 6694 **STIPULATED SURRENDER OF LICENSE AND ORDER**

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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 Xavier Becerra, Attorney General of the State of California, by Kristina T. Jarvis, Deputy Attorney General.

2. Richard Earl Appling, in his individual capacity due to his former roles as the 100% shareholder of Apothecary Health Solutions, LLC (AHS) and president of Right Value Drug Stores LLC, dba Carie Boyd's Prescription Shop (RVDS LLC) (Respondent[1] RVDS LLC) and the president and owner of Right Value Drug Stores Inc., dba Carie Boyds Prescription Shop (Respondent RVDS Inc.) is represented in this proceeding by attorneys Leah Tinney and Roger Morris at Quarles & Brady LLP Two North Central Avenue, Phoenix, AZ 85004-2391.

3. On or about March 15, 2019, the Board of Pharmacy issued Non-Resident Outsourcing Facility Permit Number NSF 126 to RVDS LLC. AHS was the sole member of RVDS LLC, and Mr. Appling served as RVDS LLC's president. The Non-Resident Outsourcing Facility Permit expired on July 15, 2019, and was not renewed. On or about March 27, 2020, Mr. Appling stepped down as President of RVDS LLC and sold all of his equity in AHS. Mr. Appling's resignation as President and sale of his equity in AHS constituted a change of ownership for RVDS LLC, and as such, the Board regards RVDS LLC after March 27, 2020 (New RVDS) as a new entity and licensee that is unrelated to this stipulation or the Accusation.

4. On or about December 1, 2017, the Board of Pharmacy issued Non-Resident Outsourcing Facility Permit Number NSF 109 to RVDS Inc. The Non-Resident Outsourcing Facility Permit was cancelled on March 15, 2019, due to the change of ownership as set forth in paragraph 3, above.

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[1] All references to "Respondent" herein are to both licenses unless otherwise specified.

JURISDICTION

5. Accusation No. 6694 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 August 7, 2019. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 6694 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6694. Respondent also has carefully read, fully discussed with counsel, 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 confront and cross-examine the witnesses against it; 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. 6694, if proven at a hearing, constitute cause for imposing discipline upon its Non-Resident Outsourcing Facility Permits numbers NSF 126 and NSF 109.

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 Respondent hereby gives up its right to contest those charges.

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11. Respondent understands that by signing this stipulation it enables the Board to issue an order accepting the surrender of its Non-Resident Outsourcing Facility Permits 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 it 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.

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. It is understood by all parties and hereby attested that on March 27, 2020, ownership of AHS, the sole member of RVDS LLC, was transferred from Richard Earl Appling to The Gilmore Trust, which now owns 90.1% of the membership in AHS, and certain other minority equity holders, none of which owns more than 10% of the membership interest in AHS. This transfer of ownership constituted a change of ownership for RVDS LLC, and as such, the Board of Pharmacy regards New RVDS as a new entity and licensee that is unrelated to this stipulation

or the Accusation. All parties understand and agree that this stipulated settlement and order in no way affects or impacts new RVDS or any future license that may be issued to new RVDS. All parties further understand and agree that the accusations and other actions complained of in the Accusation do not relate to New RVDS. In the event this matter is reported to the National Practitioner Data Bank or to any other agency or forum, it is not intended to relate to the new RVDS.

16. 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 Non-Resident Outsourcing Facility Permit No. NSF 126 issued to RVDS LLC while Richard Earl Appling was President is surrendered and accepted by the Board.

IT IS FURTHER ORDERED that Non-Resident Outsourcing Facility Permit No. NSF 109 issued to RVDS, Inc. while Richard Earl Appling was President is surrendered and accepted by the Board.

1. The surrender of Respondent's Non-Resident Outsourcing Facility Permits 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. For purposes of future actions pursuant to Code section 4307, this stipulation for surrender shall be construed to be the same as a revocation.

2. Respondent shall cause to be delivered to the Board its now-expired pocket license and, if one was issued, any corresponding wall certificate on or before the effective date of the Decision and Order.

