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

**In the Matter of the Accusation; Statement of Issues; and Statement of Issues Against:**

**OLYMPIA PHARMACY,**
**MARCO LOLEIT, CEO/SECRETARY/TREASURER/CFO,**
**Nonresident Pharmacy Permit No. NRP 1525,**
**Nonresident Sterile Compounding Permit No. NSC 100818;**

**OLYMPIA PHARMACY,**
**Applicant for Renewal of Nonresident Sterile Compounding Permit No. NSC 100818;**

**and**

**OPS INTERNATIONAL INCORPORATED, dba**
**OLYMPIA PHARMACY,**
**MARCO LOLEIT, CEO AND OWNER,**
**Nonresident Pharmacy Permit Applicant,**
**Nonresident Sterile Compounding Permit Applicant,**

**Respondents.**

**Agency Case No. 7088, 7089 & 7384**

**OAH Nos. 2022110620, 2022110622 & 2022110624**

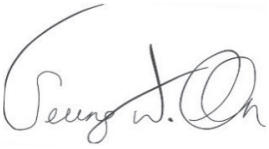
# DECISION AND ORDER

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 May 23, 2024.

It is so ORDERED on April 23, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
KAREN R. DENVIR
Supervising Deputy Attorney General
STEPHANIE ALAMO-LATIF
Deputy Attorney General
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*Attorneys for Complainant*

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

| | |
|---|---|
| In the Matters of the Accusation; Statement of Issues; and Statement of Issues Against:<br><br>**OLYMPIA PHARMACY**<br>**MARCO LOLEIT,**<br>**CEO/SECRETARY/TREASURER/CFO**<br>6700 Conroy Road, Suite 155<br>Orlando, FL 32835<br>**Nonresident Pharmacy Permit No. NRP 1525**<br>**Nonresident Sterile Compounding Permit No. NSC 100818**<br><br>**And**<br><br>**OLYMPIA PHARMACY**<br>**Applicant for Renewal of Nonresident Sterile Compounding Permit No NSC100818**<br><br>**And**<br><br>**OPS INTERNATIONAL INCORPORATED, DBA OLYMPIA PHARMACY; MARCO LOLEIT, CEO AND OWNER**<br>**Nonresident Pharmacy Permit Applicant**<br>**Nonresident Sterile Compounding Permit Applicant**<br><br>Respondents. | Case Nos. 7088, 7089, and 7384<br><br>OAH Nos. 2022110620, 2022110622, and 2022110624<br><br>**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 Stephanie Alamo-Latif, Deputy Attorney General.

2. Respondent Olympia Pharmacy (Respondent) is represented in this proceeding by attorney Joe LaMagna, Hooper, Lundy & Bookman, P.C.

3. On or about November 12, 2015, the Board issued Nonresident Pharmacy Permit No. NRP 1525 to Respondent. The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 7088, and will expire on November 1, 2024, unless renewed.

4. On or about December 15, 2015, the Board issued Nonresident Sterile Compounding Permit No. NSC 100818 to Respondent. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 7088, and expired on November 1, 2022. Prior to its expiration, Respondent applied for the renewal of Nonresident Sterile Compounding Permit No. NSC 100818. On or about September 16, 2022, Respondent's application for renewal was denied. On or about September 21, 2022, Respondent timely appealed the renewal denial.

5. On or about March 23, 2020, the Board received applications for a Nonresident Pharmacy Permit and a Nonresident Sterile Compounding Permit from OPS International Incorporated, doing business as Olympia Pharmacy, with Marco Loleit as its Chief Executive Officer and 100% stockholder (Respondent). The Board denied the applications on or about December 22, 2020. On or about December 29, 2020, Respondent timely appealed the application denials.

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## JURISDICTION

6. Third Amended Accusation No. 7088 was filed before the Board, and is currently pending against Respondent. The parties have agree to file a Third Amended Accusation upon signing of this agreement, which will be the operative pleading in this matter. The Accusation and all other statutorily required documents were properly served on Respondent on December 15, 2022. Respondent timely filed its Notice of Defense contesting the Accusation.

7. A copy of Third Amended Accusation No. 7088 is attached as exhibit A and incorporated herein by reference.

8. Second Amended Statement of Issues Number 7089 was filed before the Board, and is currently pending against Respondent. The Second Amended Statement of Issues and all other statutorily required documents were properly served on Respondent on March 8, 2024. Respondent timely filed a request for hearing.

9. A copy of Second Amended Statement of Issues No. 7089 is attached as exhibit B and incorporated herein by reference.

10. First Amended Statement of Issues Number 7384 was filed before the Board, and is currently pending against Respondent. The First Amended Statement of Issues and all other statutorily required documents were properly served on Respondent on December 16, 2022. Respondent timely filed a request for hearing.

11. A copy of First Amended Statement of Issues No. 7384 is attached as exhibit C and incorporated herein by reference.

## ADVISEMENT AND WAIVERS

12. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Third Amended Accusation No. 7088, Second Amended Statement of Issues No. 7089, and First Amended Statement of Issues No. 7384. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

13. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Third Amended Accusation No. 7088, Second

Amended Statement of Issues No. 7089, and First Amended Statement of Issues No. 7384; 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.

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

**CULPABILITY**

15. Respondent understands and agrees that the charges and allegations in Third Amended Accusation No. 7088, Second Amended Statement of Issues No. 7089, and First Amended Statement of Issues No. 7384, if proven at hearing, constitute cause for imposing discipline upon its Nonresident Pharmacy Permit NRP 1525 and Nonresident Sterile Compounding Permit No. NSC 100818, and denial of its application for its renewal of Nonresident Sterile Compounding Permit No. NSC 100818, and denial of its applications for a new Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit.

16. For the purpose of resolving Third Amended Accusation No. 7088, Second Amended Statement of Issues No. 7089, and First Amended Statement of Issues No. 7384, without the expense and uncertainty of further proceedings, Respondent agrees that, at hearing, Complainant could establish a factual basis for the charges against it in Third Amended Accusation No. 7088, Second Amended Statement of Issues No. 7089, and First Amended Statement of Issues No. 7384, and that Respondent hereby gives up its right to contest those charges.

17. Respondent agrees that in any future disciplinary proceeding before the Board the allegations set forth in Third Amended Accusation No. 7088, Second Amended Statement of Issues No. 7089, and First Amended Statement of Issues No. 7384, shall be deemed admitted.

18. Respondent agrees that its Nonresident Pharmacy Permit NRP 1525 and Nonresident Sterile Compounding Permit No. NSC 100818 are subject to discipline, the application for renewal of its Nonresident Sterile Compounding Permit No. NSC 100818 is subject to denial, and

the applications for a new Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit are subject to denial (Statement of Issues Case Number 7089) and it agrees to be bound by the Board's Disciplinary Orders and the probationary terms as set forth in the Disciplinary Order below.

**CONTINGENCY**

19. 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.

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

21. 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.

22. 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 Stipulation and Disciplinary Orders:

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**STIPULATION- First Amended Statement of Issues No. 7384 Only**

Respondent hereby withdraws its appeal and request for hearing on the denial of its renewal application for a Nonresident Sterile Compounding Permit, because a new Nonresident Sterile Compounding Permit may be granted pursuant to the below Disciplinary Order related to the Third Amended Accusation No. 7089.

**DISCIPLINARY ORDER- Third Amended Accusation No. 7088 Only**

IT IS HEREBY ORDERED that Nonresident Pharmacy Permit No. NRP 1525, and Nonresident Sterile Compounding Permit No. NSC 100818 issued to Respondent Olympia Pharmacy, shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Third Amended Accusation No. 7088.

This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

**1. Cost Recovery**. Respondent shall pay $153,676.75 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3, prior to issuance of a new or reinstated license.

**2. Cancellation of Permits.** Nonresident Pharmacy Permit No. NRP 1525, and Nonresident Sterile Compounding Permit No. NSC 100818, shall be immediately cancelled, due to the new applications filed by Respondent and the settlement in Second Amended Statement of Issues No. 7089, subject to the following terms:

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

If Respondent ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Third Amended Accusation No. 7088 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition. The Board shall not deny any future applications for licensure or petitions for reinstatement based solely on the charges and

allegations contained in the Third Amended Accusation No. 7088, but the Board may consider the allegations during its review of any future applications for licensure or petitions for reinstatement.

**DISCIPLINARY ORDER - Second Amended Statement of Issues No. 7089 Only**

IT IS HEREBY ORDERED that upon satisfaction of all statutory and regulatory requirements for issuance of a Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit, including passing the required inspection as a condition precedent to licensure, a Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit shall be issued to Respondent and immediately revoked; the order of revocation is stayed and Respondent is placed on probation for four (4) years upon the following terms and conditions.

IT IS FURTHER ORDERED that if Respondent fails to pass the required pre-licensure inspection, then Respondent's applications shall be denied.

IT IS FURTHER ORDERED that as a condition precedent to licensure, Respondent shall pay the agency its costs of investigation and enforcement in the amount of $153,676.75 prior to issuance of a new or reinstated license, pursuant to the Order in Third Amended Accusation No. 7088.

1. **Definition: Respondent**

For the purposes of these terms and conditions, "respondent" shall refer to Olympia Pharmacy, and OPS International Incorporated, doing business as Olympia Pharmacy. All terms and conditions stated 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, any 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; or
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous drug, and/or dangerous device or controlled substance.

Failure to timely report any 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. 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.

4. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent shall appear in person, via teleconference, or via video conference, 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 the 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. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. These costs will include travel costs for Board inspectors to inspect Respondent's physical facility on a quarterly basis or lesser frequency as determined by the Board or its designee. 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.

7. **Status of License/Permit**

Respondent shall, at all times while on probation, maintain a current Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit with the board. Failure to maintain current licensure shall be considered a violation of probation.

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

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

Following the effective date of this decision, should respondent wish to discontinue business, respondent may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer within five (5) days. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs and/or devices to premises licensed and approved by the board.

Respondent shall also, by the effective date of the discontinuation of business in California, arrange for the continuation of care for ongoing California patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy, or discontinuation of business in California, and that identifies one or more California licensed pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those California patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent may not apply for any new license from the board for three (3) years from the effective date of the surrender, and should any future license be granted, Respondent will be required to complete its probation term set forth in this Decision and Order. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent further stipulates that it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. **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.

10. **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 this 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 fifteen (15) 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.

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

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its 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.

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12. **Premises Open for Business**

Respondent shall remain open and engaged in its ordinary business as a Nonresident Pharmacy and Nonresident Sterile Compounding pharmacy licensed in California for a minimum of 100 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 and Nonresident Sterile Compounding pharmacy licensed for a minimum of 100 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 and Nonresident Sterile Compounding pharmacy licensed in California for a minimum of 100 hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

13. **Posted Notice of Probation**

Respondent shall prominently post a probation notice provided by the board or its designee in a place conspicuous to and readable by the public within two (2) days of receipt thereof from the board or its designee. 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 prominently post a probation notice on its website. Posting on the website shall be on Respondent's homepage may be through the use of a banner with a link labeled "Notice to California Patients," which shall be in a font size of at least 12 point and takes you to the Board's probation notice. The probation notice shall be provided by the Board or its designee

and must be posted on Respondent's website's homepage within thirty (30) days after receipt. As an alternative to posting the probation notice on its website, Respondent may provide a copy of the notice of probation in all drug or device shipments to California. Respondent shall notify the Board or its designee in writing whether the posting is on its website or in all drug or device shipments to California and may not switch the method of posting without providing the same notice in writing to the Board. Failure to timely post or provide such notice, or to maintain the posting or provide the notice 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.

14. **Violation of Probation**

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall be automatically 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.

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, 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.

15. **Completion of Probation**

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

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16. **Consultant**

Within 90 days of the effective date of this Decision and Order, Respondent shall submit to the board the name of an expert familiar with sterile compounding to act as an expert consultant subject to the prior approval of the board or its designee. The consultant shall be a California licensed pharmacist and not on probation with the Board or any other professional organization. The consultant shall be responsible for conducting quarterly inspections, or lesser frequency as determined by the Board or its designee, of the facility for compliance with the provisions of California and federal law and the terms and conditions of probation. The consultant shall provide the board with an inspection agenda for approval prior to conducting the inspection. Any inspection conducted without prior approval of the inspection agenda shall not be accepted. The consultant shall also provide the board with reports documenting their inspection. The consultant shall provide the written reports directly to the board, and receive confirmation of receipt from the board, prior to providing the report to the respondent. Should the board or its designee determine that the consultant is not appropriately assessing the operations of respondent, or providing the appropriate written reports, the board or its designee shall require respondent to obtain a different consultant through the same process outlined above, by submitting a new expert for approval within 60 days of Respondent being notified of the need for a new consultant.

17. **Pharmacist In Charge licensed in California**

Within 60 days of the effective date of this Decision and Order, Respondent shall employ a Pharmacist-in-Charge (PIC) specific to California and who maintains a pharmacist license issued by the California State Board of Pharmacy, with the designation process set forth in Business and Profession Code section 4113.

## ACCEPTANCE

I, Marco Loleit, have been authorized to act on Respondent's behalf in this matter, and have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with Respondent's attorney, Joe LaMagna. I understand the stipulation and the effect it will have Respondent's Nonresident Pharmacy Permit No. NRP 1525, Nonresident Sterile Compounding Permit No. NSC 100818, application for renewal of Nonresident Sterile Compounding Permit No.

NSC 100818, and new applications for a Nonresident Pharmacy Permit and a Nonresident Sterile Compounding Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and Respondent Olympia agrees to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

OLYMPIA PHARMACY
By Marco Loleit
*Respondent*

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

DATED: _____

JOE LAMAGNA
*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
KAREN R. DENVIR
Supervising Deputy Attorney General

STEPHANIE ALAMO-LATIF
Deputy Attorney General
*Attorneys for Complainant*

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NSC 100818, and new applications for a Nonresident Pharmacy Permit and a Nonresident Sterile Compounding Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and Respondent Olympia agrees to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 3/15/24

OLYMPIA PHARMACY
By Marco Loleit
*Respondent*

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

DATED: March 15, 2024

JOE LAMAGNA
*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
KAREN R. DENVIR
Supervising Deputy Attorney General

STEPHANIE ALAMO-LATIF
Deputy Attorney General
*Attorneys for Complainant*

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NSC 100818, and new applications for a Nonresident Pharmacy Permit and a Nonresident Sterile Compounding Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and Respondent Olympia agrees to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

OLYMPIA PHARMACY
By Marco Loleit
*Respondent*

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

DATED: _____

JOE LAMAGNA
*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
KAREN R. DENVIR
Supervising Deputy Attorney General

Stephanie Alamo-Latif
Digitally signed by Stephanie Alamo-Latif
Date: 2024.03.15 14:45:15 -07'00'

STEPHANIE ALAMO-LATIF
Deputy Attorney General
*Attorneys for Complainant*

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# Exhibit A

## Third Amended Accusation No. 7088

ROB BONTA
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KAREN R. DENVIR
Supervising Deputy Attorney General
STEPHANIE ALAMO-LATIF
Deputy Attorney General
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*Attorneys for Complainant*

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

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| In the Matter of the Third Amended Accusation Against:<br><br>**OLYMPIA PHARMACY**<br>**MARCO LOLEIT,**<br>**CEO/SECRETARY/TREASURER/CFO**<br>6700 Conroy Road, Suite 155<br>Orlando, FL 32835<br><br>**Nonresident Pharmacy Permit No. NRP 1525**<br>**Nonresident Sterile Compounding Permit No. NSC 100818**<br><br>Respondent. | Case No. 7088<br><br>**THIRD AMENDED ACCUSATION** |

## PARTIES

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

**Nonresident Pharmacy Permit**

2. On or about November 12, 2015, the Board issued Nonresident Pharmacy Permit Number NRP 1525 to Olympia Pharmacy, with Marco Loleit, as its Chief Executive Officer, Chief Financial Officer, Secretary and Treasurer (Respondent). The Nonresident Pharmacy

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Permit was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2023, unless renewed.

**Nonresident Sterile Compounding Permit**

3. On or about December 15, 2015, the Board issued Nonresident Sterile Compounding Permit Number NSC 100818 to Respondent. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein, expired on November 1, 2022, and was cancelled, the circumstances of which are set forth below.

**JURISDICTION**

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

> (a) Every license issued may be suspended or revoked.
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> (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:
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> (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.
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> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper. . . .
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> (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

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with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

**STATUTORY PROVISIONS**

7. Code section 4301 states, in pertinent part:

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

. . .

(c) Gross negligence.

. . .

(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, of any other state, or of the United States regulating controlled substances and dangerous drugs.

…

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

8. Code section 4307 states, in pertinent part:

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

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

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

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9. Code section 4022 states, in pertinent part:

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

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

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

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

10. Code section 4076 states, in pertinent part:

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

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

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

(3) The name of the patient or patients.

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

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

(i) Prescriptions dispensed by a veterinarian.

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

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

(B) This paragraph applies to outpatient pharmacies only.

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

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

11. Code section 4123 states, in pertinent part:

Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commending that compounding.

12. Code section 4126.8 states,

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

13. Code section 4127.2 states, in pertinent part:

. . .

(e) A pharmacy licensed pursuant to this section shall do all of the following:

. . .

(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.

. . .

(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 4129, subdivision (a), states,

A facility licensed as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the board as an outsourcing

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facility if it compounds sterile medication or nonsterile medication for non-patient-specific distribution within or into California. . . .

15. Code section 4129.2 states, in pertinent part:

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

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

16. Code section 4169, subdivision (a), states, in pertinent part:

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. . . .

**HEALTH AND SAFETY CODE**

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

18. Health & Saf. Code, section 111255, states, "Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."

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

20. Health and Saf. Code, section 111330, states, "Any drug or device is misbranded if its labeling is false or misleading in any particular."

21. Health and Saf. Code, section 111335, states, "Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

22. Health and Saf. Code section 111430 states, "A drug or device is misbranded if it was manufactured in an establishment not duly registered with the Secretary of Health, Education, and Welfare of the United States."

23. Health and Saf. Code section 111440 states, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

24. Health and Saf. Code section 111445 states, "It is unlawful for any person to misbrand any drug or device."

25. Health and Saf. Code section 111445 states, "It is unlawful for any person to misbrand any drug or device."

**CALIFORNIA REGULATIONS**

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

> . . .
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> (b)
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> (1) When the patient or patient's agent is not present (including, but not limited to, a prescription drug that was shipped by mail or delivery), a pharmacy shall ensure that:
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> (A) the patient receives written notice of his or her right to request consultation;
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> (B) the patient receives written notice of the hours of availability and the telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record; and
>
> (C) a pharmacist shall be available (i) to speak to the patient or patient's agent during any regular hours of operation, within an average of ten (10) minutes or less, unless a return call is scheduled to occur within one business hour, (ii) for no less than six days per week, and (iii) for a minimum of 40 hours per week. . . .

