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

In the Matter of the Accusation Against**:** **ARCHWAY APOTHECARY LLC;** **CARLY HAYDEN CAMP, PRES/53% SHAREHOLDER;** **STEPHEN M. CAMP, MEMBER/305 SHAREHOLDER;** **MATTHEW WILLIAM HARDEY, SEC/TREAS/CFO/17% SHAREHOLDER** 2190 Manton Dr. Covington, LA 70433 Nonresident Pharmacy Permit No. NRP 1974 Nonresident Sterile Compounding Pharmacy Permit No. NSC 101128 Respondent.	Case No. 7175 **STIPULATION FOR CONTINUING JURISDICTION**

IT IS HEREBY STIPULATED AND AGREED by and between the undersigned parties that the following is true:

1. The parties to this agreement are **Anne Sodergren**, acting in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs, and **Stephen M. Camp**, President, authorized representative of Archway Apothecary LLC.

2. On or about August 7, 2024, Archway Apothecary LLC, 2190 Manton Dr., Covington, Louisiana, 70433, (hereinafter "applicant") submitted an application to the Board for a change of ownership of Archway Apothecary LLC, 22190 Manton Dr., Covington, Louisiana, 70433, (Nonresident Pharmacy Permit No. NRP 1974 and Nonresident Sterile Compounding Permit NSC 101128). The granting of the application would require the cancellation of Nonresident Pharmacy Permit No. NRP 1974 and Nonresident Sterile Compounding Permit NSC 101128 issued to Archway Apothecary LLC, 22190 Manton Dr., Covington, Louisiana, 70433, and the issuance of a new nonresident pharmacy permit number and nonresident sterile compounding permit to applicant pursuant to Business and Professions Code section 4201(f).

3. The existing permit (Nonresident Pharmacy Permit No. NRP 1974 and Nonresident Sterile Compounding Permit NSC 101128) is currently the subject of a disciplinary order issued effective November 30, 2022, by the Board in the disciplinary matter entitled *In the Matter of the Accusation Against ARCHWAY APOTHECARY LLC; CARL HAYDEN CAMP, PRES/53% SHAREHOLDER; STEPHEN M. CAMP, MEMBER/30% SHAREHOLDER; MATTHEW WILLIAM HADEY, SEC/TREAS/CFO/17% SHAREHOLDER,* Board of Pharmacy Case No. 7175. A true and correct copy of the decision and order in this matter is attached hereto as **Exhibit A** and incorporated by this reference.

4. In exchange for processing and issuance of the new permits pursuant to the change of ownership, applicant understands and agrees that the Board shall have continuing jurisdiction over the new permits issued to applicant such that the disciplinary order issued by the Board in Case No. 7175, including any terms and conditions and remaining tenure of probation, shall carry forward and be applicable to the new permits issued to applicant. The Board hereby waives any right it may have had to deny issuance of the new permit.

5. A portable document format (PDF) or facsimile signature on this document shall be binding as an original signature. Parties agree to use of PDF or facsimile signatures in lieu of original signatures for all purposes relevant to enforcement of this Stipulation.

Dated: 9/19/24

STEPHEN MARK CAMP
President

Dated: _____

ANNE SODERGREN
Executive Officer
California Board of Pharmacy

3. The existing permit (Nonresident Pharmacy Permit No. NRP 1974 and Nonresident Sterile Compounding Permit NSC 101128) is currently the subject of a disciplinary order issued effective November 30, 2022, by the Board in the disciplinary matter entitled *In the Matter of the Accusation Against ARCHWAY APOTHECARY LLC; CARL HAYDEN CAMP, PRES/53% SHAREHOLDER; STEPHEN M. CAMP, MEMBER/30% SHAREHOLDER; MATTHEW WILLIAM HADEY, SEC/TREAS/CFO/17% SHAREHOLDER,* Board of Pharmacy Case No. 7175. A true and correct copy of the decision and order in this matter is attached hereto as **Exhibit A** and incorporated by this reference.

4. In exchange for processing and issuance of the new permits pursuant to the change of ownership, applicant understands and agrees that the Board shall have continuing jurisdiction over the new permits issued to applicant such that the disciplinary order issued by the Board in Case No. 7175, including any terms and conditions and remaining tenure of probation, shall carry forward and be applicable to the new permits issued to applicant. The Board hereby waives any right it may have had to deny issuance of the new permit.

5. A portable document format (PDF) or facsimile signature on this document shall be binding as an original signature. Parties agree to use of PDF or facsimile signatures in lieu of original signatures for all purposes relevant to enforcement of this Stipulation.

Dated:_____

STEPHEN MARK CAMP
President

Dated: 9/19/2024

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2024.09.19 11:55:54 -07'00'

ANNE SODERGREN
Executive Officer
California Board of Pharmacy

Exhibit A

Final Decision and Order
Board of Pharmacy Disciplinary Case No. 7175

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

In the Matter of the First Amended Accusation Against:

ARCHWAY APOTHECARY LLC,
CARL HAYDEN CAMP, PRESIDENT/53% SHAREHOLDER,
STEPHEN M. CAMP, MEMBER/30% SHAREHOLDER,
MATTHEW WILLIAM HARDEY,
SECRETARY/TREASURER/CFO/17% SHAREHOLDER,

Nonresident Pharmacy Permit No. NRP 1974, and
Nonresident Sterile Compounding Pharmacy Permit No. NSC 101128,

Respondents.