3. Respondent may not apply, reapply, or petition for any licensure or registration of the Board for three (3) years from 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. 6694 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 $11,068.00 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. 6694 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.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Leah Tinney. I understand the stipulation and the effect it will have on my Non-Resident Outsourcing Facility Permits. 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: _____

RICHARD EARL APPLING,
In his individual capacity due to his former role as owner and president of:
RVDS LLC and RVDS Inc.
Respondent

I have read and fully discussed with Richard Earl Appling the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____

LEAH TINNEY
Attorney for Richard Earl Appling

ENDORSEMENT

petition is filed, and all of the charges and allegations contained in Accusation No. 6694 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 $11,068.00 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. 6694 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.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Leah Tinney. I understand the stipulation and the effect it will have on my Non-Resident Outsourcing Facility Permits. 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: 11/12/20

RICHARD ~~EARL~~ APPLING,
In his individual capacity due to his former role as owner and president of:
RVDS LLC and RVDS Inc.
Respondent

I have read and fully discussed with Richard Earl Appling the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 11/13/2020

LEAH TINNEY
Attorney for Richard Earl Appling

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: December 10, 2020

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
KAREN R. DENVIR
Supervising Deputy Attorney General

KRISTINA T. JARVIS
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 6694

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

In the Matter of the Accusation Against**:** **RIGHT VALUE DRUG STORE, LLC** **dba CARIE BOYD'S PRESCRIPTION SHOP** **122 Grapevine Hwy** **Hurst, TX 76054** **APOTHECARY HEALTH SOLUTIONS LLC, owner** **RICHARD EARL APPLING, President** **Non-Resident Outsourcing Facility Permit No.: NSF 126** **and** **RIGHT VALUE DRUG STORE, INC** **dba CARIE BOYDS PRESCRIPTION SHOP** **122 Grapevine Hwy** **Hurst, TX 76054** **RICHARD EARL APPLING, owner and president** **Non-Resident Outsourcing Facility Permit No.: NSF 109** Respondents.	Case No. 6694 **A C C U S A T I O N**

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Complainant alleges:

PARTIES

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

2. On or about March 15, 2019, the Board of Pharmacy issued Non-Resident Outsourcing Facility Permit Number NSF 126 to Right Value Drug Stores Inc., doing business as (dba) Carie Boyd's Prescription Shop, Apothecary Health Solutions LLC member and 100% shareholder, Richard Earl Appling, president (Respondent). The Non-Resident Outsourcing Facility Permit will expire on July 15, 2019, unless renewed.

3. On or about December 1, 2017, the Board of Pharmacy issued Non-Resident Outsourcing Facility Permit Number NSF 109 to Right Value Drug Stores Inc., dba Carie Boyds Prescription Shop, Richard Earl Appling, president and 100% shareholder (Respondent). The Non-Resident Outsourcing Facility Permit was cancelled on March 15, 2019, due to a change of ownership as set forth in paragraph 2, above.

JURISDICTION

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

5. Section 4300 of the Code states in pertinent part:

"(a) Every license issued may be suspended or revoked…"

6. 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."

7. Section 4301 of the Code states in pertinent part:

"The board shall take action against any holder of a license who is guilty of unprofessional

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

"…

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

"...

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

8. 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."

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9. Section 4129.2 states in pertinent part:

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

"(b) A nonresident outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.

"…

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

"…

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

10. Section 651, subdivision (a) states:

"(a) 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.

HEALTH AND SAFETY CODE SECTIONS

11. Health and Safety Code section 111330 states:

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

12. Health and Safety Code section 111440 states:

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

13. Health and Safety Code section 111445 states:

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

CODE OF FEDERAL REGULATIONS

14. Code of Federal Regulations, title 21, (CFR) section 211.22, Responsibilities of Quality Control Unit, states in pertinent part:

"(a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

"…

"(d) The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed."

15. CFR section 211.28, Personnel Responsibilities states in pertinent part:

"(a) Personnel engaged in the manufacture, processing, packing, or holding of a drug product shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination…"

16. CFR section 211.42, Design and Construction Features, states in pertinent part:

"(a) Any building or buildings used in the manufacture, processing, packing, or holding of a drug product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations.

"(b) Any such building shall have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures,

labeling, in-process materials, or drug products, and to prevent contamination. The flow of components, drug product containers, closures, labeling, in-process materials, and drug products through the building or buildings shall be designed to prevent contamination…"

17. CFR section 211.84, Testing and approval or rejection of components, drug product containers, and closures, states in pertinent part:

"(a) Each lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit.

"…

"(d) Samples shall be examined and tested as follows:

"…

"(2) Each component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality. In lieu of such testing by the manufacturer, a report of analysis may be accepted from the supplier of a component, provided that at least one specific identity test is conducted on such component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals…"

18. CFR section 211.100, Written procedures; deviations, states in pertinent part:

"(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit…"

19. CFR section 211.110, Sampling and testing of in-process materials and drug products, states in pertinent part:

"(a) To assure batch uniformity and integrity of drug products, written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Such control procedures

shall be established to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Such control procedures shall include, but are not limited to, the following, where appropriate:

"(1) Tablet or capsule weight variation;…"

20. CFR section 211.137, Expiration dating, states in pertinent part:

"(a) To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in §211.166…"

21. CFR section 211.160, General requirements, states in pertinent part:

"(a) The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified…"

22. CFR section 211.167, Special testing requirements, states in pertinent part:

"(a) For each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be appropriate laboratory testing to determine conformance to such requirements. The test procedures shall be in writing and shall be followed…"

23. CFR section 211.186, Master production and control records, states in pertinent part:

"(a) To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed…"

DRUGS

24. Progesterone is a hormone made naturally by the female body, which can also be made in a laboratory. Progesterone is a dangerous drug pursuant to Code section 4022.