27. CCR section 1707.5, states, in pertinent part:

> (a) Labels on drug containers dispensed to patients in California shall conform to the following format:

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(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

. . .

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

. . .

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

28. CCR section 1714, subdivision (b), states, "Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

29. CCR section 1735.1, subdivision (ae), states, "'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."

30. CCR section 1735.2 states, in pertinent part:

(a) Except as specified in (b) and (c), no drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) "A reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that:

(1) Is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; and

(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and

(3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and

(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:

. . .

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

. . .

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula documents that includes at least the following elements:

. . .

(5) Specific and essential compounding steps used to prepare the drug.

. . .

(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.

. . .

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

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(A) Method Suitability Test,
(B) Container Closure Integrity Test, and
(C) Stability Studies

. . .

31. 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.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation

(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.

. . .

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

. . .

(C) Stability Studies . . . .

32. CCR section 1735.4 states, in pertinent part:

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

. . .

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

. . .

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

33. CCR section 1735.5 states, in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written polies and procedures shall constitute a basis for disciplinary action.

. . .

34. CCR section 1735.8 states, in pertinent part:

. . .

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength. . . .

35. CCR section 1751.2 states, in pertinent part:

In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, a pharmacy that compounds sterile drug preparations shall include the following information on the label for each such preparation:

(b) Instructions for storage, handling, and administration. . . .

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36. CCR section 1751.4 states, in pertinent part:

(a) No sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations.

. . .

(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISAO Class 5 PEC frequently, including:

(1) At the beginning of each shift;

(2) At least every 30 minutes when compounding involving human staff is occurring or before each lot;

(3) After each spill; and

(4) When surface contamination is known or suspected. . . .

37. CCR section 1751.6, subdivision (e), states, in pertinent part:

Pharmacies that compound sterile drug preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(F) Proper hand hygiene, gowning and gloving technique. . . .

38. CCR section 1751.8 states, in pertinent part:

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation….

**FEDERAL STATUTES AND REGULATIONS**

39. United States Code Annotated, title 21 (21 USCA) section 321 states, in pertinent part:

. . .

(ff) The term "dietary supplement" –

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

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

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

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

(2) Means a product that –

(A)

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

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

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

(C) is labeled as a dietary supplement; and

(3) does-

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

(B) not include-

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

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

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

40. 21 USCA section 331 states, in pertinent part:

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded. . . .

41. 21 USCA section 350 states, in pertinent part:

. . .

(c) Definitions

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

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

(B) which-

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

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

42. 21 USCA section 351 states, in pertinent part:

A drug or device shall be deemed to be adulterated –

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

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

(2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act [21 USCA §§ 301 et seq.] as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this Act [21 USCA §§ 301 et seq.] as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of

coloring only, a color additive which is unsafe within the meaning of section 721(a) [21 USCA § 379e(a)], or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 721(a) [21 USCA § 379e(a)]; or (5) if it is a new animal drug which is unsafe within the meaning of section 512 [21 USCA § 360b]; or (6) if it is an animal feed bearing or contaminating a new animal drug, and such animal feed is unsafe within the meaning of section 512 [21 USCA § 360f].

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

43. 21 USCA section 352 states, in pertinent part:

A drug or device shall be deemed to be misbranded—

. . .

(o) Drugs or devices from nonregistered establishments. If it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 [21 USCA § 360], if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 801(s) [21 USCA § 381(s)], if it was not included in a list required by section 510(j) [21 USCA § 360(j)], if a notice or other information respecting it was not provided as required by such section or section 510(k) [21 USCA § 360(k)], or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 510(e) [21 USCA § 360(e)] as the Secretary by regulation requires. . . .

44. 21 USCA section 353a states, in pertinent part:

(a) In general. Sections 501(a)(2)(B), 502(f)(1), and 505 [21 USCA §§ 351(a)(2)(B), 352(f)(1), and 355] shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

(1) is by—

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

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

(2)

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

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

(i) the licensed pharmacist or licensed physician; and

(ii)

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

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

(b) Compounded drug.

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

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

(i) that—

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

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

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

(ii) that are manufactured by an establishment that is registered under section 510 [21 USCA § 360] (including a foreign establishment that is registered under section 510(i) [21 USCA § 360(i)]); and

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

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

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or

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removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(2) Definition. For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

(3) Drug product. A drug product may be compounded under subsection (a) only if—

(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) such drug product is compounded in a State—

(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

…

(e) "Compounding" defined. As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

45. 21 USCA section 353b states, in pertinent part:

(a) In general. Sections 502(f)(1), 505, and 582 [21 USCA §§ 352(f)(1), 355, and 360eee-1] shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met:

(1) Registration and reporting. The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (b).

(2) Bulk drug substances. The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless—

(A)
(i) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by—

(I) publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;

(II) providing a period of not less than 60 calendar days for comment on the notice; and

(III) publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or

(ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 506E [21 USCA § 356e] at the time of compounding, distribution, and dispensing;

(B) if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substances each comply with the monograph;

(C) the bulk drug substances are each manufactured by an establishment that is registered under section 510 [21 USCA § 360] (including a foreign establishment that is registered under section 510(i)) [21 USCA § 360(i)]; and

(D) the bulk drug substances are each accompanied by a valid certificate of analysis.

(3) Ingredients (other than bulk drug substances) If any ingredients (other than bulk drug substances) are used in compounding the drug, such ingredients comply with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph if any.

(4) Drugs withdrawn or removed because unsafe or not effective. The drug does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

(5) Essentially a copy of an approved drug. The drug is not essentially a copy of one or more approved drugs.

(6) Drugs presenting demonstrable difficulties for compounding. The drug—

(A) is not identified (directly or as part of a category of drugs) on a list published by the Secretary, through the process described in subsection (c), of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients; or

(B) is compounded in accordance with all applicable conditions identified on the list described in subparagraph (A) as conditions that are necessary to prevent the drug or category of drugs from presenting the demonstrable difficulties described in subparagraph (A).

(7) Elements to assure safe use. In the case of a drug that is compounded from a drug that is the subject of a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 505-1 [21 USCA § 355-1], or from a bulk drug substance that is a component of such drug, the outsourcing facility demonstrates to the Secretary prior to beginning compounding that such facility will utilize controls comparable to the controls applicable under the relevant risk evaluation and mitigation strategy.

(8) Prohibition on wholesaling. The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. This paragraph does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 503(b)(1) [21 USCA § 353(b)(1)].

(9) Fees. The drug is compounded in an outsourcing facility that has paid all fees owed by such facility pursuant to section 744K [21 USCA § 379j-62].

(10) Labeling of drugs.

(A) Label. The label of the drug includes—

(i) the statement "This is a compounded drug." or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

(ii) the name, address, and phone number of the applicable outsourcing facility; and

(iii) with respect to the drug—

(I) the lot or batch number;

(II) the established name of the drug;

(III) the dosage form and strength;

(IV) the statement of quantity or volume, as appropriate;

(V) the date that the drug was compounded;

(VI) the expiration date;

(VII) storage and handling instructions;

(VIII) the National Drug Code number, if available;

(IX) the statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only"; and

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(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

(B) Container. The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include—

(i) the information described under subparagraph (A)(iii)(X), if there is not space on the label for such information;

(ii) the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088 (or any successor Internet Web site or phone number); and

(iii) directions for use, including, as appropriate, dosage and administration.

(C) Additional information. The label and labeling of the drug shall include any other information as determined necessary and specified in regulations promulgated by the Secretary.

(11) Outsourcing facility requirement. The drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section.

(b) Registration of outsourcing facilities and reporting of drugs.

. . .

(2) Drug reporting by outsourcing facilities.

(A) In general. Upon initially registering as an outsourcing facility, once during the month of June of each year, and once during the month of December of each year, each outsourcing facility that registers with the Secretary under paragraph (1) shall submit to the Secretary a report—

(i) identifying the drugs compounded by such outsourcing facility during the previous 6-month period; and

(ii) with respect to each drug identified under clause (i), providing the active ingredient, the source of such active ingredient, the National Drug Code number of the source drug or bulk active ingredient, if available, the strength of the active ingredient per unit, the dosage form and route of administration, the package description, the number of individual units produced, and the National Drug Code number of the final product, if assigned.

. . .

(4) Risk-based inspection frequency.

(A) In general. Outsourcing facilities—

(i) shall be subject to inspection pursuant to section 704 [21 USCA § 374]; and

(ii) shall not be eligible for the exemption under section 704(a)(2)(A) [21 USCA § 374(a)(2)(A)].

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(B) Risk-based schedule. The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect outsourcing facilities in accordance with a risk-based schedule established by the Secretary.

(C) Risk factors. In establishing the risk-based schedule, the Secretary shall inspect outsourcing facilities according to the known safety risks of such outsourcing facilities, which shall be based on the following factors:

(i) The compliance history of the outsourcing facility.

(ii) The record, history, and nature of recalls linked to the outsourcing facility.

(iii) The inherent risk of the drugs compounded at the outsourcing facility.

(iv) The inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has been inspected pursuant to section 704 [21 USCA § 374] within the last 4 years.

(v) Whether the outsourcing facility has registered under this paragraph as an entity that intends to compound a drug that appears on the list in effect under section 506E [21 USCA § 356e].

(vi) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(5) Adverse event reporting. Outsourcing facilities shall submit adverse event reports to the Secretary in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).

. . .

(d) Definitions. In this section:

(1) The term "compounding" includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

(2) The term "essentially a copy of an approved drug" means—

(A) a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 503(b) [21 USCA § 353(b)] and not subject to approval in an application submitted under section 505 [21 USCA § 355], unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 506E [21 USCA § 356e] at the time of compounding, distribution, and dispensing; or

(B) a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 503(b) [21 USCA § 353(b)] and not subject to approval in an application submitted under section 505 [21 USCA § 355], unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

(3) The term "approved drug" means a drug that is approved under section 505 [21 USCA § 355] and does not appear on the list described in subsection (a)(4) of

drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective. . . .

46. Code of Federal Regulations, title 21 (CFR), section 1302.03 states, in pertinent part:

(a) Each commercial container of a controlled substance (except for a controlled substance excepted by the Administrator pursuant to § 1308.31 of this chapter) shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. Each such commercial container, if it otherwise has no label, must bear a label complying with the requirement of this part.

(b) Each manufacturer shall print upon the labeling of each controlled substance distributed by him the symbol designating the schedule in which such controlled substance is listed.

(c) The following symbols shall designate the schedule corresponding thereto:

| Schedule | |
|---|---|
| Schedule I | CI or C-I. |
| Schedule II | CII or C-II. |
| Schedule III | CIII or C-III. |
| Schedule IV | CIV or C-IV. |
| Schedule V | CV or C-V. |

The word "schedule" need not be used. No distinction need be made between narcotic and nonnarcotic substances. . . .

**COST RECOVERY**

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

**DEFINITIONS**

48. **Aseptic process simulations** (APS), also known as media fill, are studies conducted on the aseptic filling process, which is simulated to the actual production procedure where the product is replaced with growth media.

49. **Fingertip Sampling Test** is a required USP <797> test to assess the aseptic technique of compounding personnel. The test assesses the amount of microbial contamination present on the workers' gloved fingers.

50. **Food Chemical Codex (FCC)**. The FCC and associated Reference Materials enables you to verify the identity, quality, and purity of the food ingredients you buy and sell, which help to ensure the overall safety and integrity of the food ingredient supply chain. An FCC standard can be used to characterize ingredients used in food. Monographs in the FCC consist of tests and specifications for identification, assay and impurities, as well as other tests that help describe the purity and quality of the ingredient. FCC standards are reviewed and approved by independent experts.

51. **ISO-Class 5 Environment** is an atmospheric environment that has less than 100 particles >0.5 microns or larger per cubic foot in compliance with the ISO/TC209 International Cleanroom Standards.

52. **Lyophilization** is a low temperature dehydration process where the product is frozen, the pressure lowered, and ice removed by sublimation. Lyophilization allows for ease of storage, shipping, and reconstitution to the product's original form for injection.

53. **Methionine** is a sulfur-containing essential amino acid that is a constituent of most proteins.

54. **Out-of-Specification Investigation**. A required element of the Quality Assurance Plan required as described in CCR section 1735.8 in response to a product test result outside its specification limits. A written procedure, i.e., SOP, must exist that describes the methodology for performing an OOS investigation. OOS investigations must be documented.

55. **"Prescriber's Office" or "prescriber office"** as defined by 16 CCR 1735.1, subdivision (aa), means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.

56. **Settle Plates**, also known as sedimentation plates or settling plates, are used in the pharmaceutical industry for semi-quantitative determination of microbial contamination in the air. The plate is typically a petri dish containing an agar medium. The plate is opened and exposed

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over a given period of time, allowing microbe-bearing particles to deposit onto the plate. The number of microbe bearing particles deposited onto the agar surface of the plate over the period of exposure is ascertained by incubating the plate and counting the number of microbial colonies (colony-forming units, [CFUs]).

57. **Standard Operating Procedure (SOP)** is a documented method or set of written directions to complete a specific process(es).

58. **USP 797** is a publication issued by the United States Pharmacopeia (USP) that sets forth standards for preparing compounded sterile preparations (CSPs).

59. **USP-NF** is the United States Pharmacopeia-National Formulary, a comprehensive source for over 5,000 quality standards for medicines, active pharmaceutical ingredients (API), and inactive ingredients.

60. **USP Monographs**. USP-NF publishes monographs that articulate the quality expectations for medicines approved by the U.S. Food and Drug Administration (US FDA), including the medication identity, strength, purity and performance. Monographs also describe the tests to validate that a medicine and its ingredients meet USP-NF criteria.

**DRUG DESCRIPTIONS**

61. **Amino Blend Injection**, compounded by Respondent, contains glutamine, ornithine hydrochloride, arginine hydrochloride, lysine hydrochloride, citrulline, levocarnitine, benzyl alcohol, and sterile water for injection (SWFI). It is a dangerous drug within the meaning of Code section 4022. There is no FDA approved indication for this drug.

62. **Ascorbic acid injection** (brand name *Acor*®) is indicated for short term treatment of scurvy in patients for whom oral administration is not possible, insufficient, or contraindicated. It is a dangerous drug within the meaning of Code section 4022.

63. **Bacteriostatic water** is a sterile, nonpyrogenic preparation of water for injection used to dilute or dissolve drugs for injection, and is a dangerous drug within the meaning of Code section 4022.

64. **Biotin injection,** compounded by Respondent, is a dangerous drug within the meaning of Code section 4022. There is no FDA approved indication for this drug.

65. **Benzocaine/Lidocaine/Tetracaine (BLT), Formula ID #7409,** compounded by Respondent, is a non-sterile drug preparation for topical application.

66. **Butylated hydroxytoluene (BHT)** is a synthetic organic chemical compounding which inhibits oxidation of unsaturated organic compounds. It is often used in food, cosmetics, and pharmaceutical applications to prevent oxidation.

67. **Formula ID #6924**, non-sterile preparations, compounded by Respondent, is comprised of minoxidil/ fluocinolone/retinoic acid 5/0.01/0.01%.

68. **Human Chorionic Gonadotropin (HCG) injection**, compounded by Respondent, is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (f)(32), and a dangerous drug within the meaning of Code section 4022.

69. **Gluthathione injection**, compounded by Respondent, is a dangerous drug within the meaning of Code section 4022. There is no FDA approved indication for this drug.

70. **Lipo-Mino-Mix injection**, compounded by Respondent, is comprised of amino acids, including methionine, and B vitamins, and is a dangerous drug pursuant to Code section 4022.

71. **LipoStat Plus Injection**, compounded by Respondent, contains methionine, choline chloride, inositol, hydroxocobalamin hydrochloride (vitamin B12), pyridoxine hydrochloride (vitamin B6), benzyl alcohol, and SWFI. It is a dangerous drug within the meaning of Code section 4022. There is no FDA approved indication for this drug.

72. **NAD/NAD+,** is Nicotinamide Adenine Diculeotide, a central oxidation/reduction cofactor for various metabolic processes.

73. **Olympia Vita-Complex Injection**, compounded by Respondent, contains thiamine hydrochloride (vitamin B1), niacinamide (vitamin B3), riboflavin (vitamin B2), dexpanthenol (vitamin B5), pyridoxine hydrochloride (vitamin B6), benzyl alcohol, and SWFI. It is a dangerous drug within the meaning of Code section 4022. There is no FDA approved indication for this drug.

74. **QM-2 injection**, compounded by Respondent, contains papaverine, phentolamine, alprostadil, and atropine. It is a dangerous drug within the meaning of Code section 4022. There is no FDA approved indication for this drug.

75. **Sermorelin Acetate injection**, compounded by Respondent, is a human growth hormone-releasing hormone (GHRH or GRF) used for diagnostic evaluation of pituitary function and also for increasing growth in children. It is a dangerous drug pursuant to Code section 4022.

76. **Testosterone Cypionate injection** (Respondent's tradename Ultratest), compounded by Respondent, comes only in the form of an injectable solution given into a muscle. It is used to treat symptoms of hypogonadism in males (a condition where males do not produce enough of the sex hormone testosterone). It is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (f)(30), and a dangerous drug pursuant to Code section 4022.

**BACKGROUND INFORMATION – MARCH 2019 INVESTIGATION**

77. On or about March 8, 2019, the Board received a complaint alleging that ascorbic acid compounded and sold by Respondent was essentially a copy of a commercially available ascorbic acid product. The complaint initiated an investigation by Board inspectors that revealed multiple violations of pharmacy laws and regulations.

78. In the course of the Board's investigation, Respondent was asked to provide documentation establishing the source of the ascorbic acid that Respondent used as the active pharmaceutical ingredient (API) to compound its injectable ascorbic acid. Respondent's Representative, "C.E." provided, *inter alia,* Certificates of Analysis (COAs) for ascorbic acid from United Foods Corporation (United Foods) and Northeast Pharmaceutical Group Co., Ltd. (Northeast). United Foods and Northeast are not registered as manufacturers with the FDA. Respondent's compounding log showed that on January 8, 2018, it used ascorbic acid from Letco, Lot No. 160630046, in its injectable ascorbic acid, Lot No. A95008. The source of Letco's ascorbic acid was Northeast, Batch No. DY026160757. The COA for Northeast Batch No. DY026160757 described Northeast's ascorbic acid as a food additive and showed levels of heavy metals, arsenic, lead, bacteria, and mercury.