Agency Case No. 7175

OAH No. 2022050011

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary 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 November 30, 2022.

It is so ORDERED on October 31, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
State Bar No. 258229
1300 I Street, Suite 125
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Facsimile: (916) 324-5567
Attorneys for Complainant

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

In the Matter of the First Amended Accusation Against: **ARCHWAY APOTHECARY LLC;** **CARL HAYDEN CAMP, PRES/53% SHAREHOLDER;** **STEPHEN M. CAMP, MEMBER/30% SHAREHOLDER;** **MATTHEW WILLIAM HARDEY, SEC/TREAS/CFO/17% SHAREHOLDER;** 2190 Manton Dr., Covington, LA 70433 **Nonresident Pharmacy Permit No. NRP 1974** **Nonresident Sterile Compounding Pharmacy Permit No. NSC 101128** Respondent.	Case No. 7175 OAH No. 2022050011 **STIPULATED SETTLEMENT AND DISCIPLINARY 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 Kristina T. Jarvis, Deputy Attorney General.

2. Respondent Archway Apothecary LLC, with Carl Hayden Camp as President/53% Shareholder, Stephen M. Camp as Member/30% Shareholder, Matthew William Hardey as Secretary/Treasurer/Chief Financial Officer/17% Shareholder, and Earl Raymond Wilkes, Jr. as Pharmacist-in-Charge (PIC) (Collectively "Respondent") is represented in this proceeding by attorney Sweta H. Patel, whose address is: 1981 North Broadway, Suite 220, Walnut Creek, CA 94596-3877

3. On or about July 12, 2017, the Board issued Nonresident Pharmacy Permit No. NRP 1974 to Respondent. The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 7175, and will expire on July 1, 2022, unless renewed.

4. On or about December 6, 2017, the Board issued Nonresident Sterile Compounding Pharmacy Permit No. NSC 101128 to Respondent. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 7175, and will expire on July 1, 2022, unless renewed.

JURISDICTION

5. First Amended Accusation No. 7175 was filed before the Board, and is currently pending against Respondent. The First Amended Accusation and all other statutorily required documents were properly served on Respondent on February 3, 2022. Respondent timely filed its Notice of Defense contesting the First Amended Accusation.

6. A copy of First Amended Accusation No. 7175 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 7175. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

8. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; 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.

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

CULPABILITY

10. Respondent understands and agrees that the charges and allegations in First Amended Accusation No. 7175, if proven at a hearing, constitute cause for imposing discipline upon its Nonresident Pharmacy Permit and Nonresident Sterile Compounding Pharmacy Permit.

11. For the purpose of resolving the First Amended 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.

12. Respondent agrees that its Nonresident Pharmacy Permit and Nonresident Sterile Compounding Pharmacy Permit are subject to discipline and agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order 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.

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

15. This Stipulated Settlement and Disciplinary 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 Settlement and Disciplinary 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.

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 Disciplinary Order:

DISCIPLINARY ORDER

IT IS FURTHER ORDERED that Nonresident Pharmacy Permit No. NRP 1974 and Nonresident Sterile Compounding Pharmacy Permit No. NSC 101128 issued to Respondent Archway Apothecary LLC are revoked. However, the revocations are stayed and Respondent NRP and Respondent NSC are placed on probation for three (3) years on the following terms and conditions:

1. **Definition: Respondent**

For the purposes of these terms and conditions, "respondent" shall refer to Archway Apothecary LLC. All terms and conditions states herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, and report, submission, filing, payment, or appearance required to be made by respondent to or before the board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

2. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

3. **Report to the Board**

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

In addition, respondent must provide to the board any inspection reports issued by any other regulatory or accreditation agency including any state or federal agency within two (2) business days of the report being issued.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

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4. **Interview with the Board**

Upon receipt of reasonable prior notice considering the travel and distances involved, respondent shall appear in person or via remote meeting platform such as Zoom or Microsoft Teams or telephone for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

5. **Cooperate with Board Staff**

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of respondent's probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

6. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $11,733.00. Respondent shall make said payments as follows:

Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

7. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Probation monitoring costs include travel expenses for an inspector to inspect the facility on a schedule as determined by the board. Such costs shall be

payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

8. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current Nonresident Pharmacy Permit and Nonresident Sterile Compounding Pharmacy Permit with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current Nonresident Pharmacy Permit shall be considered a violation of probation.

If respondent's Nonresident Pharmacy Permit expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

9. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may relinquish its license, including any indicia of licensure issued by the board, along with a request to surrender the license. The board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable in the event that respondent has outstanding obligations under this Decision and Order, or is subject to any investigation by the board, or is subject to subsequent administrative action. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent’s license history with the board.