25. Tadalafil is a vasodilator used to treat erectile dysfunction and enlarged prostate as well as high blood pressure in the lungs. Tadalafil is a dangerous drug pursuant to Code section 4022.

COST RECOVERY

26. Section 125.3 of the Code 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.

BACKGROUND FACTS

27. 2017 Inspection: On or about October 24-26, 2017, an outsourcing pre-license inspection was conducted at Respondent's facility. Board inspectors found that Respondent was in violation of current Good Manufacturing Practices (cGMP). Respondent submitted a corrective action plan to the Board in order to come into compliance.

28. 2018 Inspection: On or about September 18-20, 2018, an annual Outsourcing License renewal inspection was conducted at Respondent's facility. Board inspectors found that Respondent continued to violate cGMP, including in ways Respondent had promised to rectify in their corrective action plan submitted to the Board after the October 24-26, 2017, inspection.

FIRST CAUSE FOR DISCIPLINE

(Failure to Comply with Federal Current Good Manufacturing Practices)

29. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivisions (j) and (o), in that Respondent has violated Code section 4129.2, subdivision (b), by failing to ensure compliance with cGMP. The circumstances are as follows:

a. CFR 211.22, subdivision (d): Responsibilities of Quality Control Unit: Respondent failed to have appropriate standard operating procedures (SOPs) and protocols applicable to the quality control unit. During the 2017 inspection Board inspectors observed that

Respondent's standard operating procedures (SOPs) did not show the responsibilities of the quality control unit in all aspects of the manufacturer products at Respondent's facility. During the 2018 inspection, Board inspectors observed there was no true quality control unit because the individuals with some quality control responsibilities were not functionally separate from production staff.

b. CFR 211.28, subdivision (a), Personnel Responsibilities: Respondent failed to ensure its personnel engaged in the manufacture, processing, packing, or holding of a drug product wore protective apparel to protect drug products from contamination. During the 2017 inspection, Board inspectors observed employees compounding with one employee's forehead uncovered and another employee's mask failed to cover the employee's nose. During the 2018 inspection, Board inspectors observed an employee compounding with their goggles lifted off their face.

c. CFR 211.42, subdivision (b), Design and Construction Features: Respondent failed to ensure adequate space for the orderly placement of equipment and materials. During the 2017 inspection, Board inspectors noted that drug components were stored in a warm room with computer equipment just 0.4 degrees Celsius below the upper temperature for the storage of one such drug component. During the 2018 inspection, Board inspectors noted that the storeroom for raw material was cramped, very warm, and had drug components stored on the floor next to cleaning solutions.

d. CFR 211.84, subdivision (d)(2), Testing and approval or rejection of components: Respondent failed to appropriately test each drug component for conformity for purity, strength, and quality. During the 2017 inspection, Board inspectors observed there was no pre-production sampling or testing of any components or container closure systems and no SOPs with written procedures for such sampling or testing. During the 2018 inspection, Board inspectors observed there were no specific identify tests done on any drug components.

e. CFR 211.100, subdivision (a), Written procedures; deviations: Respondent failed to have and comply with written procedures for production and process control. During the 2017 inspection, Board inspectors observed the quality control unit did not have control over

written procedures and did not ensure deviations or changes were documented and reviewed. During the 2018 inspection, Board inspectors observed that a change in the drug master formula occurred during compounding and it was not approved by the quality control unit.

f. CFR 211.110, subdivision (a)(1), Sampling and testing of in-process materials and drug products: Respondent failed to establish and follow written procedures to describe the in-process controls, and tests or examinations to be conducted on appropriate samples of in-process materials of each batch, including controlling for tablet or capsule weight variations. During the 2017 inspection, Board inspectors observed Respondent failed to have documented in-process controls for aqueous solutions. Additionally, pellets being processed used an in-process material not listed on the batch record. During the 2018 inspection, Board inspectors observed that aqueous solutions still did not have in-process controls and a batch record for progesterone tablets had no in-process controls.