79. The inspectors asked Respondent for further documentation establishing the source manufacturer of ascorbic acid for 14 lots of injectable ascorbic acid that Respondent compounded between January 8, 2018, and March 24, 2020. C.E. responded that Respondent purchased ascorbic acid from Fagron, a repackager for Shandong Luwei Pharmaceutical Co. Ltd. (Shandong

Luwei), and Medisca, a repackager for Shandong Tianli Pharmaceutical Co., Ltd. (Shandong Tianli). Shandong Luwei was listed on the COA for Fagron Batch #19E06-U01-050888, which was used in five of Respondent's lots. Other COAs produced by Respondent for ascorbic acid from Fagron did not disclose the manufacturer. Shandong Luwei and Shandong Tianli are not registered with the FDA. As depicted in the table below, between at least November 1, 2019, and March 24, 2020, Respondent compounded and furnished eleven lots of injectable ascorbic acid made with ascorbic acid obtained from sources that were not registered with the FDA.

| **Date Compounded** | **Preserved Ascorbic Acid Injectable - Respondent's Lot #** | **Compounded with Ascorbic Acid Fagron Batch #** | **Quantity of 30 ml. Vials Sold in CA** |
|---|---|---|---|
| 11/01/19 | L18001 | 19H12-U01-001508 | 66 |
| 12/04/19 | L24004 | 19E06-U01-050888 | 65 |
| 01/08/20 | A24008 | 19E06-U01-050888 | 89 |
| 01/18/20 | A41115 | 19E06-U01-050888 | 81 |
| 01/22/20 | A41122 | 19E06-U01-050888 | 70 |
| 01/29/20 | A24029 | 19E06-U01-050888 | 45 |
| 02/26/20 | B24026 | 19H12-U01-001509 | 48 |
| 03/12/20 | C41112 | 19H12-U01-001509 | 41 |
| 03/19/20 | C44019 | 19H12-U01-001509 | 53 |
| 03/20/20 | C44020 | 19H12-U01-001509 | 64 |
| 03/24/20 | C41024 | 19H12-U01-001507 | 104 |
| | | | Total 726 |

80. The inspectors found that between at least November 1, 2019, and March 24, 2020, Respondent failed to include instructions for storage, handling, and administration on labels for the eleven lots of injectable preserved ascorbic acid set forth above in the table in paragraph 79.

81. The inspectors requested Respondent's records of sales in California of any compounded sterile preparation containing ascorbic acid or sodium ascorbate between January 1, 2020, and May 1, 2020. In response, C.E. provided data that revealed that between January 1, 2020, and May 1, 2020, Respondent compounded and furnished at least 186,972 mL (6,232 vials containing 30 mL each) of ascorbic acid for non-patient specific distribution within or into California. Non-patient specific medication can only be distributed in the State of California by an outsourcing facility registered in the State of California. Respondent was not licensed as an outsourcing facility in the State of California in this period.

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82. The inspectors found that between at least January 1, 2020, and May 1, 2020, Respondent's labels for at least 186,972 mL (6,232 vials containing 30 mL each) of ascorbic acid compounded for non-patient specific distribution in California stated that "Olympia Pharmacy is an FDA registered as [sic] a 503b outsourcing facility". The labels are misleading to consumers in California as this location is not licensed nor inspected by the Board to the standard of an outsourcing facility.

83. The inspectors requested documentation for any order Respondent sent as "office use", including purchase orders from prescribers or other documentation that listed the number of patients seen or to be seen in the prescriber's office for whom the drug was needed or anticipated and the quantity for each patient sufficient for office administration. The inspectors also asked for documentation of each order shipped showing delivery of the order to the prescriber's office with a signature and a statement that the agent signing for the dangerous drugs was authorized to do so. In response, C.E. informed the inspectors that orders for its injectable ascorbic acid were placed using a portal system or an "office use order form", and that the orders were not shipped with a signature required. The inspectors asked C.E. for documentation showing that the providing pharmacist had a credible basis to conclude that quantities provided were reasonable for office use considering the intended use of the compounded drug and the nature of the prescriber's practice. C.E. informed the inspectors that the prescriber placing an order entered a determination of their office use of the drug on the office use order form. C.E. also stated that Respondent compounded the ascorbic acid as an FDA approved outsourcing facility, thereby confirming that Respondent was compounding and furnishing ascorbic acid for non-patient specific distribution within or into California as an outsourcing facility when Respondent was not licensed to do so.

## FIRST CAUSE FOR DISCIPLINE

**(Failure to Properly Label Compounded Drug Preparations)**

84. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, as set forth above in paragraph 80, between at least November 1, 2019, and March 24, 2020,

Respondent failed to include on its labels instructions for the storage, handling, and administration of ascorbic acid, preserved ascorbic acid, in violation of Code section 4076, and CCR sections 1751.2, 1707.5, and 1735.4.

**SECOND CAUSE FOR DISCIPLINE**

**(Failure to Maintain Quality of Compounded Sterile Preparations)**

85. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision and (o), in that Respondent violated pharmacy law. Specifically, Respondent violated CCR section 1735.2, subdivision (g), when, between at least January 8, 2018, and March 24, 2020, it compounded and furnished injectable ascorbic acid, which lacked quality,[1] in that the ascorbic acid ingrediants used for compounding was a food additive and showed harmful levels of heavy metals, arsenic, lead, bacteria, and mercury, as set forth above in paragraphs 78 and 79. The ascorbic acid ingrediants lacked quality and were not appropriate for use in compounding sterile injectable preparations.

**THIRD CAUSE FOR DISCIPLINE**

**(Adulterated Preparations)**

86. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent violated statutes regulating dangerous drugs and pharmacy law. Specifically, as set forth above in paragraphs 78 and 79, between at least January 8, 2018, and March 24, 2020, Respondent compounded and furnished injectable ascorbic acid, which was, or may have been, contaminated with filth, putrid, or decomposed substances, and was therefore adulterated pursuant to Health & Saf. Code sections 111250, 111255, and/or 21 USCA 351, subdivision (a), in violation of Code section 4169, subdivision (a)(2), Health & Saf. Code section 111295, and 21 USCA section 331, subdivision (a).

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[1] As defined by CCR section 1735.1, subdivision (ae).

**FOURTH CAUSE FOR DISCIPLINE**

**(Unlicensed Nonresident Outsourcing Facility Compounding/Furnishing Drugs)**

87. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, as set forth above in paragraph 81, between at least January 1, 2020, and May 1, 2020, Respondent compounded and furnished at least 186,972 mL (6,232 vials containing 30 mL each) of ascorbic acid for non-patient specific distribution within or into California. Respondent was not licensed by the Board as an outsourcing facility to furnish its compounded drugs in the State of California, a violation of Code section 4129, subdivision (a).

**FIFTH CAUSE FOR DISCIPLINE**

**(Failure to Comply with Furnish a Reasonable Quantity for Prescriber Office Use)**

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

a. As set forth above in paragraph 83, between at least January 1, 2020, and May 1, 2020, Respondent compounded and furnished injectable drug preparations for non-patient specific distribution within or into California, in violation of CCR section 1735.2, subdivision (c), in that Respondent failed to:

(i) use a purchase order or other documentation that showed the number of patients seen or to be seen in the prescribers office for whom the drug was intended, in violation of CCR section 1735.2, subdivision (c)(1);

(ii) ensure the quantity for each patient was sufficient for office administration, in violation of CCR section 1735.2, subdivision (c)(3);

(iii) obtain the prescriber's signature or signature of their agent upon delivery, in violation of CCR section 1735.2, subdivision (c)(2);

(iv) have a credible basis for concluding that the quantity was reasonable for the prescriber's office use, in violation of CCR section 1735.2, subdivision (c)(4);

(v) have knowledge that the amount compounded was in compliance with pharmaceutical standards, in violation of CCR section 1735.2, subdivision (c)(5); and

(vi) confirm that the amount did not exceed that which Respondent could reasonable and safely compound, in violation of CCR section 1735.2, subdivision (c)(6).

**SIXTH CAUSE FOR DISCIPLINE**

**(Compounding and Furnishing Misbranded Drugs)**

89. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent violated statutes regulating dangerous drugs and pharmacy law. Specifically, between at least January 1, 2020, and May 1, 2020, Respondent violated Code section 4169, subdivision (a)(3), and Health and Safety Code sections 111330, 111335, and 111445, in that it sold or transferred dangerous drugs that it knew, or should have known were misbranded, in that it failed to meet predefined specifications, failed to follow USP-NF compounding standards, failed to meet labeling requirements, lacked sterility assurance, failed to maintain quality of its CSPs, and compounded adulterated CSPs, and as follows:

a. As set forth above in paragraphs 84, through 87, and 90 below; and,

b. Respondent compounded and furnished injectable ascorbic acid for non-patient specific distribution within or into California that was labeled, "Olympia Pharmacy is an FDA registered as a 503b outsourcing facility", as set forth above in paragraph 82. In fact, the labels were misleading, in that Respondent is not licensed as an outsourcing facility in the State of California.

**SEVENTH CAUSE FOR DISCIPLINE**

**(Misbranded – Compounding with Active Ingredient from Unregistered Manufacturer)**

90. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, as set forth above in paragraphs 78 and 79, between at least November 1, 2019, and March 24, 2020, Respondent compounded and furnished eleven lots of injectable ascorbic acid made with an active pharmaceutical ingredient, ascorbic acid, obtained from manufacturers Shandong Luwei, Shandong Tianli, and Northeast, that were not registered with the FDA as required by 21 USCA 353a, subdivision (b)(1)(A)(ii) and/or 21 USCA 353b, subdivision (a)(2)(C). The injectable

ascorbic acid drug compounds were misbranded under Health and Safety Code section 111430, and 21 USCA section 352, subdivision (o). Respondents sold 726 30ml vials of misbranded injectable ascorbic acid in California, in violation of Health and Safety Code sections 111440 and 111445, and 21 USCA 331, subdivision (a).

**BACKGROUND INFORMATION – MAY 2020 INVESTIGATION**

91. In or around May 2020, Board Inspector "P.P-S." (Inspector P.) received a query from a representative of an unlicensed third party entity that purchased and resold Respondent's outsourced product. The Board commenced an investigation of Respondent. Inspector P. found that Respondent was in violation of multiple laws and regulations.

92. In the course of the Board's investigation, Board Inspector P. requested from Respondent, and received documentation for, product that was shipped to a party and invoiced to a third party for the period November 2019 through June 5, 2020. Inspector P. found that Respondent was providing commercially available products to third party supplier Legere Pharmaceuticals (Legere), including HCG injection, ascorbic acid injection, bacteriostatic water for injection, sildenafil, and tadalifil. "C.E.", Respondent's representative, explained, in part, that Respondent, a federally registered outsourcing facility, dispensed compounded drugs to California patients and practitioners with the marketing assistance of Legere. Inspector P. found that Respondent shipped its product directly to the patient or practitioner and used Legere as a third-party logistics provider to resell it. Legere was not licensed as a third party logistics provider in California and federal law prohibits the resale of outsourced pharmaceutical products.

93. Inspector P. requested Respondent's batch records with COAs for bulk API used for several of Respondent's products, sales data, and documentation of Respondent's justification for compounding commercially available products. Inspector P. also requested documentation showing that Respondent completed *in vivo* scientific studies enabling Respondent to make claims regarding dissolution characteristics of the products such as slow release or rapidly dissolving. Inspector P. reviewed records produced by Respondent and found nine of the batch records and Legere sales data between on or about June 1, 2019, and June 30, 2020, revealed the following:

| Compounded Drug | Qty. Vials Sold | Volume/ Vial | Date Made | Batch Lot# | Inspector P.' Findings* |
|---|---|---|---|---|---|
| Ascorbic Acid 500 mg./mL multi dose injectable | 1,308 | 30 mL | 03/12/2020 | C41112 | i, ii, iii, x |
| Glutathione 20 mg./mL | 569 | 5 mL | 03/11/2020 | C24011 | iv |
| Glutathione 20 mg./mL | 611 | 30 mL | 03/11/2020 | C24011 | iv |
| Biotin 0.05% injectable | 293 | 10 mL | 02/19/2020 | B24019 | iii, iv |
| Olympia Vita Complex injectable | 1,056 | 30 mL | 02/25/2020 | B44025 | iii, v |
| LipoStat Plus multidose vial injectable | 1,516 | 30 mL | 02/24/2020 | B24024 | iii, vi |
| Amino Blend multidose injectable | 342 | 30 mL | 06/25/2020 | F41125 | vii |
| Human Chorionic Gonadotropin (HCG) 5000 IU single use vial for reconstitution and injection | 411 | Single use | 08/21/2019 | H18021 | viii, x |
| HCG 10000 IU single use vial for reconstitution and injection (including bacteriostatic water for reconstitution) | 1,188 | Single use | 08/19/2019 | H24019 | ix, x |
| HCG 10000 IU single use vial for reconstitution and injection | 79 | Single use | 08/19/2019 | H24019 | ix, x |
| Bacteriostatic water for injection/reconstitution with HCG | 1,188 | Single Use | 08/26/2019 | H9026 | i, x |
| Bacteriostatic water for injection/reconstitution with HCG (Individual vials) | 54 | 10 mL | 08/26/2019 | H9026 | i, x |

*Inspector P.' Findings:

i. Respondent used API that could not be determined from the COA as suitable for injectable compounding.

ii. Respondent was notified in the course of the Board's prior investigation that this was essentially a copy of a commercially available product.

iii. The label did not state discard 28 days after first use.

iv. Respondent used a dietary supplement grade API.

v. Respondent used dietary supplement grade API (riboflavin, niacinamide, dexpanthenol, pyridoxine, thiamine).

vi. Respondent used dietary supplement grade API (methionine, choline, hydroxocobalamin, pyridoxine); and, food grade (FCC) API (choline, inositol).

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vii. Respondent used ornithine API, which does not have a USP Monograph, and glutamine API with a COA that states, "This product is not intended for API usage."

viii. Respondent used dietary supplement grade mannitol API.

ix. Respondent used excipient grade mannitol.

x. Commercially available product not in shortage.

Inspector P. found that, for all of the nine batches set forth in the table above, the COA for the product manufacturer was not included, Respondent's labels stated Olympia was a registered 503B outsourcing facility (omitting that it was not registered as a nonresident outsourcing facility in California), and directions for use were not on the labels.

94. Inspector P. found that, as stated above in paragraph 93, between on or about June 1, 2019, and June 30, 2020, Respondent compounded adulterated injectables using inappropriate API; and, labeled injectable ascorbic acid, preserved ascorbic acid, glutathione, biotin, Olympia Vita-Complex, LipoStat Plus, Amino Blend, HCG, and bacteriostatic water, with, "Olympia Pharmacy is FDA Registered as a 503B Outsource facility". The labels did not have directions for use and stated "For Office Use Only" but the volume exceeded that allowable for office use. Inspector P. also found that, as stated above in paragraph 93, between on or about June 1, 2019, and June 30, 2020, Respondent compounded HCG IU lyophilized with bacteriostatic water provided for reconstitution for injection that was essentially a copy of a commercially available product. Respondent never provided an adequate medical justification for doing so.

95. Respondent did not provide records establishing that between at least June 1, 2019, and June 30, 2020, Respondent had a credible basis to conclude that quantities of compounds provided were reasonable for office use of sterile injectables compounded and furnished within or into California for non-patient specific distribution.

96. Respondent did not provide purchase orders from prescribers or other documentation that listed the number of patients seen or to be seen in the prescribers' office for whom the drug was needed or anticipated and the quantity for each patient sufficient for office administration. Respondent did not provide documentation showing delivery of the order to a prescribers' office

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with a signature and a statement that the agent signing for the dangerous drugs was authorized to do so.

**EIGHTH CAUSE FOR DISCIPLINE**

**(Failure to Properly Label Compounded Drug Preparations)**

97. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, as set forth above in paragraph 93 and 94, between at least on or about June 1, 2019, and June 30, 2020, Respondent failed to include on its labels on vials of sterile injectables for non-patient specific distribution within or into California instructions for the storage, handling, and administration of: ascorbic acid, preserved ascorbic acid, glutathione, biotin, Olympia Vita-Complex, LipoStat Plus, Amino Blend, HCG, and bacteriostatic water, in violation of Code section 4076, and CCR sections 1751.2, 1707.5, and 1735.4.

**NINTH CAUSE FOR DISCIPLINE**

**(Failure to Maintain Quality of Compounded Sterile Preparations)**

98. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, Respondent violated CCR section 1735.2, subdivision (g), when, between at least on or about June 1, 2019, and June 30, 2020, as set forth above in paragraphs 93 and 94, Respondent compounded and furnished at least the following drugs that lacked quality:

| No. Vials | Volume/ Vial | Drug |
|---|---|---|
| 1,308 | 30 mL | Ascorbic Acid 500 mg./mL |
| 569 | 5 mL | Gluthathione |
| 611 | 30 mL | Gluthathione |
| 293 | 10 mL | Biotin 0.05% injectable |
| 1,056 | 30 mL | Olympia Vita-Complex Injection |
| 1,516 | 30 mL | LipoStat Plus Injection |
| 342 | 30 mL | Amino Blend Injection |

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## TENTH CAUSE FOR DISCIPLINE

**(Adulterated Preparations)**

99. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent violated statutes regulating dangerous drugs and pharmacy law. Specifically, between at least on or about June 1, 2019, and June 30, 2020, as set forth above in paragraphs 93 and 94, Respondent compounded and the following drugs which were, or may have been, contaminated with filth, putrid, or decomposed substances, and were therefore adulterated pursuant to Health & Saf. Code sections 111250, 111255, and/or 21 USCA 351, subdivision (a), in violation of Code section 4169, subdivision (a)(2), Health & Saf. Code section 111295, and 21 USCA section 331, subdivision (a).

| No. Vials | Volume/ Vial | Drug |
|---|---|---|
| 1,308 | 30 mL | Ascorbic Acid 500 mg./mL |
| 569 | 4 mL | Gluthathione |
| 611 | 30 mL | Gluthathione |
| 293 | 10 mL | Biotin 0.05% injectable |
| 1,056 | 30 mL | Olympia Vita-Complex Injection |
| 1,516 | 30 mL | LipoStat Plus Injection |
| 342 | 30 mL | Amino Blend Injection |

## ELEVENTH CAUSE FOR DISCIPLINE

**(Unlicensed Nonresident Outsourcing Facility Compounding/Furnishing Drugs)**

100. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, as set forth above in paragraphs 93 and 94, between at least on or about June 1, 2019, and June 30, 2020, Respondent compounded and furnished sterile injectables for non-patient specific distribution within or into California. Respondent was not licensed by the Board as an outsourcing facility to furnish its compounded drugs in the State of California, a violation of Code sections 4129, subdivision (a), and 4129.2, subdivision (a).