Upon acceptance of the surrender, respondent shall relinquish its pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

10. **Sale or Discontinuance of Business**

During the period of probation, should respondent sell, trade, or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to respondent, or should practice at that location be assumed by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

11. **Notice to Employees**

Respondent shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by the provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent shall submit written notification to the board, within thirty (30) days of the effective date of this decision, that this term has been satisfied. Failure to timely provide such notification to employees, or to timely submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

12. **Owners and Officers: Knowledge of the Law**

Respondent shall provide, within ninety (90) days after the effective date of this decision, signed and dated statements from its indirect, natural person owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and all of

its officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. **Premises Open for Business**

Respondent shall remain open and engaged in its ordinary business as a nonresident pharmacy facility for a minimum of forty (40) hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during with this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is informed otherwise in writing by the board or its designee. If respondent is not open and engaged in its ordinary business as a nonresident pharmacy or nonresident sterile compounding pharmacy for a minimum of forty (40) hours in any calendar month, for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at minimum all of the following: the date(s) and hours respondent was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which respondent will resume business as required. Respondent shall further notify the board in writing with ten (10) days following the next calendar month during which respondent is open and engaged in its ordinary business as a nonresident pharmacy for a minimum of forty (40) hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

14. **Posted Notice of Probation**

Respondent shall prominently post a probation notice in its physical facility in a place conspicuous to and readable by the public, and on its website. The probation notice shall be provided by the board or its designee and must be posted within two (2) business days of receipt. Respondent shall also provide a copy of the notice of probation in all shipments of sterile compounded preparations to California. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation.

Respondent shall not, directly or indirectly, engage in any conduct or make any statement

which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

15. **Violation of Probation**

If respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and the board shall provide notice to respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

16. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

17. **Restricted Practice**

Respondent's practice as a Nonresident Pharmacy and Nonresident Sterile Compounding Pharmacy shall be prohibited from sterile compounding Beta Nicotinamide Adenine Dinucleotide (NAD) for shipment into California until respondent’s probation monitor inspects the pharmacy and confirms in writing that respondents are no longer compounding with any non-pharmaceutical grade NAD material. At any time, respondents may submit documentation or any other evidence in any form to prove that respondents are compounding with pharmaceutical grade materials and if such proof is sufficient to the board or its designee it shall confirm in writing that

this restriction is lifted and respondents may begin compounding NAD for shipment into California even if an inspection has not yet occurred.

18. **No New Ownership or Management of Licensed Premises**

None of respondent's owners or officers shall acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Sweta H. Patel. I understand the stipulation and the effect it will have on my Nonresident Pharmacy Permit and Nonresident Sterile Compounding Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

_____
ARCHWAY APOTHECARY LLC
Respondent

_____
By: (Print Name and Title)

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this restriction is lifted and respondents may begin compounding NAD for shipment into California even if an inspection has not yet occurred.

18. **No New Ownership or Management of Licensed Premises**

None of respondent's owners or officers shall acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Sweta H. Patel. I understand the stipulation and the effect it will have on my Nonresident Pharmacy Permit and Nonresident Sterile Compounding Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 9/2/2022

ARCHWAY APOTHECARY LLC
Respondent

Carl Camp President
By: (Print Name and Title)

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///

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///

///

I have read and fully discussed with Respondent Archway Apothecary LLC the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

SWETA H. PATEL
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: _____

Respectfully submitted,

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

KRISTINA T. JARVIS
Deputy Attorney General
Attorneys for Complainant

I have read and fully discussed with Respondent Archway Apothecary LLC the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 9/2/2022

SWETA H. PATEL
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: 9/6/2022

Respectfully submitted,

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

KRISTINA T. JARVIS
Deputy Attorney General
Attorneys for Complainant

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Archway Counter-Offer.docx

Exhibit A

First Amended Accusation No. 7175

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
SETH A. CURTIS
Deputy Attorney General
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1300 I Street, Suite 125
P.O. Box 944255
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Facsimile: (916) 324-5567
Attorneys for Complainant

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

In the Matter of the First Amended Accusation Against: **ARCHWAY APOTHECARY LLC;** **CARL HAYDEN CAMP, PRES/53% SHAREHOLDER;** **STEPHEN M. CAMP, MEMBER/30% SHAREHOLDER;** **MATTHEW WILLIAM HARDEY, SEC/TREAS/CFO/17% SHAREHOLDER;** 2190 Manton Dr., Covington, LA 70433 **Nonresident Pharmacy Permit No. NRP 1974** **Nonresident Sterile Compounding Pharmacy Permit No. NSC 101128** Respondent.	Case No. 7175 **FIRST AMENDED ACCUSATION**

PARTIES

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

2. On or about July 12, 2017, the Board issued Nonresident Pharmacy Permit Number NRP 1974 to Archway Apothecary LLC, with Carl Hayden Camp as President/53% Shareholder,

Stephen M. Camp as Member/30% Shareholder, Matthew William Hardey as Secretary/Treasurer/Chief Financial Officer/17% Shareholder, and Earl Raymond Wilkes, Jr. as Pharmacist-in-Charge (PIC) (Collectively "Respondent"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2022, unless renewed.

