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

In the Matter of the Accusation Against:

APOTHECARY HOLDINGS INC. AND AVELLA OF DEER VALLEY, INC. dba AVELLA OF DEER VALLEY, INC. #38,

Non-Resident Outsourcing Facility Permit No. NSF 104,

Respondent

Agency Case No. 6695; OAH No. 2020020339

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on September 2, 2020.

It is so ORDERED on August 3, 2020.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

Greg Lippe
Board President

XAVIER BECERRA
Attorney General of California
KAREN R. DENVIR
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
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Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **APOTHECARY HOLDINGS INC. AND AVELLA OF DEER VALLEY, INC. DBA AVELLA OF DEER VALLEY, INC. #38** **24416 N. 19th Avenue** **Phoenix, AZ 85085** **Non-Resident Outsourcing Facility Permit No. NSF 104** Respondent.	Case No. 6695 OAH No. 2020020339 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

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

PARTIES

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

2. Respondent Apothecary Holdings Inc. and Avella of Deer Valley, Inc. dba Avella of Deer Valley, Inc. #38 (Respondent) is represented in this proceeding by attorney Alissa Brice

Castañeda whose address is: Quarles & Brady, LLP., Renaissance One, Two North Central Avenue, Phoenix, AZ 85004-2391.

3. On or about June 9, 2017, the Board of Pharmacy issued Non-Resident Outsourcing Facility Permit Number NSF 104 to Apothecary Holdings Inc., 100% shareholder, and Avella of Deer Valley, Inc., dba Avella of Deer Valley, Inc. #38 (Respondent). The Non-Resident Outsourcing Facility Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2020, unless renewed.

JURISDICTION

4. Accusation No. 6695 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on August 7, 2019. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 6695 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6695. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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

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CULPABILITY

8. Nothing in this Stipulated Settlement and Disciplinary Order for Public Reproval shall constitute or be construed as an admission of liability on behalf of Respondent, its agents, affiliates, assigns, parents, subsidiaries, and/or successors, or an admission as to the validity of the allegations in Accusation No. 6695. However, for the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up its right to an evidentiary hearing on the causes in the Accusation and agrees that its Non Resident Outsourcing Facility Permit is subject to discipline (public reproval) and agrees to be bound by the Board's terms as set forth in the Disciplinary Order below.

CONTINGENCY

9. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that 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 Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

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

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

supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Non-Resident Outsourcing Facility Permit No. NSF 104 issued to Respondent Apothecary Holdings Inc. and Avella of Deer Valley, Inc. dba Avella of Deer Valley, Inc. #38 (Respondent) shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 6695, attached as exhibit A.

Cost Recovery. Respondent shall pay $10,320.50 to the Board for its costs associated with the investigation and enforcement of this matter. Respondent shall be permitted to pay these costs in a payment plan approved by the Board. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew their Non-Resident Outsourcing Facility Permit until Respondent pays costs in full.

Full Compliance. As a resolution of the charges in Accusation No. 6695, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Non-Resident Outsourcing Facility Permit No. NSF 104.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Alissa Brice Castañeda. I understand the stipulation and the effect it will have on my Non-Resident Outsourcing Facility Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily,

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knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: June 8 2020

APOTHECARY HOLDINGS INC. AND
AVELLA OF DEER VALLEY, INC. DBA
AVELLA OF DEER VALLEY, INC. #38
Richard J. Mattera
Print Name of Signatory
EVP, Chief Legal Officer Optum
Title of Signatory
Respondent

I have read and fully discussed with Respondent Apothecary Holdings Inc. and Avella of Deer Valley, Inc. dba Avella of Deer Valley, Inc. #38 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: June 8 2020

ALISSA BRICE CASTAÑEDA
Attorney for Respondent

ENDORSEMENT

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

DATED: 6/8/2020

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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knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

APOTHECARY HOLDINGS INC. AND
AVELLA OF DEER VALLEY, INC. DBA
AVELLA OF DEER VALLEY, INC. #38

Print Name of Signatory

Title of Signatory
Respondent

I have read and fully discussed with Respondent Apothecary Holdings Inc. and Avella of Deer Valley, Inc. dba Avella of Deer Valley, Inc. #38 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: _____

ALISSA BRICE CASTAÑEDA
Attorney for Respondent

ENDORSEMENT

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

DATED: _____

Respectfully submitted,

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. 6695

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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**:** **APOTHECARY HOLDINGS INC., 100% SHAREHOLDER, and AVELLA OF DEER VALLEY, INC DBA AVELLA OF DEER VALLEY, INC. #38** **24416 N. 19th Avenue** **Phoenix, AZ 85085** **Non-Resident Outsourcing Facility Permit No. NSF 104** Respondent.	Case No. 6695 **A C C U S A T I O N**

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 June 9, 2017, the Board of Pharmacy issued Non-Resident Outsourcing Facility Permit Number NSF 104 to Apothecary Holdings Inc., 100% shareholder, and Avella of Deer Valley, Inc., dba Avella of Deer Valley, Inc. #38 (Respondent). The Non-Resident

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Outsourcing Facility Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2019, unless renewed.