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**TWELFTH CAUSE FOR DISCIPLINE**

**(Failure to Comply with Requirements to Furnish a Reasonable Quantity for Prescriber Office Use)**

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

a. As set forth above in paragraphs 93 through 96, between at least on or about June 1, 2019, and June 30, 2020, Respondent compounded and furnished vials of sterile injectable drug preparations for non-patient specific distribution within or into California, in violation of CCR section 1735.2, subdivision (c), in that Respondent failed to:

(i) use a purchase order or other documentation that showed the number of patients seen or to be seen in the prescribers office for whom the drug was intended, in violation of CCR section 1735.2, subdivision (c)(1);

(ii) ensure the quantity for each patient was sufficient for office administration, in violation of CCR section 1735.2, subdivision (c)(3);

(iii) obtain the prescriber's signature or signature of their agent upon delivery, in violation of CCR section 1735.2, subdivision (c)(2);

(iv) have a credible basis for concluding that the quantity was reasonable for the prescriber's office use, in violation of CCR section 1735.2, subdivision (c)(4);

(v) have knowledge that the amount compounded was in compliance with pharmaceutical standards, in violation of CCR section 1735.2, subdivision (c)(5); and

(vi) confirm that the amount did not exceed that which Respondent could reasonable and safely compound, in violation of CCR section 1735.2, subdivision (c)(6).

**THIRTEENTH CAUSE FOR DISCIPLINE**

**(Compounding and Furnishing Misbranded Drugs)**

102. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent violated statutes regulating dangerous drugs and pharmacy law. Specifically, as set forth above in paragraphs 93 and 94, between at least on or about June 1, 2019, to June 30, 2020, Respondent violated Code section

4169, subdivision (a)(3), and Health and Safety Code sections 111330, 111335, and 111445**,** when it compounded and furnished sterile injectables for non-patient specific distribution within or into California with labels that stated that Olympia Pharmacy is an FDA Registered as a 503b outsourcing facility. Such labels were misleading in that, in fact, Respondent is not licensed as an outsourcing facility in the State of California.

**FOURTEENTH CAUSE FOR DISCIPLINE**

**(Compounding Limitations and Requirements)**

103. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, as set forth above in paragraphs 93 and 94, between at least on or about June 1, 2019, and June 30, 2020, Respondent compounded and dispensed products that were copies of commercially available products, including vials of HCG lyophilized injection, HCG IU lyophilized with bacteriostatic water provided for reconstitution, HCG IU lyophilized for reconstitution, bacteriostatic water for injection with HCG, and bacteriostatic water for injection. Respondent did so without documenting that the drugs were in short supply or that a medical need was made known to Respondent prior to compounding, in violation of CCR section 1735.2, subdivision (d)(3)**.**

**BACKGROUND INFORMATION – OCTOBER 2021 INSPECTION**

104. On or about October 7, 2021, Board inspector J.F. (Inspector J.F.) requested from Respondent documentation to facilitate renewal of its Nonresident Sterile Compounding Permit No. NSC 100818.

105. On or about October 18, 2021, Inspector J.F. conducted an onsite, annual, nonresident sterile compounding renewal inspection of Respondent's facility in Orlando, Florida. In addition to his October 7, 2021, request for documentation, Inspector J.F. subsequently requested, and Respondent provided, numerous documents for evaluation. On or about October 19, 2021, after reviewing Respondent's documentation and conclusion of the on-site inspection, Inspector J.F. provided Respondent with an inspection report that included "Written

Notice" for multiple violations of Pharmacy Law and an "Order of Correction". The cited violations are set forth below.

**Written Notice #1**

106. Inspector J.F. found that Respondent compounded and distributed cyanocobalamin 2mg/mL, calcium chloride l00rng/mL, preserved diluent, lidocaine 1%/2%, magnesium chloride 200mg/mL, testosterone cyp 200mg/mL, pyridoxine 100mg/mL, and acetylcysteine 200mg/mL, drugs that were essentially copies of commercially available medications.[2] Respondent did not document drug shortages or a specific medical need known to Respondent prior to compounding those drugs. On or about October 19, 2021, Inspector J.F. notified Respondent in writing that it was in violation of 16 CCR section 1735.2, subdivision (d)(3) (a pharmacy shall not compound a copy of a commercially available drug product unless it establishes and documents that the drug is in short supply and is justified by a specific medical need).

**Written Notice #2**

107. Inspector J.F. found that Respondent continued to compound injectable drug products using bulk ingredients that are either dietary grade and do not have an applicable USP/NF drug monograph, or are sourced from manufacturers without active FDA registration. For example, Respondent compounded NAD, alpha lipoic acid, choline chloride, glutathione, and methylcobalarnin that either are dietary grade and do not have an applicable USP/NF drug monograph, or are sourced from manufacturers without active FDA registration. On or about October 19, 2021, Inspector J.F. notified Respondent in writing that it was in violation of Health and Safety Code section 111250, section 503A of the Federal Food, Drug, and Cosmetic Act, and FDA guidance for industry document Insanitary Conditions at Compounding Facilities.

**Written Notice #3**

108. Inspector J.F. found that of 100 CSPs being produced by Respondent at the time of the investigation, 45 had not been fully tested and verified by Respondent for stability to support an extended beyond-use date (BUD), including, but not limited to, methylcobalamin (6 month BUD), glutathione (4 month BUD), Myer's Cocktail (6 month BUD), Semorelin Acetate (12

[2] The listed drug products are dangerous drugs within the meaning of Code section 4022.

month BUD), Olympia Vita Complex (6 month BUD), NAD+ (12 month BUD), and Tri-Immune Boost (6 month BUD). On or about October 19, 2021, Inspector J.F. notified Respondent in writing that it was in violation of 16 CCR section 1735.2, subdivision (i)(3)(C), which requires a stability study for a sterile CSP with an extended BUD.

109. On or about October 25, 2021, and October 26, 2021, Respondent affirmed that it did not intend to dispense or distribute products to California that did not possess completed stability data to support the extended BUD or products that did not conform to default USP BUD requirements. Respondent committed to providing completed stability data to support extended BUDs. The status of stability studies for products cited in Written Notice #3 was provided with estimated completion dates, as follows:

| **Compound**[3] | **BUD** | **Status** | **Estimated Completion Date** |
|---|---|---|---|
| Methylcobalamin | 6 months | Method validation in process | July 2022 |
| Glutathione | 4 months | Study in progress | April 2022 |
| Myer's Cocktail | 6 months | Study in progress | July 2022 |
| Semorelin Acetate | 12 months | Study in progress | July 2022 |
| Olympia Vita Complex | 6 months | Study in progress | July 2022 |
| NAD+ | 6 months | Study in progress | December 2022 |
| Tri-Immune Boost | 6 months | Study in process | September 2022 |

**Written Notice #4**

110. Inspector J.F. found that instructions on labels for vials that contained CSPs differed from the studied storage condition during stability. For example, phenylephrine HCL was stored at 25C +/- 2C during stability evaluation, yet the final label lists the storage condition as 15-30C. Further, some of Respondent's frozen products had alternate storage conditions and extended BUDs without a valid stability study to support those conditions. For example, QM-2 requires frozen storage. Respondent's label states, "Refrigerate after first use up to 90 days". On or about October 19, 2021, Inspector J.F. notified Respondent in writing that it was in violation of 16 CCR section 1751.2, subdivision (b) (label shall include instructions for storage, handling, and administration), and/or 16 CCR section 1735.2(i)(3)(C) (BUD for CSPs only allowed when supported by stability studies).

[3] The compounds listed are dangerous drugs within the meaning of Code section 4022.

**Written Notice #5**

111. Inspector J.F. found that Respondent continued to furnish non-patient specific orders within California, yet did not hold a Nonresident Outsourcing license. This was a repeat of the violation cited in the Board's May 2020 inspection, set forth above in paragraphs 82 and 83. On or about October 19, 2021, Inspector J.F. notified Respondent in writing that it was in violation of Code section 4129.2, subdivision (a) (FDA-licensed outsourcing facility shall be concurrently licensed as an outsourcing facility in California if distributing CSPs in California).

**Written Notice #6**

112. Inspector J.F. found that Respondent failed to collect and document necessary information prior to furnishing a reasonable quantity of compounded product for prescribers' office use. Inspector J.F. found that orders were not accompanied by the number of patients seen or to be seen in the prescriber's office for whom the drug was intended; did not ensure that the quantity for each patient was sufficient for office administration; and/or did not require the prescriber's signature or the signature of their agent upon delivery (for all orders). On or about October 19, 2021, Inspector J.F. notified Respondent in writing that it was in violation of CCR section 1735.2, subdivision (c) (reasonable quantity of CSP furnished to prescriber is to be delivered to prescriber's office and must be signed by prescriber or prescriber's agent).

113. On or about November 24, 2021, Inspector J.F. reviewed Respondent's distribution records for the period November 17, 2021, to November 18, 2021. Of the 36 products that were shipped, nine did not have the required documentation.

**Order of Correction, No. 1**

114. Inspector J.F. found that a written notice of a patient's right to a consultation with a pharmacist was not provided in Respondent's shipment to a prescriber in California. Further, Respondent was only open five days a week and so could not provide a patient with a consultation six days per week during regular hours of operation.

115. On or about October 20, 2021, in response to the Order of Correction No. 1 issued by the Board, above, Respondent committed to modify by October 31, 2021, the patient consultation

leaflet that accompanied its shipping orders to in order to comply with the consultation requirements.

**Order of Correction, No. 2**

116. Inspector J.F. found that on or about August 18, 2021, a cleanroom certifier[4] reported that opening the doors inside one of Respondent's cleanrooms[5] created air currents that affected the performance of its biological safety cabinets.[6] USP requires that the PEC be placed out of the traffic flow in a manner that avoids disruption of air currents from the HVAC system and room. As noted in the inspection report, Inspector J.F. also advised Respondent that rust was found on chairs and carts in a cleanroom.

**Follow-Up to October 2021 Inspection**

117. After the October 18, 2021, on-site inspection, Inspector J.F. requested, and reviewed, further records from Respondent. Specifically, J.F. requested records of physician orders and the final labels for each national drug code (NDC) product[7] for product distributed by Respondent in California between on or about October 8, 2020, and October 19, 2021.

118. Between or about February 14, 2022, and March 22, 2022, the FDA performed an outsourcing inspection (the FDA Inspection) at Respondent's facility. Inspector J.F. and the FDA investigator found that Respondent had committed further violations, and on or about July 6, 2022, Inspector J.F. issued another Written Notice to Respondent, notifying Respondent of the following violations:

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[4] Cleanrooms used to create CSPs must be certified at least every six months. Recertification includes airflow testing, which is performed to determine the acceptability of air velocity and volume, the air exchange rate, and the room pressure differential in doorways between adjacent rooms to ensure consistent airflow and that the appropriate quality of air is maintained. Certification must be in accord with the Controlled Environment Testing Association certification guide, or its equivalent.

[5] A cleanroom is the area where primary engineering controls (PECs) used to compound sterile preparations, are located. The cleanroom is where the preparation, compounding, and staging of CSPs occurs.

[6] A biological safety cabinet (BSC) is a ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. The BSC is designed to protect workers from exposure to airborne drugs and to provide a better environment for CSPs.

[7] The FDA requires a current list of all drugs manufactured, prepared, propagated, compounded, or processed by pharmacies intended for commercial distribution. Drug products are identified and reported using the NDC, a unique product identifier.

**Written Notice #1**

119. Respondent compounded drug products using, *inter alia,* folic acid, a bulk drug substance that was essentially a copy of a commercially available drug product. Respondent did not document drug shortages or a specific medical need known to Respondent prior to compounding those drugs. This was a repeat violation of those found during the Board's May 2020 and October 2021 inspections, as set forth above in paragraphs 93, 94, and 106.

120. On or about March 24, 2022, an FDA inspector found that Respondent's labels omitted the address and phone number of the outsourcing facility, storage and handling information, the route of administration, or information to facilitate adverse event reporting (www.fda.gov/medwatch and 1-800-FDA-1088) on its CSPs, including, but not limited to, the following products:[8]

Chloramphenicol 50mg,
Sulfamethoxazole, 50mg
Amphotericin B 5mg capsules

Failure to include Respondent's address and phone number, storage and handling information, the route of administration were repeat violations during the Board's March 2019 and May 2020 and inspections, as set forth above in paragraphs 80 and 120.

121. On or about March 24, 2022, an FDA inspector found that Respondent's labels did not list the quantity or portion of each inactive ingredient in its CSPs, including, but not limited to the following products:

Lipoderm (Benzocaine 20%, Lidocaine 10%, Tetracaine 10%) Topical Cream
Lipoderm (Benzocaine 20%, Lidocaine 8%, Tetracaine 6%) Topical Cream
Lipoderm (Benzocaine 20%, Lidocaine 6%, Tetracaine 4%) Topical Cream
Lipoderm (Benzocaine 23%, Tetracaine 7%) Topical Cream
Lidocaine 23%/Prilocaine 10%/Phenylephrine 0.5% Topical Ointment

122. Respondent omitted at least 30 different drug products that it compounded from its production report for the previous six months that it submitted to the FDA in December 2021.

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[8] The listed drug products in paragraph 117 are dangerous drugs within the meaning of Code section 4022.

123. Inspector J.F. notified Respondent that acts set forth in paragraphs 119 through 121 above, were in violation of Code section 4301, subdivision (j) (unprofessional conduct/failure to comply with state and federal regulations regarding controlled and/or dangerous drugs).

**Written Notice #2**

124. Respondent compounded a sterile drug preparation that was labeled with a BUD that exceeded the shortest expiration date or BUD of any ingredient in the compounded drug. Specifically, on or about April 1, 2021, Respondent compounded sincalide 5mcg/vial lot# D24001 with a BUD of April 1, 2022, with polysorbate 80 lot# 2002140003 with an expiration date of February 13, 2021. Inspector J.F. notified Respondent that it was in violation of CCR section 1751.8 (every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation).

**Written Notice #3**

125. Respondent used API sincalide bulk lot# G24020 in compounding at least lot #D24001 that did not have a recorded expiration date and for which a certificate of analysis could not be located. Inspector J.F. notified Respondent that it was in violation of CCR section 1735.3, subdivision (c) (API shall be obtained from FDA-registered supplier & 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). Inspector J.F. also notified Respondent that it had failed to maintain and retain proper documentation for bulk API sincalide lot #G24020.

**Written Notice #4**

126. In the course of the FDA Inspection, Respondent's Quality Manager admitted to an FDA inspector that Respondent did not have stability studies for at least 45 products types, including its erectile dysfunction formulations, vitamin, vein care, IV therapy, and anti-aging sterile injectable drug products. Respondent did not conduct stability studies to demonstrate that specifications remained suitable through each product's shelf life including, but not limited to, potency, endotoxin, sterility, and container closure integrity. The FDA inspector found that

between July 1, 2021, and February 14 2022, Respondent distributed approximately 540,254 units of product without supporting stability studies, including, but not limited to:

| Product Name[9] | BUD (Months) | Vials |
|---|---|---|
| MICC 10ml and 30ml | 6 | 16911 |
| Lipostat Plus | 6 | 25149 |
| Lipo-Mino-Mix 10ml and 30ml | 6 | 65214 |
| Semorelin 3mg and 9mg | 6 | 2963 |
| Ascorbic Acid 30ml | 6 | 60781 |
| Biotin | 6 | 12930 |
| Methylcobalamin 10ml and 30ml | 6 | 38108 |
| Erectile Dysfunction Single mix drugs | 12 | 1292 |
| Erectile Dysfunction Double mix drugs | 12 | 271 |
| Erectile Dysfunction Tri-Mix drugs | 12 | 4558 |
| Erectile Dysfunction Quad-Mix drugs | 12 | 570 |
| NAD | 12 | 37417 |
| Myers Cocktail | 6 | 58108 |
| Olympia Vita Complex | 6 | 25649 |
| Vit D 3 | 6 | 14352 |
| Tri Immune Boost | 6 | 14273 |
| Glycerin | 6 | 1908 |
| Sodium Bicarbonate | 6 | 1663 |
| Alpha Lipoic | 6 | 4728 |
| Folic Acid | 6 | 2353 |
| L Proline | 6 | 1045 |
| Ondansetron | 6 | 1424 |
| Sodium Tetradecyl (STS) | 6 | 9208 |
| L Carnitine | 6 | 10734 |
| Ultratest | 12 | 1586 |
| Olympia Mineral Blend | 6 | 13747 |
| Amino Blend | 6 | 16813 |
| Pyridoxine | 6 | 4501 |
| Calcium Chloride | 6 | 8573 |
| L-Taurine | 6 | 6914 |
| L-Glutamine | 6 | 3903 |
| L-Arginine | 6 | 1259 |
| Dexpanthenol | 6 | 3192 |
| Zinc Chloride | 6 | 16721 |
| Magnesium Chloride | 6 | 13122 |
| Acetyl Cysteine | 6 | 4865 |
| Sod Selenite | 6 | 4847 |
| L-Lysine | 6 | 1684 |
| B12 Hydroxo | 12 | 12049 |
| B12 Cyano | 6 | 2066 |
| Sincalide | 12 | 1344 |
| Lidocaine 1% | 6 | 2846 |
| Lidocaine 2% | 6 | 1906 |
| Lido 1% and Epi | 6 | 3823 |
| Glyc/Lido/Epi | 6 | 2884 |

[9] The listed drug products are dangerous drugs within the meaning of Code section 4022.

This was a repeat violation of written notice #3 issued by Inspector J.F. on October 19, 2021, as set forth above in paragraph 108.

127. The FDA investigator found that Respondent's Glutathione 5ml stability study failed potency at its three-month timepoint in December 2021. Respondent paused the stability study but continued to manufacture and distribute Glutathione with a three to four month BUD. Between July 1, 2021, and February 14, 2022, Respondent manufactured and distributed 33,956 vials of Glutathione.

128. The FDA investigator found that Respondent's January 2021 Mitomycin 30ml stability study failed container-closure testing at its zero and three-month timepoints.

129. The FDA investigator found that Respondent's products (F2, Erectile dysfunction drugs, semorelin, Vit D3, Sincalide, and Mitomycin) had not undergone antimicrobial effectiveness studies to verify that the preservative system for those products was effective and protected the products over their shelf life.

130. This was a repeat violation of the Board's October 2021 inspection, as set forth above in paragraph 109. Inspector J.F. notified Respondent that the acts set forth in paragraphs 126 through 129 were in violation of CCR section 1735.2, subdivision (i)(3)(C) (requiring stability studies in support of BUD extensions).

**Written Notice #5**

131. The FDA investigator and Inspector J.F. both observed rust on carts and chair legs in Respondent's cleanroom that could not be adequately cleaned and sanitized. Inspector J.F. brought to Respondent's attention during his October 18, 2021, inspection that the chairs and carts in Respondent's cleanroom had rust. Inspector J.F. notified Respondent that it remained in violation of CCR section 1714, subdivision (b) (pharmacy shall maintain facilities, space, fixtures, equipment so that drugs are safely and properly prepared, maintained, secured, distributed).