3. On or about December 6, 2017, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 101128 to Respondent. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2022, unless renewed.

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.

7. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code § 11000 et seq.].

STATUTORY PROVISIONS

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 . . . Unprofessional conduct shall include, but is not limited to, any of the following:

. . .

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

. . .

(j) The violation of any of the statutes of this state, or 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 that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

(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 4303, subdivision (b), states:

The board may cancel, deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy, provided that the grounds for the action are also grounds

for action in the state in which the nonresident pharmacy is permanently located.

10. 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.

11. Section 4022 of the Code states:

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

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

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

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

12. Code section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

13. Code section 4127.2 states, in pertinent part:

. . .

(f) Adverse effects reported or potentially attributable to a nonresident pharmacy's sterile compounded drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

14. Code section 4169 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.

15. 21 U.S. Code section 353a states, in pertinent part:

. . .

(b) Compounded drug

(1) Licensed pharmacist and licensed physician

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

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

(i) that—

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United 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.

16. 42 U.S. Code section 262 states, in pertinent part:

(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

. . .

HEALTH AND SAFETY CODE SECTIONS

17. Health and Safety (Health & Saf.) Code section 111250 states that any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

18. Health & Saf Code section 111295 states that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

REGULATORY PROVISIONS

19. California Code of Regulations, title 16 (CCR), section 1707.2 states, in pertinent part:

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all settings:

. . .

(4) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

20. CCR section 1717 states, in pertinent part:

. . .

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders

as defined in section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

21. CCR section 1735.1 states, in pertinent part:

. . .

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

22. CCR section 1735.2 states, in pertinent part:

. . .

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

. . .

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,

(B) the chemical stability of any one ingredient in the compounded drug preparation,

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,

(E) for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and

(F) for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.

(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision; and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:

(i) the nature of the drug and its degradation mechanism,

(ii) the dosage form and its components,

(iii) the potential for microbial proliferation in the preparation,

(iv) the container in which it is packaged,

(v) the expected storage conditions, and

(vi) the intended duration of therapy.

Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,

(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,

(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

(D) The beyond use date assigned for sterility in section 1751.8.

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subdivision may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

23. CCR, section 1735.3 states, in pertinent part:

. . .

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA- registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

24. CCR, section 1751.7 states, in pertinent part:

. . .

(e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71[1] compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

25. CCR, section 1761 states, in pertinent part:

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

. . .

COST RECOVERY

26. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licensee to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DRUG DESCRIPTION

27. *Peptides* are a string of amino acids held together by peptide bonds. Peptides were made up of smaller chains of amino acids than proteins, a peptide contains 2 to about 100 amino acids. A polypeptide was a chain of 10 or more amino acids. A protein was greater than 100 amino acid in a chain. Most peptides found in the human body are about 20 amino acids long.

[1] The suffix "USP" is to indicate that the product meets the standards of the U.S. Pharmacopeia (a collection of concise but detailed drug information) for the United States published annually by the United States Pharmacopeial Convention (usually also called the USP), a nonprofit organization that owns the trademark and also owns the copyright on the pharmacopeia itself. USP has no role in enforcing its standards; enforcement is the responsibility of the U.S. Food and Drug Administration (FDA) and other government authorities in the United States.

The Food and Drug Administration (FDA) considers any polymer composed of 40 or fewer amino acids to be a peptide.

FACTUAL ALLEGATIONS

28. On or about March 4, 2021, the Board was notified about the hospitalization of a patient (Patient MV) who developed *Pseudomonas fluorescens* sepsis requiring hospitalization after injections of compounded preparations administered at the Age Management Institute in Santa Barbara, California. (Santa Barbara Clinic).

29. During the investigation by Public Health officers, open vials of used medications were confiscated from the Santa Barbara Clinic.

30. One of the confiscated vials was Thymosin Alpha-1 compounded by Respondent.

31. On or about March 8, 2021, the Board requested that Respondent provide various documents including records of sales for all compounded sterile preparations into California from January 1, 2020, through March 8, 2021.

32. On or about March 10, 2021, the Board received various documents from Respondent including the following:

(a) Dispensing records showing drugs sold into California between January 1, 2020, and March 8, 2021, (5,093 prescriptions);

(b) Certificates of Analysis (COA);

(c) Customer complaint record for patient JL who had an anaphylactic reaction when using CJC-1295/Ipamorelin acetate, lot number 01-08-2021:98@37;

(d) Licensing information.

33. On or about March 16, 2021, the Board received additional documents from Respondent including the following:

(a) A letter signed by Carl H. Camp, President/53% Shareholder (Owner Camp), stating that Respondent has stopped compounding peptides and biologicals[2] and that Respondent doesn't perform end product testing because the lots fall outside the threshold for required testing;

(b) Compounding logs;

(c) Patient demographics for CM;

[2] Section 351(a)(1) of the Public Health Service (PHS) Act prohibits the introduction into interstate commerce of any biological product unless "a biologics license…is in effect for the biological product."