JURISDICTION

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

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

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

"…

"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

5. Section 4300.1 of the Code states:

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

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

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

"…

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

"…

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

7. Section 4307 of the Code states:

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

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

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

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law."

8. Section 4129.2 of the Code states in pertinent part:

"(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…"

CODE OF FEDERAL REGULATIONS

9. Title 21, Code of Federal Regulations, (CFR) section 211.67, Equipment Cleaning and Maintenance, states in pertinent part:

"…

"(b) Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product. These procedures shall include, but are not necessarily limited to, the following:

"(1) Assignment of responsibility for cleaning and maintaining equipment;…"

10. CFR section 211.80, General Requirements, states in pertinent part:

"(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures; such written procedures shall be followed…"

11. 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…"

12. 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…"

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13. 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.

"(b) Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity…"

COST RECOVERY

14. 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

15. 2017 Inspection: On or about July 18-20, 2017, an Outsourcing License pre-licensure inspection was conducted at Respondent's facility. Board inspectors found that Respondent was in violation of Federal current Good Manufacturing Practices (cGMP). Respondent submitted a corrective action plan to the Board in order to come into compliance, and a non-resident Outsourcing Facility Permit was issued to Respondent by the Board.

16. 2018 Inspection: On or about June 26-29, 2018, an annual Non-Resident Outsourcing Facility Permit renewal inspection was conducted at Respondent's facility. Board inspectors found that Respondent continued to violate cGMP, including in ways Respondent had promised

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to rectify in their corrective action plan submitted to the Board after the July 18-20, 2017, inspection.

CAUSE FOR DISCIPLINE

(Failure to Comply with Federal Current Good Manufacturing Practices)

17. 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 211.67, subdivision (b)(1), Equipment Cleaning and Maintenance: Respondent failed to properly assign responsibility for equipment cleaning and maintenance. During the 2017 inspection, Board inspectors observed that a systematic assignment of responsibility for equipment used on the pharmacy was not available. During the 2018 inspection, Board inspectors observed there was no assignment of responsibility for control of the equipment master list.

b. CFR 211.84, subdivision (d)(2), Testing and approval or rejection of components in conjunction with CFR 211.80, subdivision (a), General Requirements: Respondent failed to appropriately test each drug component for conformity for purity, strength, and quality or have the appropriate vendor qualifications for drug vendors, and failed to have appropriate written procedures. During the 2017 inspection, Board inspectors observed Respondent did not have vendor qualifications for all vendors, and policy 03-OS-20 had not been revised since 2014 describing vendor qualification, and policy 03-OS-12 had not been revised since 2015 and described analytical laboratory qualification. During the 2018 inspection, Board inspectors observed the vendor qualifications had no acceptance criteria and there was no indication that the contract laboratory's analyses and tests had been validated.

c. CFR 211.137, subdivision (a), Expiration Dating: Respondent failed to complete appropriate stability testing to ensure the drug products meet the applicable standards of identity, strength, quality, and purity at the time of use. During the 2017 inspection, Board inspectors observed Respondent used potency over time for expiration dating, and failed to do stability testing. During the 2018 inspection, Board inspectors observed Respondent continued to use

potency over time for expiration dating. Additionally, batch number 138-20180703@96 did not have a stability study and container closure studies had not been completed for each drug product made by Respondent.

d. CFR 211.160, subdivision (b), General Requirements: Respondent failed to establish scientifically sound and appropriate specifications, standards, sampling plans, and test procedures to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity. During the 2017 inspection, Board inspectors observed Respondent's staff fail to do a visual inspection on completed drug products. Board inspectors also reviewed batch records and observed there was no documentation of visual inspections, and Respondent's standard operating procedure (SOP) 03-HVOS-037 only briefly mentions any visual inspection. During the 2018 inspection, Board inspectors observed Respondent failed to document a visual inspection in 100% of the drug products produced. Additionally, a Food and Drug Administration (FDA) form 483 from April 2018, noted Respondent's staff failing to perform visual inspections.

OTHER MATTERS

18. Pursuant to section 4307 of the Code, if discipline is imposed on Non-Resident Outsourcing Facility Permit Number NSF 104 issued to Apothecary Holdings Inc., 100% shareholder, and Avella of Deer Valley, Inc., dba Avella of Deer Valley, Inc. #38, then Apothecary Holdings Inc., and Avella of Deer Valley, Inc., 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 Outsourcing Facility Permit Number NSF 104 is placed on probation; or, 2) if the permit is revoked, the prohibition shall continue until the 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:

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1. Revoking or suspending Non-Resident Outsourcing Facility Permit Number NSF 104, issued to Apothecary Holdings Inc., 100% shareholder, and Avella of Deer Valley, Inc., dba Avella of Deer Valley, Inc. #38;

2. Prohibiting Apothecary Holdings 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 Avella of Deer Valley, Inc., from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any Pharmacy licensee;

4. Ordering Apothecary Holdings Inc., 100% shareholder, and Avella of Deer Vally 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,

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

DATED: August 6, 2019

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

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