**Written Notice #6**

132. Respondent's SOP, *Cleaning of the Compounding Facility*, required specific cleaning agents and surface contact times for all but one of the cleaning agents (Sterile 70% IPA), and

monthly cleaning. Respondent's SOP also required daily, weekly, and monthly cleaning of the lyophilizer but failed to document the amount of time cleaning agents remained on surfaces as necessary to ensure that the cleaning occurred in accord with specifications in Respondent's SOP. Respondent was unable to provide the FDA investigator with the manufacturer's specified contact time for one of the cleaning agents that it used (0.525% sodium hypochlorite).

133. The FDA investigator found that Respondent had not conducted any challenges for the cleaning validation/sterilization of a filling machine and there was therefore no documentation ensuring that residual determents from the cleaning operations or residue from previous APIs had been adequately removed.

134. Inspector J.F. notified Respondent that the acts set forth above in paragraphs 132 and 133 were in violation of CCR section 1751.4, subdivision (e) (Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently).

**Written Notice #7**

135. Respondent's SOP entitled *Complaint Handling, Drug Safety, and Surveillance",* states that the investigation of a complaint may include review of the batch, dispensing and shipping records, an examination of the returned complaint sample, and examination or testing of the retained sample. On or about April 27, 2021, Respondent received a product quality complaint for ST-2, lot #H24B03 (Customer Complaint #CC2021-039) for low fill volume. On or about July 21, 2021, Respondent received a product quality complaint for Methylcobalamin (Customer Complaint #CC 2021-079) for low fill volume. Respondent did not implement adequate corrective and preventative actions, such as evaluating the set-up of the Flexicon filling machine used to fill vials, addressing the lack of instructions provided in the batch production record, or implementing in-process checks throughout the filling process.

136. The FDA investigator found that on or about September 1, 2021, Respondent received a product quality complaint for NAD+ (Customer Complaint #CC 2021-092). The Complainant stated the vials it received had evaporated and a yellow-like gel substance remained. Respondent attributed the error, without supporting documentation or providing a scientific rationale, to an inadequate visual inspection. Respondent determined that the stopper depth was too low in the

vial, causing sublimation during the lyophilization cycle. Respondent's Production Manager admitted to the FDA investigator that the set-up instructions for the filling machine were not documented in Respondent's protocols or the batch production record. Stopper height is a critical parameter during the filling of NAD+ (lyophilized). It was determined that the root cause was related to inadequate manufacturing controls for the stopper height during lyophilization and a failure to implement corrective and preventative action to prevent re-occurrence. Respondent failed to evaluate other batches of drug product that were filled on the same filling machine (Colanar). Preventative maintenance was not conducted on the machine. Respondent did not investigate the discrepancy or any failure of batch components to meet product specifications.

137. The FDA investigator found that the target fill volume for Respondent's Biotin 0.05% (0.5mg/mL) injection 10 mL MDV lot #B24007-22, was 50,000 mL. Respondent produced 53,312 mL. When asked about the deviation from its SOPs, Respondent's Production Manager admitted that Respondent may have an issue with under-filled vials. The 3,312 mL deviation was not extended to other batches filled on the same filling machine (Flexicon). Respondent did not have set-up instructions for the Flexicon filling machine. Respondent was also found to lack in-process volume checks during filling operations.

138. The FDA investigator found that on August 8, 2021, Respondent recorded a deviation from its SOPs for its Lipo Mino Mix, lot #H41A16, due to a high assay[10] for cyanocobalamin. Respondent attributed the deviation to a technician error during mixing operations. The batch record states, add 50% of the final volume of water for injection (WFI) to the admixture. It also states to add the appropriate amount of benzyl alcohol. Respondent did not evaluate whether the batch record instructions were clear or required revision.

139. As stated above in paragraph 135, between April and July 2021, Respondent received two separate complaints for low fill volumes. Respondent did not investigate batches with documented low fill volume or production yields that failed to meet Respondent's defined specifications. The FDA investigator also found that the target fill volume for Respondent's preserved Ascorbic Acid 500 mg/mL, produced June 8, 2021, lot #s F42A08, F42B08 and

[10] A high assay means that it has a high potency.

F42C08 was 100,000mL. Respondent produced 106,800 mL. A note on the batch record stated, "some low fills". Respondent released and distributed the batch without quality review and despite being misbranded and/or adulterated, in that the fill volumes were low. Portions of those lots were distributed in California. Potency assays of released lots having low fill volumes did not meet Respondent's specifications.

140. Inspector J.F. notified Respondent that the acts set forth above in paragraphs 135 through 139 were in violation of CCR section 1735.2, subdivision (e)(5) (failure to have a written master formula documenting specific and essential steps to compound the drug).

**Written Notice #8**

141. On or about September 5, 2021, Respondent acknowledged deviation from its SOPs due to post-process fingertip sampling out-of-specification results found on sticky notes. Respondent's investigation stated that between September 15, 2020, and September 15, 2021, all environmental monitoring showed no action limits within the critical filling zone. Respondent's Quality Unit failed to evaluate Respondent's current cleaning practices to determine whether they were effective in the inactivation or removal of microorganisms within Respondent's ISO-5 environment. Between in or around July 2021 and February 2022, Respondent's Quality Unit released potentially impacted batches of CSPs that passed Respondent's sterility and endotoxin tests despite the deviation due to fingertip sampling. During its February to March 2022 investigation, the FDA investigator found three settle plate failures in two separate auto-fillers and two post-processing fingertip sampling failures. The FDA investigator identified 185 microbiological recoveries between July 2021 and February 2022. On or about March 2, 2022, the FDA notified Respondent of its lack of environmental control.

142. Respondent did not conduct a recall of potentially contaminated CSPs as the result of Respondent's lack of environmental control, described above in paragraph 141, until on or about April 4, 2022. Between in or around April 30, 2021, and February 14, 2022, a total of 638 shipments to California customers were recalled. Respondent's recall notice to its customers stated, "… Olympia has concluded that, prior to October 1, 2021, environmental and personnel

monitoring Out of Action Limit (OOAL) excursions were not being properly investigated as per Olympia Policy."

143. Inspector J.F. notified Respondent that the acts set forth above in paragraphs 141 and 139 were in violation of CCR section 1735.5, subdivision (a) (any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action).

**Written Notice #9**

144. As set forth above in paragraph 141, Respondent released CSPs based on the product passing Respondent's sterility and endotoxin tests. Between on or around February 23, 2021, and May 31, 2021, personnel monitoring contamination recovery rates were 63.3%; between on or around June 1, 2021, to September 30, 2021, the contamination recovery rates were 21.1%. Respondent's other ISO-5 locations also exceeded the <1% recovery rate recommendation for ISO-5 environments, pursuant to USP <1116>.

145. The FDA investigator found that Respondent SOP, *Environmental Monitoring for the Positive and Negative Pressure Cleanrooms. . .”* did not identify critical sampling locations within Respondent's ISO 5 laminar airflow workbench (LAFW) during filling operations using the Flexicon and Colanar filling machines. Further, Respondent did not account for environmental monitoring (EM) samples collected during or after each batch production. On or about February 14, 2022, an FDA investigator observed Respondent's Quality Assurance specialist (specialist) unload EM plates from the incubator and discard the sample if no growth was observed. When growth was observed, Respondent's specialist set the sample aside to later count the colonies. This process was not documented. The specialist recorded on environmental monitoring forms the plates that contained growth and marked zero counts for plates he discarded. On February 14, 2022, an FDA investigator found that the specialist recorded seven CFUs on a plate. The FDA investigator documented and photographed over 20 CFUs on that same plate. The FDA investigators found that Respondent's monitoring sampling plan was not justified, Respondent did not maintain accountability for testing results, and that areas intimate to Respondent's production process were not sampled.

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146. Inspector J.F. notified Respondent that the acts set forth above in paragraphs 141 and 142 were in violation of CCR section 1751.4, subdivision (a) (no CSP shall be compounded if compounding environment is known/should be known to fall below the compounding pharmacy's specifications).

**Written Notice #10**

147. Inspector J.K. found that, as set forth in paragraph 139 above, Respondent did not ensure that its CSP batches were thoroughly reviewed and did not take effective action on lots not meeting Respondent's specifications. J.F. notified Respondent that it was in violation of CCR section 1735.8, subdivision (d) (quality assurance plan shall include a written procedure for scheduled action in event any CSP is found to be outside minimum standards).

**Written Notice #11**

148. Inspector J.K. found that Respondent had contractual agreements to compound drug for parenteral therapy for other pharmacies within thirty days, yet had not notified the Board of those agreements. Specifically, Olympia signed agreements with Mint Rx (NRP 1968) initiated March 24, 2021, Post Haste (NRP 1800) initiated July 25, 2017, Pharmacy 90210 (PHY 51013) initiated January 20, 2021, and Pharmalabs LLC (NRP 1662) initiated March 19, 2019. Inspector J.F. notified Respondent that it was in violation of Code section 4123 (any pharmacy entering a contract to compound for parenteral therapy shall notify the board thirty days before compounding under that contract).

**Written Notice #12**

149. Inspector J.K. found that Respondent failed to deliver CSPs to the prescriber's office and/or to obtain the signature of the prescriber or the prescriber's agent upon receipt. During the review period October 8, 2020, to October 19, 2021, approximately 4650 units of CSPs were shipped to locations representing a hotel, three different Postal Boxes or Annexes, one self-storage business, five residential addresses, and 36 UPS Stores. This was a repeat of the violation found during the Board's October 2021 inspection, as set forth above in paragraphs 112 and 113. Inspector J.F. notified Respondent that it was in violation of CCR section 1735.2, subdivision (c)(2) (requiring delivery to prescriber's office).

**Written Notice #13**

150. Inspector J.K. found, as set forth above in paragraph 150, that Respondent compounded and distributed Ascorbic Acid Lots F42A08, F42B08, and F42C08 that were below their labeled claim strength. Inspector J.F. notified Respondent that it was in violation of Code section 4169, subdivision (a)(3) (misbranding).

**FIFTEENTH CAUSE FOR DISCIPLINE**

**(Stability Study Required to Support Extended BUD)**

151. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, Respondent violated CCR section 1735.2, subdivision (i)(3)(C), which requires stability studies for BUD extensions for CSPs. Specifically:

a. Respondent's label for QM-2 stated "Refrigerate after first use up to 90 days". Respondent did not have a valid stability study to support the alternate storage condition or an extended BUD, as set forth above in paragraph 110.

b. Respondent stored phenylephrine HCL at 25C +/- 2C during a stability evaluation. The final label listed the storage condition as 15-30C, as set forth above in paragraph 110.

c. Between at least on or about July 1, 2021, and February 14, 2022, Respondent distributed approximately 540,254 units of CSPs without supporting stability studies, as set forth above in paragraphs 108 and 126.

d. Between on or about July 1, 2021, and February 14, 2022, Respondent paused a stability study for Glutathione 5 ml that failed a potency test at its three-month timepoint, but continued to manufacture and distribute Glutathione with a three to four month BUD, as set forth above in paragraph 127.

e. Respondent's January 2021 stability study for CSP, Mitomycin 30 mL failed container-closure testing at its zero and three-month timepoints, as set forth above in paragraph 128.

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f. Between on or about July 1, 2021, and February 14, 2022, Respondent distributed products that had not undergone antimicrobial effectiveness studies to verify that the preservative system for those products was effective and protected the products over their shelf life, as set forth above in paragraph 129.

**SIXTEENTH CAUSE FOR DISCIPLINE**

**(Failure to Properly Label Compounded Drug Preparations)**

152. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, Respondent violated federal and state laws and regulations governing pharmacy, as follows:

a. Respondent violated Code section 4076, and CCR sections 1751.2, subdivision (b), 1707.5, and 1735.4, to wit:

i. Respondent's compound, QM-2 requires frozen storage, yet the final label states, "Refrigerate after first use up to 90 days", as set forth above in paragraph 110.

ii. Respondent's labels omitted Respondent's address and phone number and failed to include the route of administration on its containers, as set forth above in paragraph 120, in violation of CCR section 1751.2, subdivision (b).

b. Respondent's containers omitted information to facilitate adverse event reporting (www.fda.gov/medwatch and 1-800-FDA-1088 or any successor Internet Web site or phone number), as set forth in paragraph 120, in violation of 21 USC section 353b, subdivision (a)(10)(B)(ii).

c. Respondent's labels omitted an adequate listing of ingredients, as well as the quantity or portion of each ingredient, as set forth above in paragraph 121, in violation of 21 USC section 353b, subdivision (a)(10)(A)(iii).

**SEVENTEENTH CAUSE FOR DISCIPLINE**

**(CSP Labeled with BUD Exceeding the Shortest BUD of Ingredients Compounded)**

153. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, as set forth above in paragraph 124, on or about April 1, 2021, Respondent compounded and labeled

sincalide with a BUD of April 1, 2022, that was compounded with polysorbate that had an expiration date of February 13, 2021, in violation of CCR section 1751.8.

**EIGHTEENTH CAUSE FOR DISCIPLINE**

**(Failure to Maintain Quality of Compounded Sterile Preparations)**

154. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, Respondent violated CCR section 1735.2, subdivision (g), to wit:

a. Respondent compounded drug products using bulk ingredients that were either dietary grade or did not have an applicable USP-NF drug monograph or were sourced from manufacturers without active FDA registration, as set forth above in paragraph 107.

b. On or about June 8, 2021, Respondent produced and distributed in California preserved Ascorbic Acid 500 mg/mL with low fill volumes, as set forth above in paragraph 139 and 150.

c. On or about April 21, 2022, Respondent produced Sincalide, lot D24001, using expired polysorbate, as set forth above in paragraph 124.

d. Respondent produced Methylcobalamin without proper instructions, resulting in low-fill volume, as set forth above in paragraph 135.

e. Respondent produced lyophilized NAD+ without proper instructions, resulting in a product that did not conform to Respondent's Quality Assurance Plan. Specifically the product was evaporated and failed to conform to Respondent's predefined release specifications, as set forth above in paragraph 136.

f. On or about February 7, 2022, Respondent produced Biotin without proper instructions, resulting in low-fill volume, as set forth above in paragraph 137.

g. Respondent produced Lipo Mino Mix without proper instructions, resulting in a high assay for cyanocobalarnin, as set forth above in paragraph 138.

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## NINETEENTH CAUSE FOR DISCIPLINE

**(Adulterated Preparations)**

155. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent violated statutes regulating dangerous drugs and pharmacy law. Specifically, Respondent compounded and furnished at least the following compounded drugs, set forth below, which were, or may have been, contaminated with filth, putrid, or decomposed substances, and were therefore adulterated pursuant to Health & Saf. Code sections 111250, 111255, and/or 21 USCA 351, subdivision (a), in violation of Code section 4169, subdivision (a)(2), Health & Saf. Code section 111295, and 21 USCA section 331, subdivision (a):

a. Respondent compounded drug products using bulk ingredients that were either dietary grade or did not have an applicable USP-NF drug monograph or were sourced from manufacturers without active FDA registration, as set forth above in paragraph 107.

b. On or about June 8, 2021, Respondent produced and distributed in California preserved Ascorbic Acid 500 mg/mL with low fill volumes, as set forth above in paragraphs 139 and 150.

c. On or about April 1, 2022, Respondent produced Sincalide, lot D24001, using expired polysorbate, as set forth above in paragraph 124.

d. Respondent produced Methylcobalamin without proper instructions, resulting in low-fill volume, as set forth above in paragraph 135.

e. Respondent produced lyophilized NAD+ without proper instructions, resulting in a product that did not conform to Respondent's Quality Assurance Plan. Specifically the product was evaporated and failed to conform to Respondent's predefined release specifications, as set forth above in paragraph 136.

f. On or about February 7, 2022, Respondent produced Biotin without proper instructions, resulting in low-fill volume, as set forth above in paragraph 137.

g. Respondent produced Lipo Mino Mix without proper instructions, resulting in a high assay for cyanocobalarnin, as set forth above in paragraph 138.

**TWENTIETH CAUSE FOR DISCIPLINE**

**(Failure to Have a Written Master Formula for Compounding)**

156. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, Respondent violated CCR section 1735.2, subdivision (e)(5), in that Respondent failed to have a written master formula documenting specific and essential steps to compound its drug preparations. Specifically, Respondent failed to have a master formula document that included the compounding procedure and equipment required to compound, as follows:

a. On or about June 8, 2021, Respondent compounded preserved Ascorbic Acid 500 mg/mL without proper instructions, resulting in a low fill volume, as set forth above in paragraph 139 and 150.

b. Respondent produced Methylcobalamin without proper instructions, resulting in low-fill volume, as set forth above in paragraph 135.

c. Respondent produced lyophilized NAD+ without proper instructions, resulting in a product that did not conform to the Quality Assurance Plan, as set forth above in paragraph 136. Specifically, the product was evaporated and non-conforming to the predefined release specifications.

d. On or about February 7, 2022, Respondent produced Biotin without proper instructions, resulting in low-fill volume, as set forth above in paragraph 137.

e. Respondent produced Lipo Mino Mix without proper instructions, resulting in a high assay for cyanocobalamin, as set forth above in paragraph 138.

**TWENTY-FIRST CAUSE FOR DISCIPLINE**

**(Compounding Limitations and Requirements)**

157. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, Respondent compounded and dispensed products that were copies of commercially available products without documenting that the drugs were in short supply or that a medical need was made known to Respondent prior to compounding those drugs, in violation of CCR section

1735.2, subdivision (d)(3), and 21 USCA section 353b, subdivision (a)(2)(A). To wit, Respondent compounded and distributed:

a. Cyanocobalamin 2mg/mL, calcium chloride l00rng/mL, preserved diluent, lidocaine 1%/2%, magnesium chloride 200mg/mL, testosterone cyp 200mg/mL, and pyridoxine 100mg/mL, acetylcysteine 200mg/mL, as set forth above in paragraph 106.

b. Drug products using folic acid, as set forth above in paragraph 119.

**TWENTY-SECOND CAUSE FOR DISCIPLINE**

**(Failure to Obtain Prescriber's Signature)**

158. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, Respondent failed to deliver compounded drug product to the prescriber's office and obtain the signature of the prescriber or the prescriber's agent upon receipt. As set forth above in paragraph 149, during the review period between October 8, 2020, to October 19, 2021, approximately 4650 units of CSPs were shipped to locations representing a hotel, three different Postal Boxes or Annexes, one self-storage business, five residential addresses, and 36 UPS Stores, in violation of CCR section 1735.2, subdivision (c).