(d) Copies of prescriptions 239204 and 242788;

(e) Licensing and FDA information for Darmerica, LLC;

(f) Darmerica COA for Thymosin Alpha-1 lot DL5672.

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34. On or about March 22, 2021, the Board received an email from Owner Camp stating the following:

(a) Respondent did not have documentation that the Active Pharmaceutical Ingredient's (API's) of the 10 requested bulk substances met the requirements of 503a[3] (503);

(b) With respect to Thymosin Beta, Respondent did not have any documentation to evidence that the API's meet the requirements of 503 and that Respondent ceased compounding this product immediately upon learning that it had been reclassified as a biologic;

(c) With respect to Chorionic Gonadotropin, Respondent ceased compounding this product immediately after learning that it had been reclassified as a biologic by the FDA on March 23, 2020.

(d) That Respondent had relied on the relabeler or repackager to ensure compliance with FDA regulations in sourcing the products provided.

35. On or about March 30, 2021, the Board received additional correspondence from Owner Camp including the following:

(a) A statement that Respondent had not received any reports of an adverse event other than the Board's March 12 email;

(b) A statement that the API COA for JBJ-1295/Ipamorelin acetate, lot number 01-08-2021:98@37 was the made from the same lot of API thus the COA would be the same as previously provided;

[3] 503a of the Federal Food, Drug, and Cosmetic Act includes certain restrictions on the bulk drug substances that can be used in compounding. State-licensed physicians and pharmacists that compound under section 503A may only compound drug products using bulk substances that: (1) comply with an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph if one exists, and the USP chapter on pharmacy compounding; (2) are components of FDA-approved drug products if an applicable USP or NF monograph does not exists; or (3) appear on FDA's list of bulk drug substances that can be used in compounding (503A bulks list) if such a monograph does not exist and the substance is not a component of an FDA-approved drug product.

(c) A copy of the prescription for Patient JL;

(d) A statement that the BUD for Thymosin Alpha-1 is established at 45 days refrigerated, not room temperature;

(e) Dispensing records;

(f) Documentation in respondent to a request to show the QI Medical sterility tests were USP 71 compliant;

(g) In regards to prescription 239204, that the prescriber did not provide information on what the patient was being treated for, what other drugs the patient was taking, and that the consultation consisted of shipping to the drug to the physician's office for instruction by the physician.

(h) A statement that Respondent did not recall any of the peptides or biologicals on or about March 16, 2021.

36. In addition to the correspondence from Owner Camp on or about March 30, 2021, additional documentation was provided to the Board that showed the following:

(a) The sterility test for lot number 01-08-2021:98@37 was not USP 71 compliant in that it was incubated at the incorrect temperature and the incorrect number of vials was tested.

(b) No pyrogen test was performed on lot number 01-08-2021:98@37.

(c) The Quality Analysis (QA) records for Thymosin Alpha-1, lot number 01-06-2021:84@2 show it was incubated at the wrong temperature, the number of vials tested was not recorded, no pyrogen testing was performed, and the dispensing records showed dispensing starting on January 6, 2021 when sterility testing was not done until January 26, 2021.

37. On or about April 13, 2021, Respondent provided a list of products shipped into California between April 1, 2020, and March 31, 2021.

38. A review of the compounding information from Respondent showed that none of the following products had end product endotoxins or a USP 71 compliant sterility test:

Lot number	**Date Made**	**Drug**	**Amount made**	**Expiration date**	**API**	**Used to dispense**
01-06-2021:84@2	1/6/21	Thymosin Alpha-1 300mcg/ml	110 mls 20 x 5ml	2/20/21	Thymosin Alpha DL5554	239185 239190 239204 CM 239215 239227 239239 239240 239247 239257 15 x 5 ml =75 mls

01-11-2021:24@26	2/1/21	Thymosin Alpha-1 300mcg/ml	110 mls 20 x 5	3/28/21	Thymosin Alpha DL5672	242722 242729 242771 242788 CM 243193 19 x 5ml = 95mls
02-16-2021:16@25	2/16/21	Thymosin Alpha-1 300mcg/ml	111 mls 20 x 5	4/2/21	Thymosin Alpha DL5672	242788 CM 242792 237071 242832 242837 242845 242847 242897 242904 242925 242942 242964 242986 242988 19 x 5ml = 95mls
01-08-2021:98@37	1/8/21	CJC-1295/ Ipamorelin acetate 1,200mcgl/ 3,000mcg/ml	110ml 20 x 5	2/22/21	Ipamorelin acetate lot DL5443 CJC-1295 Lot DL5417-1	239516 239535 239562 239598 239603 239622 239656 239661 239662 239667 239668 239671 239691 JL 19 x 5ml = 95mls

FIRST CAUSE FOR DISCIPLINE

(Use of Non-Compliant Bulk Drug Substance)