g. CFR 211.137, subdivision (a), Expiration dating: Respondent failed to determine expiration dates by appropriate stability testing. During the 2017 inspection, Board inspectors observed the data used to assign expiration dates was data expressing the potency over time. There were no reliable, meaningful, and specific test methods to determine the stability of products manufactured. During the 2018 inspection, Board inspectors observed the expiration date studies being used by Respondent did not include method suitability for chemistry for all of the stability portion of the test.

h. CFR 211.160, subdivision (a), General requirements: Respondent failed to ensure that specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms were documented, and followed, and deviations were recorded and justified. During the 2017 inspection, Board inspectors observed that no visual inspection was completed prior to compounded drug products being labeled. During the 2018 inspection, Board inspectors observed that compounded pellets were not visually inspected and it was unknown whether 100% of all other sterile products had been visually inspected against and black and white board.

i. CFR 211.167, subdivision (c), Special testing requirements: Respondent failed to conduct appropriate laboratory testing for each batch of controlled-release dosage to determine

conformance to the specifications for the rate of release of each ingredient. During the 2018 inspection, Board inspectors observed that progesterone and tadalafil capsules were labeled sustained release and advertised as such on Respondent's website. There were no studies to show that the product was indeed sustained release.

j. CFR 211.186, subdivision (a), Master production and control records: Respondent failed to assure uniformity from batch to batch by preparing, dating, and signing and a master production and control record for each drug product, which were then independently verified, dated, and signed by a second person. During the 2017 inspection, Board inspectors observed the master formulas for both sterile and non-sterile products did not include all pertinent steps of the formulation process and no labeling or inspections post production. During the 2018 inspection, Board inspectors observed the master formulas for both sterile and non-sterile products did not include all pertinent steps of the formulation process and no labeling or inspections post production.

SECOND CAUSE FOR DISCIPLINE

(Unlawful Misbranding of Drugs)

30. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), in that Respondent violated Health and Safety Code sections 111330, and 111445, by misbranding progesterone and tadalafil capsules. The circumstances are that Respondent labeled progesterone and tadalafil capsules sustained release but failed to conduct any laboratory testing to determine conformance to the specifications for the rate of release. There was no scientific evidence the product was sustained release and therefore the label was false and misleading and the drugs were misbranded.

THIRD CAUSE FOR DISCIPLINE

(Unlawful Sale of Misbranded Drugs)

31. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), in that Respondent violated Health and Safety Code section 111440, by manufacturing, selling, delivering, holding, and offering for sale a misbranded drug. The circumstances are that Respondent manufactured, sold, and delivered for sale misbranded

progesterone and tadalafil capsules by labeling them as sustained release when in fact there was no laboratory resting to determine conformance to the specifications for the rate of release of each active ingredient and there was no scientific evidence the products were sustained release.

FOURTH CAUSE FOR DISCIPLINE

(False Advertising)

32. Respondent is subject to disciplinary for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent violated Code section 651, subdivision (a), by falsely advertising progesterone and tadalafil capsultes on Respondent's website as sustained release, when in fact there was no laboratory resting to determine conformance to the specifications for the rate of release of each active ingredient and there was no scientific evidence the products were sustained release.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Notify Board of Recall)

33. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent violated Code section 4129.2, subdivision (e)(2), by failing to notify the Board within 24 hours of the initiation of a drug recall. The circumstances are that on September 27, 2018, Respondent initiated a recall of misbranded progesterone and tadalafil capsules and failed to notify the Board of this recall within 24 hours.

OTHER MATTERS

34. Pursuant to section 4307 of the Code, if discipline is imposed on Non-Resident Outsourcing Facility Permit Number NSF 126 issued to Right Value Drug Stores Inc., dba Carie Boyd's Prescription Shop, Apothecary Health Solutions LLC member and 100% shareholder, Richard Earl Appling, president, then Right Value Drug Stores, Inc., Apothecary Health Solutions LLC, and Richard Earl Appling, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five (5) years if Non-Resident Outsourcing Facility Permit number NSF 126 is placed on probation; or, 2) if the pharmacy permit is revoked, the prohibition shall continue until the non-resident outsourcing facility permit is reinstated.

PRAYER

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

1. Revoking or suspending Non-Resident Outsourcing Facility Permit Number NSF 126 issued to Right Value Drug Stores Inc., dba Carie Boyd's Prescription Shop, Apothecary Health Solutions LLC, owner, Richard Earl Appling, president;

2. Prohibiting Right Value Drug Stores Inc., from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

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

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

5. Revoking or suspending Non-Resident Outsourcing Facility Permit Number NSF 109 issued to Right Value Drug Stores Inc., dba Carie Boyds Prescription Shop, Richard Earl Appling, owner and president;

6. Ordering Right Value Drug Stores Inc. to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: August 6, 2019

Anne Sodergren

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

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