**TWENTY-THIRD CAUSE FOR DISCIPLINE**

**(Unlicensed Nonresident Outsourcing Facility Compounding/Furnishing Drugs)**

159. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, as set forth above in paragraph 111, Respondent furnished non-patient specific orders within California, yet Respondent is not licensed by the Board as an outsourcing facility, a violation of Code sections 4129.2, subdivision (a).

**TWENTY-FOURTH CAUSE FOR DISCIPLINE**

**(Failure to Maintain USP-NF Compounding Standards)**

160. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o). Specifically, Respondent knew, or should have known, that its compounding environment failed to meet criteria specified in its SOPs for the safe

compounding of sterile drug preparation, in violation of CCR section 1751.4, subdivision (a), and failed to follow USP-NF compounding standards in, violation of Code section 4126.8. To wit:

a. On or about August 18, 2021, Respondent failed to ensure that air currents in a cleanroom did not affect the performance of its biological safety cabinets, as set forth above in paragraph 116.

b. Respondent failed to control aseptic conditions in its compounding environment that contributed to microbial contamination of its CSPs, resulting in a recall on or about April 4, 2022, of CSPs distributed by Respondent, including, but not limited to, CSPs distributed in California, as set forth above in paragraphs 141 and 142.

**TWENTY-FIFTH CAUSE FOR DISCIPLINE**

**(Failure to Acquire and Retain Certificate of Analysis)**

161. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o). Specifically, Respondent failed to acquire and retain a certificate of analysis for Sincalide bulk lot G24020, as set forth above in paragraph 125, in violation of CCR section 1735.3, subdivisions (c) and (d); and, 21 USCA, section 353b, subdivision (a)(2)(D).

**TWENTY-SIXTH CAUSE FOR DISCIPLINE**

162. This paragraph has been deleted.

**TWENTY-SEVENTH CAUSE FOR DISCIPLINE**

**(Failure to Maintain Facility Sanitation)**

163. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o). Specifically, Respondent failed to follow statutes and regulations to ensure that its cleanroom and equipment were adequately cleaned and disinfected, as follows:

a. Respondent allowed carts and chairs with rust in the cleanroom that could not be adequately cleaned, as set forth above in paragraphs 116 and 131, in violation of CCR section 1714, subdivision (b).

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b. Respondent failed to document contact times to verify that disinfection occurred as specified, and was unable to provide the manufacturer's specified contact time for a cleaning agent, as set forth above in paragraph 131, in violation of CCR section 1714, subdivision (b), and CCR section 1751.4, subdivision (e).

c. Respondent failed to ensure that its SOPs were adequate to ensure the removal of residual API from a filling machine, as set forth above in paragraph 133, in violation of CCR section 1751.4, subdivision (e).

**TWENTY-EIGHTH CAUSE FOR DISCIPLINE**

**(Failure to Maintain and Follow SOPs for Compounding)**

164. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o). Specifically Respondent failed to follow its SOPs, in violation of CCR section 1735.5, subdivision (a), in that Respondent failed to evaluate its current cleaning practices to determine whether they were effective in the inactivation or removal of microorganisms in its ISO-5 environment, as set forth above in paragraphs 132, 132, 141, 142, and 144.

**TWENTY-NINTH CAUSE FOR DISCIPLINE**

**(Failure to Include a Written Procedure if CSP Found Outside Minimum Standards)**

165. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o). Specifically, Respondent failed to perform quality reviews on multiple lots of CSPs that failed to meet Respondent's specifications, in violation of CCR section 1735.8, as set forth above in paragraphs 137, 139, and 147.

**THIRTIETH CAUSE FOR DISCIPLINE**

**(Failure to Consult)**

166. Respondent is subject is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that it violated CCR section 1707.2, subdivision (b)(1), as set forth above in paragraph 114, as follows:

a. Respondent failed to provide written notice of a patient's right to a consultation with a pharmacist in Respondent's shipment to a prescriber in California.

b. Respondent was not available for oral consultation with a patient or their agent six days per week during regular hours of operation as required.

**THIRTY-FIRST CAUSE FOR DISCIPLINE**

**(Compounding and Furnishing Misbranded Drugs)**

167. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent violated statutes regulating dangerous drugs and pharmacy law. Specifically, Respondent violated Code section 4169, subdivision (a), and Health & Saf. Code sections 111330, 111335, and 111445 when it sold or transferred dangerous drugs that it knew, or should have known were misbranded. To wit, Respondent failed to meet labeling requirements, failed to maintain quality of its CSPs, compounded adulterated CSPs, failed to meet predefined specifications, failed to meet exemption criteria for compounding CSPs pursuant to 21 USCA sections 353a or 353b, failed to follow USP-NF compounding standards, and lacked sterility assurance, as set forth above in paragraphs 151 through 157, 159, 160, and 162 through 165.

**BACKGROUND INFORMATION – AUGUST 2022 INVESTIGATION**

168. On or about August 1 and 2, 2022, Inspector J.F. conducted an on-site, annual, nonresident sterile compounding renewal inspection of Respondent's facility in Orlando, Florida. Inspector J.F. requested, and Respondent provided, numerous documents for evaluation. At the conclusion of the inspection and upon review of Respondent's documentation, Inspector J.F. found multiple violations of Pharmacy Law, many of which constituted cause for denial of Respondent's application to renew its nonresident sterile compounding license. On or about September 19, 2022, Inspector J.F. issued another Written Notice to Respondent, notifying Respondent of the following violations:

**Written Notice #1**

169. Inspector J.F. found that Respondent failed to follow its own SOPs. Specifically, Respondent's *Policy on Current Good Documentation Practices* states, in pertinent part, "Never sign a task that is not completed". Respondent's quality associate, L.S., admitted to Inspector J.F. that he documented for a future date of August 2, 2022, that dispositioned passive viable air

plates were sampled on July 27, 2022, and passed with 0 CFU counts. Respondent's *Policy on Current Good Documentation Practices*, also states, in pertinent part, "Never sign or initial anyone else's name or initials". L.S. admitted to Inspector J.F. that it was his practice to document the samplers' initials on Respondent's environmental monitoring form without personally performing the sampling.

170. Inspector J.F. found that Respondent did not follow its own SOPs for conducting and reviewing aseptic processing simulations. For example, Respondent's *Aseptic Process Simulation 2* (APS2) procedure required mixing the final completed volume on the stir plate for no less than 60 minutes. On March 10, 2022, Lot APS2-A10-22 was mixed for 40 minutes. The procedure further required filtration time "of no less than 2 hours". On March 10, 2022, the total filtration time for Lot APS2-A10-22 was 22 minutes. The procedure required completion of the filling process prior to lyophilization. The filling for Lot APS2-A10-22 was documented as completed at 18:13 hours, yet lyophilization was documented as having started at 18:00 hours, thirteen minutes before filling was completed. On April 1, 2022, the lot was verified to conform to the finished product specification for quality assurance release and adhere to cGMP requirements.

171. Respondent's APS2 procedure required six filling personnel. On March 17, 2022, only five filling personnel participated in filling for Lot APS2-B017-22. Respondent's procedure also required no less than two hours for filtration. On March 17, 2022, the total filtration time was documented at 30 minutes. On April 6, 2022, the lot was verified to conform to the finished product specification for quality assurance release and adhere to cGMP requirements.

172. Inspector J.F. notified Respondent that the act set forth in paragraphs 169 through 171 were in violation of CCR section 1735.5, subdivision (a).

**Written Notice #2**

173. Inspector J.F. found that Respondent's SOP, *Shipping of Compounded Preparations,* requires, in pertinent part, that "Temperature sensitive compounded preparations must be maintained at a temperature of <8C for the entire duration of the transit." The labeled requirement for frozen products, however, is to store frozen (-10C to -25C/-13º to 14ºF). The

three different box sizes used by Respondent were not adequately described in Respondent's procedures. Respondent's 2021 study of its use of Nordic ice packs for shipping lacked sufficient information. The date the study was performed, the materials and equipment used, and the configuration employed were not fully documented. The study concluded in part, "These products are more than enough to preserve the efficacy of all medications that require room temperature or cold delivery demands." The study did not support adequate temperature control for frozen product. This is a repeat violation as set forth above in paragraph 110. Inspector J.F. notified Respondent that it was in violation of Code section 4126.8.

**Written Notice #3**

174. Inspector J.F. found that Respondent used secondary packaging for its "Vitamindrip" kit, consisting of a box containing three vials, each containing a different sterile product compounded by Respondent. One vial contained ascorbic acid 30mL, the second vial contained Olympia mineral blend 30mL, and the third vial contained VitaComplex 30mL. The kit is labeled as "Hydration Injection, USP". Inspector J.F. found that there is not, and never was, a United States Pharmacopeia (USP) monograph for "Hydration Injection". Inspector J.F. notified Respondent that it was in violation of Code section 4169, subdivision (a)(3).

**Written Notice #4**

175. Inspector J.F. found that labels on Respondent's compounded products identified the pharmacy as "Olympia Pharmaceuticals." However, the licensee's registered name is "Olympia Pharmacy". For example, the primary label on released lot# F24020-22 for Biotin 0.05% listed the name of the producing pharmacy as "Olympia Pharmaceuticals". Inspector J.F. notified Respondent that it was in violation of CCR section 1735.4, subdivision (a)(1).

**Written Notice #5**

176. On or about July 20, 2022, in its formal response to a *Written Notice* generated by the Board on July 6, 2022, Respondent provided written assurance to the Board that as of September 2, 2021, its updated *Batch Release* policy required two signatures for each batch released. One signature would be from a member of its quality assurance unit and a second from a pharmacist. Respondent assured the Board that this measure was taken to ensure that its batches

are approved for release only after ensuring that all required specifications are met. Inspector J.F. found that batch records for phenylephrine, lmg/mL, Lot #'s D24A26-22, D24B26-22, and D24C26-22, released on or about June 27, 2022, had one signature only on the batch release documentation. The final release for those batches was missing a pharmacist's signature. Inspector J.F. notified Respondent that it was in violation of Code section 4301, subdivision (g).

**Written Notices #s 6, 15, 19**

177. On or about April 26, 2022, Respondent was notified of a customer's complaint describing a patient's anaphylaxis and subsequent hospitalization after an IM[11] injection of a drug compounded by Respondent. Respondent was informed that the patient had a sulfa allergy. Respondent determined that its customer should have advised the patient that the product was not appropriate for her to take because it contained methionine. Respondent stated that methionine was known to be related to sulfa allergies. In its final impact assessment related to the complaint, Respondent documented that "This was a one-time incident caused by a customer error. . . Not an unexpected adverse event, methionine known to cause potential reactions to persons allergic to sulfur. Methionine is listed as an ingredient on the product label." Methionine does not contain any sulfonamide group or sulfites. On or about August 7, 2022, Respondent submitted to the Board a written statement that there had been no adverse events regarding its compounded sterile products in the last twelve months. Inspector J.F. documented in his October 19, 2021, inspection report that he had reminded Respondent of the requirements of mandatory reporting, including the reporting of adverse events, recalls, and complaints. Inspector J.F. notified Respondent that the acts were in violation of Code sections 4301, subdivision (g), 4127.2, subdivision (f), and 4301, subdivision (c).

**Written Notice #7**

178. Inspector J.F. found that Respondent's lyophilized product, Sermorelin 9mg., was labeled as a multi-dose vial. Inspector J.F. also found antimicrobial effectiveness testing had not been completed as part of stability testing, which considers the possible diluent(s) used.

[11] An intramuscular (IM) injection is a technique used to deliver a medication deep into the muscles. This allows the medication to be absorbed into the bloodstream quickly.

Sermorelin is not directly formulated with a preservative, and it is unknown whether this product has inherent antimicrobial effectiveness properties making it suitable for multi-dose label claims. Respondent's label does not specify the required diluent(s) for use. Respondent only completed method suitability for its multi-dose product, SB4. Preservative effectiveness had not been demonstrated, and test results were pending. This is a repeat violation as set forth above in paragraph 129. Inspector J.F. notified Respondent that it was in violation of CCR section 1751.2, subdivision (b).

**Written Notice #8**

179. Respondent holds a Food and Drug Administration (FDA) 503B registration for an outsourcing facility. Inspector J.F. found that Respondent's Storage Instructions leaflets, as well as other informational material, that generally accompany Respondent's product shipments into California, represent that Respondent is "A 503B Outsourcing Facility". Respondent does not hold a license as a nonresident outsourcing facility in the State of California. This is a repeat violation as set forth above in paragraphs 82 and 93. Inspector J.F. notified Respondent that it was in violation of Code section 4129.2, subdivision (a).

**Written Notice #10**

180. Inspector J.F. found that Respondent's testosterone injection, Lot #J24014, compounded on October 14, 2021, with a BUD of October 14, 2022, failed to include a controlled substance designation on the label. Inspector J.F. notified Respondent that it was in violation of Code section 4301, subdivision (j).

**Written Notice #11**

181. Inspector J.F. found that on or about April 26, 2022, Respondent recalled all lots produced prior to March 1, 2022. Respondent's SOP, *Recall of Compounded Product,* states, in pertinent part, that, "the states that received the products from the affected lots must be notified immediately or within 12 hours of product being deemed as a recall, whichever is sooner." The initial recall notification provided to the Board did not include the recall of all products. Inspector J.F. notified Respondent that it was in violation of Code section 4127.2, subdivision (e)(3).

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**Written Notice #12**

182. Respondent had a Central Fill agreement with Mint Pharmacy and Skin Clinic, (NRP 1968), located at 1201 US HWY 1 STE# 305C, North Palm Beach, Florida. On or about June 8, 2022, Mint pharmacy changed its location to 7960 Central Industrial Dr. STE 120, West Palm Beach, Florida (NRP 2728). On or about June 8, 2022, Respondent began shipping compounded products to 7960 Central Industrial Dr. STE 120, West Palm Beach, Florida (new location). On or about June 20, 2022, Respondent began shipping compounded sterile products for injection to the new location. A new Central Fill agreement was not executed until August 2, 2022, during the Board's onsite inspection. The Board was not notified within 30 days of commencing central fill activities with NRP 2728. This is a repeat violation as set forth above in paragraph 148. Inspector J.F. notified Respondent that it was in violation of Code section 4123.

**Written Notice #13**

183. Inspector J.F. concluded that Respondent's quality assurance plan was inadequate in that he found that not all integral units produced by Respondent in its aseptic process simulation were properly incubated. Inspector J.F. found that media fill lots APS2-A10-22 and APS2-B017-22 failed to incubate a total of 72 vials for 14 days. Samples were prematurely sent to the contract lab for growth promotion testing. Inspector J.F. notified Respondent that it was in violation of CCR section 1735.8, subdivision (b).

**Written Notices #s 14 and 16**

184. Inspector J.F. found that the inactive ingredient "BHT" was not listed on the master formula for compounding formula ID# 7409 for Benzocaine/Lidocaine/Tetracaine (BLT) 20/4/5, a cream. The equipment required for trituration, mixing, pouring, and measuring was not defined in Respondent's master formula. Quality reviews were not described and adequacy of mixing was not documented.

185. Customer complaint CC-2022-011 documented a complaint of product separation for BLT, Lot #210130. The compounding technician for that product acknowledged that separation was "caused by not leaving mix spin for a while." The product was not recalled from other customers who received the same batch. Inspector J.F. found that other steps for compounding

formula ID #7409 were also not followed as required. Specifically, BHT, pluronic acid and polysorbate were required ingredients for formula ID #7409, but were not added. Inspector J.F. reviewed Respondent's March 15, 2022, compounding of formula ID# 7409, and confirmed that there were no changes to the master formula's essential compounding steps and no preventative action was taken to prevent reoccurrence of inadequate mixing. This is a repeat violation as set forth above in paragraphs 135 and 136.

186. Inspector J.F. found that the master formulation and compounding logs for compounding formula ID #6924, lots K210219, K210202, compounded on November 29, 2021, and November 2, 2021, respectively, for minoxidil/fluocinolone/retinoic acid 5/0.01/0.01% called for the addition of vitamin E liquid, which was not added. Further, the final packaging requirements were not described and the final packout quantity for lot K210202 was unclear. Lastly, the labels did not include the compounding date.

187. Inspector J.F. found that the master formulation for Sermorelin 9mg formula ID# 5679 calls for 18 grams of API; however, the pharmacy routinely added a 10% overage without documenting an explanation for doing so.

188. Inspector J.F. notified Respondent that the acts set forth in paragraphs 184 through 187 above were in violation of Code section 4169, subdivision (a)(2) and CCR section 1735.2, subdivision (c).

**Written Notice #17**

189. Inspector J.F. found that Respondent's SOPs addressing hand hygiene did not require persistent activity hand sanitizer and that Respondent did not have a related competency assessment. Respondent's competency assessment for hand hygiene also did not evaluate operators for use of a nail pick to remove debris or the application of a waterless surgical scrub with persistent activity. Inspector J.F. notified Respondent that it was in violation of CCR section 1751.6, subdivision (e)(1)(F).

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**THIRTY-SECOND CAUSE FOR DISCIPLINE**

**(Failure to Maintain Written Policies and Procedures for Compounding)**

190. Respondent is subject to disciplinary action pursuant to Code section 4301 subdivision (o), on the grounds that it engaged in unprofessional conduct. Specifically, Respondent failed to follow its written policies and procedures, in violation of CCR section 1735.5, subdivision (a), as follows:

a. Respondent's employee, L.S., admitted that he signed that a specific task was completed at a specific time when, in fact that task had not been completed at that time, contrary to Respondent's SOPs, as set forth in paragraph 169, above.

b. Respondent's employee, L.S., admitted that he entered initials of other employees on environmental monitoring forms without personally performing the task for which the initials were entered, contrary to Respondent's SOPs, as set forth in paragraph 169 above.

c. On or about April 1, 2022, Respondent verified that Lot APS-A10-22 met Respondent's finished product specifications for quality assurance when, in fact, Respondent's specifications had not been followed, as set forth in paragraph 170, above.

d. On or about April 6, 2022, Respondent verified that Lot APS-B017-22 met Respondent's finished product specifications for quality assurance when, in fact, Respondent's specifications had not been followed, as set forth in paragraph 171 above.

**THIRTY-THIRD CAUSE FOR DISCIPLINE**

**(Failure to Maintain United States Pharmacopeia-National Formulary Compounding Standards)**

191. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), on the grounds that it engaged in unprofessional conduct. Specifically, Respondent failed to follow United States Pharmacopeia-National Formulary (USP-NF) compounding standards in, violation of Code section 4126.8, as set forth in paragraph 173, above. To wit:

a. Respondent's labels for packaging and shipping procedures for compounded sterile products requiring frozen storage conditions indicating that the compound is to be stored

frozen (-25C to -10C/-13º to 14ºF) is incongruent with Respondent's procedure, which states that temperature sensitive compounded preparations must be maintained at a temperature of <8C for the entire duration of the transit.

b. Respondent failed to describe adequately box sizes for shipping.

c. Respondent failed to ensure adequate temperature control for shipped frozen product.