39. Respondent's Nonresident Sterile Compounding Pharmacy Permit is subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), in conjunction with 21 U.S. Code section 353a, subdivision (b)(1)(A)(i), in that between at least January 1, 2020, and March 8, 2021, Respondent compounded with bulk drug substances, including CJC-1295 and Thymosin Alpha-1, which did not have a USP monograph, were not components of drugs approved by the Secretary, not did they appear on a list developed by the Secretary. Respondent dispensed at least

1,020 orders and 1,874 vials into California as more thoroughly set forth in paragraph 38 above, and incorporated herein by reference

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain the Quality of a Compounded Sterile Preparation)

40. Respondent's Nonresident Sterile Compounding Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.1, subdivision (ae), in that between January 1, 2020, and March 8, 2021, Respondent compounded and furnished into California at least 1,020 orders and 1,874 vials made from a non-compliant bulk drug substance including CJC-1295 and Thymosin Alpha-1 as more thoroughly set forth in paragraph 39, above.

THIRD CAUSE FOR DISCIPLINE

(Adulterated Preparations)

41. Respondent's Nonresident Sterile Compounding Pharmacy Permit is subject to discipline pursuant to Code section 4169, subdivision (a), in conjunction with Health & Saf. Code sections 111250 and 111295, in that between January 1, 2020, and March 8, 2021, Respondent compounded and furnished into California at least 1,020 orders and 1,874 vials made from a non-compliant bulk drug substance including CJC-1295 and Thymosin Alpha-1 as more thoroughly set forth in paragraph 39, above.

FOURTH CAUSE FOR DISCIPLINE

(Assignment of an Unsupported Extended Beyond Use Date (BUD))

42. Respondent's Nonresident Sterile Compounding Pharmacy Permit is subject to discipline pursuant to CCR, 1735.2, subdivision (i), in that between January 1, 2020, and March 8, 2021, Respondent compounded and assigned an extended BUD without first having a method suitability test, container closure integrity test, and stability studies for at least 4 lots, 41 orders and 72 vials of Thymosin Alpha-1 3000mcg/ml injectable and CJC-1295 / Ipamorelin acetate 1200mcg/3,000mcg/ml injectable sold into California[4].

[4] Based on the previous evidence, the assignment of an extended BUD without first having method suitability test, container closure integrity test, and stability studies, is also expected to be true for least 549 orders and 1,217 vials of Thymosin Alpha-1-3000mcg/ml injectable and 471 orders and 657 vials of CJC-1295 / Ipamorelin acetate 1200mcg/3,000mcg/ml injectables sold into California.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Obtain Active Ingredient (Bulk Drug Substances) from a Manufacturer Registered with the FDA)

43. Respondent's Nonresident Sterile Compounding Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.3, subdivision (c), in conjunction with 21 U.S. Code section 353a, subdivision (b)(1)(A)(ii)(III), in that Respondent used active ingredients without proof that the manufacturer of the active ingredient was registered with the Food and Drug Administration (FDA) for the following active ingredients: Thymosin Alpha-1, lot DL5554; Thymosin Alpha-1, lot DL5672; Thymosin Alpha-1, lot DL5443; and CJC-1295, lot DL5417-1.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Quarantine Until Sterility Testing Confirmed via USP Chapter 71 and Pyrogens Testing Confirms Acceptable Levels of Pyrogens per USP Chapter 85 Limits Compliant Test)

44. Respondent's Nonresident Sterile Compounding Pharmacy Permit is subject to discipline pursuant to Code sections 4301, subdivisions (j), in conjunction with CCR, section 1751.7, subdivision (e)(1), in that between January 1, 2020, and March 8, 2021, Respondent furnished into California at least 41 prescriptions for 72 vials of Thymosin Alpha-1 3000mcg/ml injectable and CJC-1295 / Ipamorelin acetate 1200mcg/3,000mcg/ml injectable without the required USP chapter 71 compliant end product testing to confirm sterility and the required USP chapter 85 pyrogen testing[5].

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Report and Adverse Effect)

45. Respondent's Nonresident Sterile Compounding Pharmacy Permit is subject to discipline pursuant to Code sections 4301, subdivisions (j), and 4127.2, subdivision (f), in that Respondent failed to report to the Board within 12 hours and to the MedWatch program of the Federal Food and Drug Administration a reported adverse effect or potentially attributable adverse effect upon being notified on March 2, 2021, that patient JL had an anaphylactic reaction

[5] Based on the previous evidence, this is also expected to be true for least 549 orders and 1,217 vials of Thymosin Alpha-1-3000mcg/ml injectable and 471 orders and 657 vials of CJC-1295 / Ipamorelin acetate 1200mcg/3,000mcg/ml injectables sold into California.

with flushing and heart palpitations when given CJC-1295/Ipamorelin, lot number 01-08-2021:98@37.

EIGHTH CAUSE FOR DISCIPLINE

(No Biologics License)

46. Respondent's Nonresident Sterile Compounding Pharmacy Permit is subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), and 42 U.S. Code section 262, subdivision (a)(1)(A), in that between January 1, 2020, and March 8, 2021, Respondent shipped at least 301 orders and 956 vials of Thymosin beta-4 3,000mcg/ml and 224 orders and 297 vials of Thymosin Beta-4 6,000mcg/ml into California, without a Biologics license to introduce or deliver it into interstate commerce.

NINTH CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

47. Respondent's Nonresident Sterile Compounding Pharmacy Permit is subject to discipline pursuant to CCR, section 1761, subdivision (a), in on or about January 6, 2021, Respondent dispensed prescription number 239204 to patient CM without calling the prescriber to obtain the information needed to validate the prescription and that the prescription number 239204 lacked directions for use.

TENTH CAUSE FOR DISCIPLINE

(Failure to Provide a Consultation)

48. Respondent's Nonresident Sterile Compounding Pharmacy Permit is subject to disciplinary action under Code section 1707.2(a)(4), in that on or about January 6, 2021, Respondent dispensed prescription number 239204 to patient CM for Thymosin Alpha-1 300mcg/ml, a new prescription, and failed to provide the required consultation.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Properly Receive an Orally Transmitted Prescription)

49. Respondent's Nonresident Sterile Compounding Pharmacy Permit is subject to disciplinary action under Code section 1717, subdivision (c), in that on or about January 5, 2021,

technician C.Y., who was not a pharmacist, received a prescription for patient CM for Thymosin Alpha-1 300mcg/ml that failed to document any directions for use.

TWELFTH CAUSE FOR DISCIPLINE

(Use of Non-Compliant Bulk Drug Substance)

50. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), in conjunction with 21 U.S. Code section 353a, subdivision (b)(1)(A)(i), in that between at least January 1, 2020, and March 8, 2021, Respondent compounded with bulk drug substances, including CJC-1295 and Thymosin Alpha-1, which did not have a USP monograph, were not components of drugs approved by the Secretary, nor did they appear on a list developed by the Secretary. Respondent dispensed at least 1,020 orders and 1,874 vials into California as more thoroughly set forth in paragraph 38 above, and incorporated herein by reference

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain the Quality of a Compounded Sterile Preparation)

51. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.1, subdivision (ae), in that between January 1, 2020, and March 8, 2021, Respondent compounded and furnished into California at least 1,020 orders and 1,874 vials made from a non-compliant bulk drug substance including CJC-1295 and Thymosin Alpha-1 as more thoroughly set forth in paragraph 39, above.

FOURTEENTH CAUSE FOR DISCIPLINE

(Adulterated Preparations)

52. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to Code section 4169, subdivision (a), in conjunction with Health & Saf. Code sections 111250 and 111295, in that between January 1, 2020, and March 8, 2021, Respondent compounded and furnished into California at least 1,020 orders and 1,874 vials made from a non-compliant bulk drug substance including CJC-1295 and Thymosin Alpha-1 as more thoroughly set forth in paragraph 39, above.

FIFTEENTH CAUSE FOR DISCIPLINE

(Assignment of an Unsupported Extended Beyond Use Date (BUD))

53. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, 1735.2, subdivision (i), in that between January 1, 2020, and March 8, 2021, Respondent compounded and assigned an extended BUD without first having a method suitability test, container closure integrity test, and stability studies for at least 4 lots, 41 orders and 72 vials of Thymosin Alpha-1 3000mcg/ml injectable and CJC-1295 / Ipamorelin acetate 1200mcg/3,000mcg/ml injectable sold into California[6].

SIXTEENTH CAUSE FOR DISCIPLINE

(Failure to Obtain Active Ingredient (Bulk Drug Substances) from a Manufacturer Registered with the FDA)

54. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1735.3, subdivision (c), in conjunction with 21 U.S. Code section 353a, subdivision (b)(1)(A)(ii)(III), in that Respondent used active ingredients without proof that the manufacturer of the active ingredient was registered with the Food and Drug Administration (FDA) for the following active ingredients: Thymosin Alpha-1, lot DL5554; Thymosin Alpha-1, lot DL5672; Thymosin Alpha-1, lot DL5443; and CJC-1295, lot DL5417-1.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Failure to Quarantine Until Sterility Testing Confirmed via USP Chapter 71 and Pyrogens Testing Confirms Acceptable Levels of Pyrogens per USP Chapter 85 Limits Compliant Test)

55. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to Code sections 4301, subdivisions (j), in conjunction with CCR, section 1751.7, subdivision (e)(1), in that between January 1, 2020, and March 8, 2021, Respondent furnished into California at least 41 prescriptions for 72 vials of Thymosin Alpha-1 3000mcg/ml injectable and CJC-1295 / Ipamorelin acetate 1200mcg/3,000mcg/ml injectable without the required USP chapter 71

[6] Based on the previous evidence, the assignment of an extended BUD without first having method suitability test, container closure integrity test, and stability studies, is also expected to be true for least 549 orders and 1,217 vials of Thymosin Alpha-1-3000mcg/ml injectable and 471 orders and 657 vials of CJC-1295 / Ipamorelin acetate 1200mcg/3,000mcg/ml injectables sold into California.

compliant end product testing to confirm sterility and the required USP chapter 85 pyrogen testing[7].