**THIRTY-FOURTH CAUSE FOR DISCIPLINE**

**(Omission of Licensee's Name on Label)**

192. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), on the grounds that it engaged in unprofessional conduct. Specifically, as set forth above in paragraph 175, Respondent's drug product labels identified the pharmacy as "Olympia Pharmaceuticals", when, in fact, Respondent's licensed name is "Olympia Pharmacy", in violation of CCR section 1735.4, subdivision (a)(1).

**THIRTY-FIFTH CAUSE FOR DISCIPLINE**

**(False Certification/Documentation of Facts)**

193. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (g), on the grounds that it engaged in unprofessional conduct by knowingly making or signing a certificate or other document that falsely represents the existence or nonexistence of a state of facts. To wit:

a. As set forth above in paragraph 176, Respondent released compounded sterile drug product without a pharmacist's final signature, contrary to its assurances to the Board that its compounded sterile drug batches would be reviewed and signed by a member of its Quality Unit as well as a pharmacist prior to release.

b. As set forth above in paragraph 177, Respondent stated to the Board that it had no adverse events regarding its compounded sterile products. In fact, on or about April 26, 2022, Respondent was notified of a customer's complaint describing anaphylaxis and subsequent hospitalization after use of a drug compounded by Respondent.

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**THIRTY-SIXTH CAUSE FOR DISCIPLINE**

**(Labeling Requirements – Inappropriate Instructions for Storage, Handling, Administration)**

194. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), for unprofessional conduct. Specifically, as set forth above in paragraph 178, Respondent failed to demonstrate that multi-dose vials used for sermorelin and SB4 were suitable for multi-dose label claims, in violation of CCR section 1751.2, subdivision (b).

**THIRTY-SEVENTH CAUSE FOR DISCIPLINE**

**(Unlicensed Activity - Outsourcing)**

195. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), on the grounds of unprofessional conduct. Specifically, as set forth above in paragraph 179, Respondent represented to California consumers that it is a 503B outsourcing facility. Respondent does not hold a license as a nonresident outsourcing facility in the State of California, in violation of Code section 4129.2, subdivision (a).

**THIRTY-EIGHTH CAUSE FOR DISCIPLINE**

**(Improper Labeling of a Controlled Substance)**

196. Respondent is subject to disciplinary action pursuant to Code 4301, subdivision (o), on the grounds of unprofessional conduct. Specifically, as set forth above in paragraph 180, Respondent failed to label testosterone as a controlled substance, in violation of 21 CFR 1302.03.

**THIRTY-NINTH CAUSE FOR DISCIPLINE**

**(Failure to Provide Board with Timely Notice of Recall)**

197. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), on the grounds of unprofessional conduct. Specifically, as set forth above in paragraph 181, Respondent failed to provide the Board within twelve hours of its notice of recall for a sterile drug product that it compounded and shipped into California, in violation of Code section 4127.2, subdivision (e)(3).

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**FORTIETH CAUSE FOR DISCIPLINE**

**(Failure to Provide Board with Notice of Contract to Compound Drug for Parenteral Therapy)**

198. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), on the grounds of unprofessional conduct. Specifically, as set forth above in paragraph 182, Respondent failed to notify the Board, within 30 days of commencing compounding a drug for another pharmacy for parenteral therapy, of its contract with that pharmacy to do so, in violation of Code section 4123.

**FORTY-FIRST CAUSE FOR DISCIPLINE**

**(Quality Assurance Plan – Written Procedures)**

199. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), on the grounds of unprofessional conduct. Respondent failed to ensure the adequacy of its compounding processes, in violation of CCR section 1735.8, subdivision (b). Specifically, as set forth above in paragraph 183, Respondent failed to adequately incubate for aseptic conditions and failed to have a pre-defined set of compounding instructions for its aseptic process simulation.

**FORTY-SECOND CAUSE FOR DISCIPLINE**

**(Written Master Formula)**

200. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), on the grounds of unprofessional conduct. Specifically, Respondent failed to prepare a written master formula adequate for compounding, in violation of CCR section 1735.2, subdivision (e), as follows:

a. As set forth above in paragraph 184, Respondent's master formulation for compound formula ID #7409 for BLT 20/4/5 was inadequate, to wit:

i. "BHT" was not listed on the master formula.

ii. Equipment required for trituration, mixing, pouring, and measuring was not defined.

iii. Quality reviews were not described.

iv. Adequacy of mixing was not documented.

b. As set forth above in paragraph 186, Respondent's master formulation for compound formula ID #6924, lot #K210219, compounded on or about November 29, 2021, and lot #K210202, compounded on or about November 2, 2021, was inadequate, to wit:

i. The addition of vitamin E liquid was not added, contrary to the mixing directions.

ii. The final packout quantity could not be determined for lot #K210202.

iii. The labels were missing the compounding date.

c. As set forth above in paragraph 187, Respondent's master formulation for compound formula Sermorelin 9 mg. formula, ID# 5679 called for 18 grams of Active API; however, the pharmacy routinely adds a 10% overage without documenting an explanation for doing so.

**FORTY-THIRD CAUSE FOR DISCIPLINE**

**(Adverse Effects Reporting)**

201. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), on the grounds of unprofessional conduct. Specifically, as set forth in paragraph 177, above, Respondent failed to notify the Board within twelve hours of an adverse drug reaction for anaphylaxis of a patient resulting from use of a drug compounded by Respondent, in violation of Code section 4127.2, subdivision (f).

**FORTY-FOURTH CAUSE FOR DISCIPLINE**

**(Failure to Maintain Quality of Compounded Sterile Preparations)**

202. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, Respondent violated CCR section 1735.2, subdivision (g), in that, as set forth in paragraph 185, above, Respondent compounded Lot #210130, a BLT cream preparation, which Respondent knew to have a compounding error and for which compounding steps were unclear, resulting in separation.

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**FORTY-FIFTH CAUSE FOR DISCIPLINE**

**(Adulterated Preparation)**

203. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent violated statutes regulating dangerous drugs and pharmacy law. Specifically, as set forth in paragraph 185, above, Respondent compounded and furnished Lot #210130, a BLT cream preparation, which was, or may have been, contaminated with filth, putrid, or decomposed substances, and was therefore adulterated pursuant to Health & Saf. Code sections 111250, 111255, and/or 21 USCA 351, subdivision (a), in violation of Code section 4169, subdivision (a)(2), Health & Saf. Code section 111295, and 21 USCA section 331, subdivision (a).

**FORTY-SIXTH CAUSE FOR DISCIPLINE**

**(Training and Evaluation of Compounding Staff – Hand Hygiene)**

204. Respondent is subject to disciplinary action pursuant to Code 4301, subdivision (o), on the grounds of unprofessional conduct. Specifically, as set forth above in paragraph 189, Respondent failed to include proper hand hygiene in its SOPs/written program of training and its evaluation of the hand hygiene of staff, in violation of CCR section 1751.6, subdivision (e)(1)(F).

**FORTY-SEVENTH CAUSE FOR DISCIPLINE**

**(Gross Negligence)**

205. Respondent is subject to disciplinary action pursuant to Code 4301, subdivision (c), on the grounds of unprofessional conduct. Specifically, Respondent committed gross negligence when it erroneously concluded that methionine caused a customer's anaphylactic reaction, as set forth in paragraph 177, above.

**FORTY-EIGHTH CAUSE FOR DISCIPLINE**

**(Compounding and Furnishing Misbranded Drugs)**

206. Respondent is subject to disciplinary action Respondent is subject to disciplinary action on the grounds that it engaged in unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o). Specifically, Respondent violated Code section 4169, subdivision (a), and Health & Safety Code sections 111330, 111335, and 111445, in that it sold or transferred

dangerous drugs that it knew, or should have known were misbranded, in that it failed to meet predefined specifications, failed to follow USP-NF compounding standards, failed to meet labeling requirements, lacked sterility assurance, failed to maintain quality of its CSPs, and compounded adulterated CSPs, and as set forth above in paragraphs 190 through 195, 199, 200, 202, and 203.

**DISCIPLINE CONSIDERATIONS**

207. To determine the degree of discipline, if any, to be assessed against Respondent, Complainant alleges as follows:

208. On or about August 3, 2017, the Board issued to Respondent Olympia Pharmacy, Permit No. NRP 1525, Citation No. CI 2017 75966 for violating Code section 4301, subdivision (o) (violation of regulations governing pharmacy), in conjunction with CCR sections 1735.7, subdivisions (a) and (b) (failure to maintain written documentation sufficient to demonstrate that pharmacy personnel have skills and training required to perform compounding responsibilities/failure to develop and maintain ongoing competency evaluation process); and, 1751.7, subdivision (b) (failure of individual(s) involved in preparation of sterile injectable products to complete a validation process on technique before preparing sterile injectable products). The citation was final on or about August 3, 2017.

209. On or about August 3, 2017, the Board issued to Respondent Olympia Pharmacy, Permit No. NSC 100818, Citation No. CI 2016 72741 for violating Code section 4301, subdivision (o), in conjunction with CCR sections 1735.7, subdivisions (a) and (b), and 1751.7, subdivision (b) (failure of individual(s) involved in preparation of sterile injectable products to complete a validation process on technique before preparing sterile injectable products). A fine in the amount of $1,000 was issued. The citation was final on or about August 3, 2017. Respondent complied with the fine on or about October 27, 2017.

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## OTHER MATTERS

210. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 1525, or Nonresident Sterile Compounding Permit Number NSC 100818, issued to Olympia Pharmacy, Olympia Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy Permit Number NRP 1525, or Nonresident Sterile Compounding Permit Number NRP SC 100818, are placed on probation or until said permits are reinstated if revoked.

211. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 1525, or Nonresident Sterile Compounding Permit Number NSC 100818, issued to Olympia Pharmacy, Marco Loleit shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy Permit Number NRP 1525, or Nonresident Sterile Compounding Permit Number NRP SC 100818, are placed on probation or until said permits are reinstated if revoked.

## PRAYER

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

1. Revoking or suspending Nonresident Pharmacy Permit Number NRP 1525, issued to Olympia Pharmacy;

2. Revoking or suspending Nonresident Sterile Compounding Permit Number NSC 100818, issued to Olympia Pharmacy;

3. Prohibiting Olympia Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy Permit Number NRP 1525 is placed on probation or until Nonresident Pharmacy Permit Number NRP 1525 is reinstated if Nonresident Pharmacy Permit Number NRP 1525 issued to Olympia Pharmacy is revoked;

///

4. Prohibiting Marco Loleit from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy Permit Number NRP 1525 is placed on probation or until Nonrsident Pharmacy Permit Number NRP 1525 is reinstated if Nonresident Pharmacy Permit Number NRP 1525 issued to Olympia Pharmacy is revoked;

5. Ordering Olympia Pharmacy and Marco Loleit 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,

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

DATED: 3/25/2024

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2024.03.25 08:23:37 -07'00'

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

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# Exhibit B

**Second Amended Statement of Issues No. 7089**

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

| | |
|---|---|
| In the Matter of the Statement of Issues Against**:** | Case No. 7089 |
| **OPS INTERNATIONAL INCORPORATED, DBA OLYMPIA PHARMACY; MARCO LOLEIT, CEO AND OWNER**<br><br>**Nonresident Pharmacy Permit Applicant**<br>**Nonresident Sterile Compounding Permit Applicant**<br><br>Respondent. | **SECOND AMENDED STATEMENT OF ISSUES** |

## PARTIES

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

2. On or about March 23, 2020, the Board received applications for a Nonresident Pharmacy Permit and a Nonresident Sterile Compounding Permit ("applications") from OPS International Incorporated, doing business as Olympia Pharmacy, with Marco Loleit as its Chief Executive Officer and 100% stockholder (Respondent). On or about March 11, 2020, Marco

Loleit certified under penalty of perjury to the truthfulness of all statements, answers, and representations in the application. The Board denied the applications on or about December 22, 2020.

## JURISDICTION

3. This Second Amended Statement of Issues is brought before the Board, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Code Section 4302 states:

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

## STATUTORY PROVISIONS

5. Code section 4307, subdivision (a), states, in pertinent part:

> 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, or partner of any partnership, corporation, 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, or partner 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, or partner of a licensee as follow:
>
> (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. . . .

## FACTUAL ALLEGATIONS

6. Marco Loleit signed Respondent's applications as Respondent's Chief Executive Officer and "owner". Mr. Loleit was the only listed officer for Respondent on its applications.

7. Mr. Loleit is also currently listed in the Board's records as the Chief Executive Officer, Chief Financial Officer, Secretary and Treasurer of Olympia Pharmacy, Nonresident

Pharmacy Permit Number NRP 1525 and Nonresident Compounding Permit Number NSC 100818 (hereinafter Olympia Pharmacy).

8. On December 13, 2022, Second Amended Accusation No. 7088 was filed against Olympia Pharmacy, alleging violations of pharmacy law. A true copy of Second Amended Accusation No. 7088 is attached as Exhibit A.

## CAUSE FOR DENIAL OF APPLICATION

**(Conditions Exist Constituting Grounds for Disciplinary Action)**

9. Respondent's applications are subject to denial pursuant to Code sections 4302 in that conditions exist in relation to a person owning 10 percent or more of the ownership interest or serving as an officer of Respondent that would constitute grounds for disciplinary action. The circumstances are that a Second Amended Accusation has been filed against Olympia Pharmacy alleging violations of pharmacy law. Marco Loleit is an officer of Olympia Pharmacy and is listed as an officer and owner of Respondent, as set forth in paragraphs 6-8 above.

## OTHER MATTERS

10. Pursuant to Code section 4307, if Respondent's applications are denied or if discipline is imposed on a permit issued to Respondent, then Respondent shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee until said permit is issued or for five years if a permit is issued and placed on probation.

## 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. Denying the applications of OPS International Incorporated, dba Olympia Pharmacy for a Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit;

2. Prohibiting OPS International Incorporated, dba Olympia Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee until a permit is issued if the applications are denied or for five years if a permit is issued and placed on probation;

3. Prohibiting Marco Loleit from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee until a permit is issued if the applications are denied or for five years if a permit is issued and placed on probation; and,

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

DATED: 3/8/2024

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2024.03.08 11:24:57 -08'00'

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

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# Exhibit C

**First Amended Statement of Issues No. 7384**

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

| | |
|---|---|
| In the Matter of the Statement of Issues Against**:**<br><br>**OLYMPIA PHARMACY**<br><br>**Applicant for Renewal of Non-Resident Sterile Compounding License No. NSC100818**<br><br>Respondent. | Case No. 7384<br><br>**FIRST AMENDED STATEMENT OF ISSUES** |

## PARTIES

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

2. On or about December 15, 2015, the Board issued Non-Resident Sterile Compounding License Number NSC 100818 to OPS International Incorporated, doing business as Olympia Pharmacy (Respondent), with Marco Loleit, its 100% shareholder, as its Chief Executive Officer, Chief Financial Officer, Secretary and Treasurer. The Non-Resident Sterile Compounding License was in full force and effect at all times relevant to the charges brought

herein and will expire on November 1, 2022, unless renewed. Prior to its expiration, Respondent applied for the renewal of Nonresident Sterile Compounding License No. NSC 100818. On or about September 16, 2022, Respondent's application for renewal was denied.

3. On or about September 26, 2022, the Board received Respondent's timely appeal of the Board's denial of Respondent's Nonresident Sterile Compounding License No. NSC 100818.

## JURISDICTION

4. This First Amended Statement of Issues 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.
> . . .
>
> (c) The board may refuse a license to any applicant guilty of unprofessional conduct. . . .
> . . .
>
> (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 4301 states, in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct includes, but is not limited to, any of the following:
>
> . . .
>
> (c) Gross negligence.
>
> . . .

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

. . .

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

. . .

8. Section 4342, subdivision (a) of the Code, states:

The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code

**STATUTORY PROVISIONS**

9. Code section 4123 states:

Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.

10. Code section 4126.8 states:

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

11. Code section 4127.2 states, in pertinent part:

(a) A nonresident pharmacy shall not compound sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

. . .

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident pharmacy shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually pursuant to subdivision (v) of Section 4400.

. . .

(e) A pharmacy licensed pursuant to this section shall do all of the following:

. . .

(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.

. . .

(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. . . .

12. Code section 4129.1 states, in pertinent part:

(a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) and with an address in this state shall also be licensed by the board as an outsourcing facility before doing business within this state. The license shall be renewed annually and is not transferable.

(b) An outsourcing facility shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) An outsourcing facility license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) An outsourcing facility license shall not be issued or renewed until the board does all of the following:

(1) Prior to inspection, reviews a current copy of the outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the outsourcing facility's premises conducted in the prior 12 months.

(3) Prior to inspection, receives a list of all sterile drugs and nonsterile drugs compounded by the outsourcing facility as reported to the FDA in the last 12 months.

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

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

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

(3) A copy of any clinically related complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.

(4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to the outsourcing facility's products.

13. Code section 4129.2 states, in pertinent part:

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

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

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. Code section 4307 states, in pertinent part:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer,

director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

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

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

(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.

**HEALTH AND SAFETY CODE**

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

17. Health & Saf. Code, section 111255, states, "Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."

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

19. Health and Saf. Code, section 111330, states, "Any drug or device is misbranded if its labeling is false or misleading in any particular."

20. Health and Saf. Code, section 111335, states, "Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

21. Health and Saf. Code section 111430 states, "A drug or device is misbranded if it was manufactured in an establishment not duly registered with the Secretary of Health, Education, and Welfare of the United States."

22. Health and Saf. Code section 111440 states, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

23. Health and Saf. Code section 111445 states, "It is unlawful for any person to misbrand any drug or device."

24. Health and Saf. Code section 111445 states, "It is unlawful for any person to misbrand any drug or device."

**CALIFORNIA REGULATIONS**

25. California Code of Regulations, title 16 (CCR), section 1735.2 states, in pertinent part:

> . . .
>
> (e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:
>
> . . .
>
> (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.
>
> . . .

26. CCR section 1735.4 states, in pertinent part:

> (a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:
>
> (1) Name of the compounding pharmacy and dispensing pharmacy (if different). . . .

27. CCR section 1735.5, subdivision (a) states, in pertinent part:

> Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

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28. CCR section 1735.8 states, in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel. . . .

29. CCR section 1751.6, subdivision (e), states, in pertinent part:

Pharmacies that compound sterile drug preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(F) Proper hand hygiene, gowning and gloving technique. . . .

**FEDERAL STATUTES AND REGULATIONS**

30. United States Code Annotated, title 21 (21 USCA) section 321 states, in pertinent part:

. . .

(ff) The term "dietary supplement" –

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

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

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

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

(2) Means a product that –

(A)

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

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

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

(C) is labeled as a dietary supplement; and

(3) does-

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

(B) not include-

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

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

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

31. 21 USCA section 331 states, in pertinent part:

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded. . . .