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EIGHTEENTH CAUSE FOR DISCIPLINE

(Failure to Report and Adverse Effect)

56. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to Code sections 4301, subdivisions (j), and 4127.2, subdivision (f), in that Respondent failed to report to the Board within 12 hours and to the MedWatch program of the Federal Food and Drug Administration a reported adverse effect or potentially attributable adverse effect upon being notified on March 2, 2021, that patient JL had an anaphylactic reaction with flushing and heart palpitations when given CJC-1295/Ipamorelin, lot number 01-08-2021:98@37.

NINETEENTH CAUSE FOR DISCIPLINE

(No Biologics License)

57. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to Code section 4301, subdivisions (j) and (o), and 42 U.S. Code section 262, subdivision (a)(1)(A), in that between January 1, 2020, and March 8, 2021, Respondent shipped at least 301 orders and 956 vials of Thymosin beta-4 3,000mcg/ml and 224 orders and 297 vials of Thymosin Beta-4 6,000mcg/ml into California, without a Biologics license to introduce or deliver it into interstate commerce.

TWENTIETH CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

58. Respondent's Nonresident Pharmacy Permit is subject to discipline pursuant to CCR, section 1761, subdivision (a), in on or about January 6, 2021, Respondent dispensed prescription number 239204 to patient CM without calling the prescriber to obtain the information needed to validate the prescription and that the prescription number 239204 lacked directions for use.

[7] Based on the previous evidence, this is also expected to be true for least 549 orders and 1,217 vials of Thymosin Alpha-1-3000mcg/ml injectable and 471 orders and 657 vials of CJC-1295 / Ipamorelin acetate 1200mcg/3,000mcg/ml injectables sold into California.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Failure to Provide a Consultation)

59. Respondent's Nonresident Pharmacy Permit is subject to disciplinary action under Code section 1707.2(a)(4), in that on or about January 6, 2021, Respondent dispensed prescription number 239204 to patient CM for Thymosin Alpha-1 300mcg/ml, a new prescription, and failed to provide the required consultation.

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Failure to Properly Receive an Orally Transmitted Prescription)

60. Respondent's Nonresident Pharmacy Permit is subject to disciplinary action under Code section 1717, subdivision (c), in that on or about January 5, 2021, technician C.Y., who was not a pharmacist, received a prescription for patient CM for Thymosin Alpha-1 300mcg/ml that failed to document any directions for use.

TWENTY-THIRD CAUSE FOR DISCIPLINE

(Out of State Discipline)

61. Respondent's Nonresident Pharmacy Permit pharmacy permit is subject to discipline under Code section 4301, subdivision (n), in that Respondent was disciplined as a pharmacy by an out of state agency as follows: On or about August 18, 2021, in the case entitled *In the Matter of: Archway Apothecary, LLC*, Case No. 21-0097, the Louisiana Board of Pharmacy (Louisiana Board) entered into a Consent Agreement with Respondent in which Respondent pled no contest to violating Louisiana Revised Statute, Tit. 37, section 1241, subdivision (A)(1), and Louisiana Administrative Code, Tit. 46, section 2535, in that Respondent practiced improper sterile compounding in violation of 503A of the Food, Drug and Cosmetic Act. As a result, Respondent ordered to pay a fine of $25,000, ordered to reimburse the Louisiana Board $250.00 for administrative costs, and ordered to pay $2,236.49 for investigative costs.

OTHER MATTERS

62. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 1974 or on Nonresident Sterile Compounding Pharmacy Permit No. NSC 101128 issued to Archway Apothecary LLC, with Carl Hayden Camp as President/53%

Shareholder, Stephen M. Camp as Member/30% Shareholder, Matthew William Hardey as Secretary/Treasurer/Chief Financial Officer/17% Shareholder, and Earl Raymond Wilkes, Jr. Pharmacist-in-Charge, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five (5) years if either or both of the pharmacy permits are placed on probation; or, 2) if either or both of the pharmacy permits are revoked, the prohibition shall continue until either of the permits are reinstated.

PRAYER

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

1. Revoking or suspending Nonresident Pharmacy Permit Number NRP 1974, issued to Archway Apothecary LLC, with Carl Hayden Camp as President/53% Shareholder, Stephen M. Camp as Member/30% Shareholder, Matthew William Hardey as Secretary/Treasurer/Chief Financial Officer/17% Shareholder, and Earl Raymond Wilkes, Jr. Pharmacist-in-Charge;

2. Revoking or suspending Nonresident Sterile Compounding Pharmacy Permit Number NSC 101128, issued to Archway Apothecary LLC, with Carl Hayden Camp as President/53% Shareholder, Stephen M. Camp as Member/30% Shareholder, Matthew William Hardey as Secretary/Treasurer/Chief Financial Officer/17% Shareholder, and Earl Raymond Wilkes, Jr. Pharmacist-in-Charge;

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

5. Prohibiting Stephen M. Camp from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

6. Prohibiting Matthew William Hardey 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;

7. Prohibiting Earl Raymond Wilkes, Jr. 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;

8. Ordering Archway Apothecary 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,

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

DATED: 1/27/2022

Signature on File

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

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