32. 21 USCA section 350 states, in pertinent part:

. . .

(c) Definitions

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

///

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

(B) which-

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

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

33. 21 USCA section 351 states, in pertinent part:

A drug or device shall be deemed to be adulterated –

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

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

(2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act [21 USCA §§ 301 et seq.] as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this Act [21 USCA §§ 301 et seq.] as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 721(a) [21 USCA § 379e(a)], or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 721(a) [21 USCA § 379e(a)]; or (5) if it is a new animal drug which is unsafe within the meaning of section 512 [21 USCA § 360b]; or (6) if it is an animal feed bearing or contaminating a new animal drug, and such animal feed is unsafe within the meaning of section 512 [21 USCA § 360f].

(b) Strength, quality, or purity differing from official compendium. If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. . . . Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the

Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia. . . .

34. 21 USCA section 352 states, in pertinent part:

A drug or device shall be deemed to be misbranded—

. . .

(o) Drugs or devices from nonregistered establishments. If it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 [21 USCA § 360], if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 801(s) [21 USCA § 381(s)], if it was not included in a list required by section 510(j) [21 USCA § 360(j)], if a notice or other information respecting it was not provided as required by such section or section 510(k) [21 USCA § 360(k)], or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 510(e) [21 USCA § 360(e)] as the Secretary by regulation requires. . . .

35. 21 USCA section 353a states, in pertinent part:

(a) In general. Sections 501(a)(2)(B), 502(f)(1), and 505 [21 USCA §§ 351(a)(2)(B), 352(f)(1), and 355] shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

(1) is by—

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

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

(2)

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

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

(i) the licensed pharmacist or licensed physician; and

(ii)

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

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

(b) Compounded drug.

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

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

(i) that—

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

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

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

(ii) that are manufactured by an establishment that is registered under section 510 [21 USCA § 360] (including a foreign establishment that is registered under section 510(i) [21 USCA § 360(i)]); and

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

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

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

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(2) Definition. For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

(3) Drug product. A drug product may be compounded under subsection (a) only if—

(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) such drug product is compounded in a State—

(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

…

(e) "Compounding" defined. As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

36. 21 USCA section 353b states, in pertinent part:

(a) In general. Sections 502(f)(1), 505, and 582 [21 USCA §§ 352(f)(1), 355, and 360eee-1] shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met:

(1) Registration and reporting. The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (b).

(2) Bulk drug substances. The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless—

(A)
(i) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by—

(I) publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;

(II) providing a period of not less than 60 calendar days for comment on the notice; and

(III) publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or

(ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 506E [21 USCA § 356e] at the time of compounding, distribution, and dispensing;

(B) if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substances each comply with the monograph;

(C) the bulk drug substances are each manufactured by an establishment that is registered under section 510 [21 USCA § 360] (including a foreign establishment that is registered under section 510(i)) [21 USCA § 360(i)]; and

(D) the bulk drug substances are each accompanied by a valid certificate of analysis.

(3) Ingredients (other than bulk drug substances) If any ingredients (other than bulk drug substances) are used in compounding the drug, such ingredients comply with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph if any.

(4) Drugs withdrawn or removed because unsafe or not effective. The drug does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

(5) Essentially a copy of an approved drug. The drug is not essentially a copy of one or more approved drugs.

(6) Drugs presenting demonstrable difficulties for compounding. The drug—

(A) is not identified (directly or as part of a category of drugs) on a list published by the Secretary, through the process described in subsection (c), of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients; or

(B) is compounded in accordance with all applicable conditions identified on the list described in subparagraph (A) as conditions that are necessary to prevent the drug or category of drugs from presenting the demonstrable difficulties described in subparagraph (A).

(7) Elements to assure safe use. In the case of a drug that is compounded from a drug that is the subject of a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 505-1 [21 USCA § 355-1], or from a bulk drug substance that is a component of such drug, the outsourcing facility demonstrates to the Secretary prior to beginning compounding that such facility will utilize controls comparable to the controls applicable under the relevant risk evaluation and mitigation strategy.

(8) Prohibition on wholesaling. The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. This paragraph does not prohibit administration of a drug in a health care setting or dispensing a

drug pursuant to a prescription executed in accordance with section 503(b)(1) [21 USCA § 353(b)(1)].

(9) Fees. The drug is compounded in an outsourcing facility that has paid all fees owed by such facility pursuant to section 744K [21 USCA § 379j-62].

(10) Labeling of drugs.

(A) Label. The label of the drug includes—

(i) the statement "This is a compounded drug." or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

(ii) the name, address, and phone number of the applicable outsourcing facility; and

(iii) with respect to the drug—

(I) the lot or batch number;

(II) the established name of the drug;

(III) the dosage form and strength;

(IV) the statement of quantity or volume, as appropriate;

(V) the date that the drug was compounded;

(VI) the expiration date;

(VII) storage and handling instructions;

(VIII) the National Drug Code number, if available;

(IX) the statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only"; and

(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

(B) Container. The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include—

(i) the information described under subparagraph (A)(iii)(X), if there is not space on the label for such information;

(ii) the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088 (or any successor Internet Web site or phone number); and

(iii) directions for use, including, as appropriate, dosage and administration.

(C) Additional information. The label and labeling of the drug shall include any other information as determined necessary and specified in regulations promulgated by the Secretary.

(11) Outsourcing facility requirement. The drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section.

(b) Registration of outsourcing facilities and reporting of drugs.

. . .

(2) Drug reporting by outsourcing facilities.

(A) In general. Upon initially registering as an outsourcing facility, once during the month of June of each year, and once during the month of December of each year, each outsourcing facility that registers with the Secretary under paragraph (1) shall submit to the Secretary a report—

(i) identifying the drugs compounded by such outsourcing facility during the previous 6-month period; and

(ii) with respect to each drug identified under clause (i), providing the active ingredient, the source of such active ingredient, the National Drug Code number of the source drug or bulk active ingredient, if available, the strength of the active ingredient per unit, the dosage form and route of administration, the package description, the number of individual units produced, and the National Drug Code number of the final product, if assigned.

. . .

(4) Risk-based inspection frequency.

(A) In general. Outsourcing facilities—

(i) shall be subject to inspection pursuant to section 704 [21 USCA § 374]; and

(ii) shall not be eligible for the exemption under section 704(a)(2)(A) [21 USCA § 374(a)(2)(A)].

(B) Risk-based schedule. The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect outsourcing facilities in accordance with a risk-based schedule established by the Secretary.

(C) Risk factors. In establishing the risk-based schedule, the Secretary shall inspect outsourcing facilities according to the known safety risks of such outsourcing facilities, which shall be based on the following factors:

(i) The compliance history of the outsourcing facility.

(ii) The record, history, and nature of recalls linked to the outsourcing facility.

(iii) The inherent risk of the drugs compounded at the outsourcing facility.

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(iv) The inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has been inspected pursuant to section 704 [21 USCA § 374] within the last 4 years.

(v) Whether the outsourcing facility has registered under this paragraph as an entity that intends to compound a drug that appears on the list in effect under section 506E [21 USCA § 356e].

(vi) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(5) Adverse event reporting. Outsourcing facilities shall submit adverse event reports to the Secretary in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).

. . .

(d) Definitions. In this section:

(1) The term "compounding" includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

(2) The term "essentially a copy of an approved drug" means—

(A) a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 503(b) [21 USCA § 353(b)] and not subject to approval in an application submitted under section 505 [21 USCA § 355], unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 506E [21 USCA § 356e] at the time of compounding, distribution, and dispensing; or

(B) a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 503(b) [21 USCA § 353(b)] and not subject to approval in an application submitted under section 505 [21 USCA § 355], unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

(3) The term "approved drug" means a drug that is approved under section 505 [21 USCA § 355] and does not appear on the list described in subsection (a)(4) of

drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective. . . .

37. Code of Federal Regulations, title 21 (CFR), section 1302.03 states, in pertinent part:

(a) Each commercial container of a controlled substance (except for a controlled substance excepted by the Administrator pursuant to § 1308.31 of this chapter) shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. Each such commercial container, if it otherwise has no label, must bear a label complying with the requirement of this part.

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(b) Each manufacturer shall print upon the labeling of each controlled substance distributed by him the symbol designating the schedule in which such controlled substance is listed.

(c) The following symbols shall designate the schedule corresponding thereto:

| Schedule | |
|---|---|
| Schedule I | CI or C-I. |
| Schedule II | CII or C-II. |
| Schedule III | CIII or C-III. |
| Schedule IV | CIV or C-IV. |
| Schedule V | CV or C-V. |

The word "schedule" need not be used. No distinction need be made between narcotic and nonnarcotic substances. . . .

**DEFINITIONS**

38. **Aseptic process simulations** (APS), also known as media fill, are studies conducted on the aseptic filling process, which is simulated to the actual production procedure where the product is replaced with growth media.

39. **Food Chemical Codex (FCC)**. The FCC and associated Reference Materials enables you to verify the identity, quality, and purity of the food ingredients you buy and sell, which help to ensure the overall safety and integrity of the food ingredient supply chain. An FCC standard can be used to characterize ingredients used in food. Monographs in the FCC consist of tests and specifications for identification, assay and impurities, as well as other tests that help describe the purity and quality of the ingredient. FCC standards are reviewed and approved by independent experts.

40. **Lyophilization** is a low temperature dehydration process where the product is frozen, the pressure lowered, and ice removed by sublimation. Lyophilization allows for ease of storage, shipping, and reconstitution to the product's original form for injection.

41. **Methionine** is a sulfur-containing essential amino acid that is a constituent of most proteins.

42. **Out-of-Specification Investigation**. A required element of the Quality Assurance Plan required as described in CCR section 1735.8 in response to a product test result outside its specification limits. A written procedure, i.e., SOP, must exist that describes the methodology for performing an OOS investigation. OOS investigations must be documented.

43. **Settle Plates**, also known as sedimentation plates or settling plates, are used in the pharmaceutical industry for semi-quantitative determination of microbial contamination in the air. The plate is typically a petri dish containing an agar medium. The plate is opened and exposed over a given period of time, allowing microbe-bearing particles to deposit onto the plate. The number of microbe bearing particles deposited onto the agar surface of the plate over the period of exposure is ascertained by incubating the plate and counting the number of microbial colonies (colony-forming units, [CFUs]).

44. **Standard Operating Procedure (SOP)** is a documented method or set of written directions to complete a specific process(es).

45. **USP-NF** is the United States Pharmacopeia-National Formulary, a comprehensive source for over 5,000 quality standards for medicines, active pharmaceutical ingredients (API), and inactive ingredients.

46. **USP Monographs**. USP-NF publishes monographs that articulate the quality expectations for medicines approved by the U.S. Food and Drug Administration (US FDA), including the medication identity, strength, purity and performance. Monographs also describe the tests to validate that a medicine and its ingredients meet USP-NF criteria.

## DRUG DESCRIPTIONS

47. **Ascorbic acid injection** (brand name *Acor*®) is indicated for short term treatment of scurvy in patients for whom oral administration is not possible, insufficient, or contraindicated. It is a dangerous drug within the meaning of Code section 4022.

48. **Biotin injection,** compounded by Respondent, is a dangerous drug within the meaning of Code section 4022. There is no FDA approved indication for this drug.

49. **Benzocaine/Lidocaine/Tetracaine (BLT), Formula ID #7409,** compounded by Respondent, is a non-sterile drug preparation for topical application.

50. **Butylated hydroxytoluene (BHT)** is a synthetic organic chemical compounding which inhibits oxidation of unsaturated organic compounds. It is often used in food, cosmetics, and pharmaceutical applications to prevent oxidation.

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51. **Formula ID #6924**, non-sterile preparations, compounded by Respondent, is comprised of minoxidil/ fluocinolone/retinoic acid 5/0.01/0.01%.

52. **Olympia Vita-Complex Injection**, compounded by Respondent, contains thiamine hydrochloride (vitamin B1), niacinamide (vitamin B3), riboflavin (vitamin B2), dexpanthenol (vitamin B5), pyridoxine hydrochloride (vitamin B6), benzyl alcohol, and SWFI. It is a dangerous drug within the meaning of Code section 4022. There is no FDA approved indication for this drug.

53. **Sermorelin Acetate injection**, compounded by Respondent, is a human growth hormone-releasing hormone (GHRH or GRF) used for diagnostic evaluation of pituitary function and also for increasing growth in children. It is a dangerous drug pursuant to Code section 4022.

54. **Testosterone Cypionate injection** (Respondent's tradename Ultratest), compounded by Respondent, comes only in the form of an injectable solution given into a muscle. It is used to treat symptoms of hypogonadism in males (a condition where males do not produce enough of the sex hormone testosterone). It is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (f)(30), and a dangerous drug pursuant to Code section 4022.

## STATEMENT OF FACTS

55. On or about August 1 and 2, 2022, Inspector J.F. conducted an on-site, annual, nonresident sterile compounding renewal inspection of Respondent's facility in Orlando, Florida. Inspector J.F. requested, and Respondent provided, numerous documents for evaluation. At the conclusion of the inspection and upon review of Respondent's documentation, Inspector J.F. found multiple violations of Pharmacy Law, many of which constituted cause for denial of Respondent's application to renew its nonresident sterile compounding license. On or about September 19, 2022, Inspector J.F. issued another Written Notice to Respondent, notifying Respondent of the following violations:

**Written Notice #1**

56. Inspector J.F. found that Respondent failed to follow its own SOPs. Specifically, Respondent's *Policy on Current Good Documentation Practices* states, in pertinent part, "Never sign a task that is not completed". Respondent's quality associate, L.S., admitted to Inspector

J.F. that he documented for a future date of August 2, 2022, that dispositioned passive viable air plates were sampled on July 27, 2022, and passed with 0 CFU counts. Respondent's *Policy on Current Good Documentation Practices*, also states, in pertinent part, "Never sign or initial anyone else's name or initials". L.S. admitted to Inspector J.F. that it was his practice to document the samplers' initials on Respondent's environmental monitoring form without personally performing the sampling.

57. Inspector J.F. found that Respondent did not follow its own SOPs for conducting and reviewing aseptic processing simulations. For example, Respondent's *Aseptic Process Simulation 2* (APS2) procedure required mixing the final completed volume on the stir plate for no less than 60 minutes. On March 10, 2022, Lot APS2-A10-22 was mixed for 40 minutes. The procedure further required filtration time "of no less than 2 hours". On March 10, 2022, the total filtration time for Lot APS2-A10-22 was 22 minutes. The procedure required completion of the filling process prior to lyophilization. The filling for Lot APS2-A10-22 was documented as completed at 18:13 hours, yet lyophilization was documented as having started at 18:00 hours, thirteen minutes before filling was completed. On April 1, 2022, the lot was verified to conform to the finished product specification for quality assurance release and adhere to cGMP requirements.

58. Respondent's APS2 procedure required six filling personnel. On March 17, 2022, only five filling personnel participated in filling for Lot APS2-B017-22. Respondent's procedure also required no less than two hours for filtration. On March 17, 2022, the total filtration time was documented at 30 minutes. On April 6, 2022, the lot was verified to conform to the finished product specification for quality assurance release and adhere to cGMP requirements.

59. Inspector J.F. notified Respondent that the act set forth in paragraphs 56 through 58 were in violation of CCR section 1735.5, subdivision (a).

**Written Notice #2**

60. Inspector J.F. found that Respondent's SOP, *Shipping of Compounded Preparations,* requires, in pertinent part, that "Temperature sensitive compounded preparations must be maintained at a temperature of <8C for the entire duration of the transit." The labeled

requirement for frozen products, however, is to store frozen (-10C to -25C/-13º to 14ºF). The three different box sizes used by Respondent were not adequately described in Respondent's procedures. Respondent's 2021 study of its use of Nordic ice packs for shipping lacked sufficient information. The date the study was performed, the materials and equipment used, and the configuration employed were not fully documented. The study concluded in part, "These products are more than enough to preserve the efficacy of all medications that require room temperature or cold delivery demands." The study did not support adequate temperature control for frozen product. This is a repeat violation. Inspector J.F. notified Respondent that it was in violation of Code section 4126.8.

**Written Notice #3**

61. Inspector J.F. found that Respondent used secondary packaging for its "Vitamindrip" kit, consisting of a box containing three vials, each containing a different sterile product compounded by Respondent. One vial contained ascorbic acid 30mL, the second vial contained Olympia mineral blend 30mL, and the third vial contained VitaComplex 30mL. The kit is labeled as "Hydration Injection, USP". Inspector J.F. found that there is not, and never was, a United States Pharmacopeia (USP) monograph for "Hydration Injection". Inspector J.F. notified Respondent that it was in violation of Code section 4169, subdivision (a)(3).

**Written Notice #4**

62. Inspector J.F. found that labels on Respondent's compounded products identified the pharmacy as "Olympia Pharmaceuticals." However, the licensee's registered name is "Olympia Pharmacy". For example, the primary label on released lot# F24020-22 for Biotin 0.05% listed the name of the producing pharmacy as "Olympia Pharmaceuticals". Inspector J.F. notified Respondent that it was in violation of CCR section 1735.4, subdivision (a)(1).

**Written Notice #5**

63. On or about July 20, 2022, in its formal response to a *Written Notice* generated by the Board on July 6, 2022, Respondent provided written assurance to the Board that as of September 2, 2021, its updated *Batch Release* policy required two signatures for each batch released. One signature would be from a member of its quality assurance unit and a second from

a pharmacist. Respondent assured the Board that this measure was taken to ensure that its batches are approved for release only after ensuring that all required specifications are met. Inspector J.F. found that batch records for phenylephrine, lmg/mL, Lot #'s D24A26-22, D24B26-22, and D24C26-22, released on or about June 27, 2022, had one signature only on the batch release documentation. The final release for those batches was missing a pharmacist's signature. Inspector J.F. notified Respondent that it was in violation of Code section 4301, subdivision (g).

**Written Notices #s 6, 15, 19**

64. On or about April 26, 2022, Respondent was notified of a customer's complaint describing a patient's anaphylaxis and subsequent hospitalization after an IM[1] injection of a drug compounded by Respondent. Respondent was informed that the patient had a sulfa allergy. Respondent determined that its customer should have advised the patient that the product was not appropriate for her to take because it contained methionine. Respondent stated that methionine was known to be related to sulfa allergies. In its final impact assessment related to the complaint, Respondent documented that "This was a one-time incident caused by a customer error. . . Not an unexpected adverse event, methionine known to cause potential reactions to persons allergic to sulfur. Methionine is listed as an ingredient on the product label." Methionine does not contain any sulfonamide group or sulfites. On or about August 7, 2022, Respondent submitted to the Board a written statement that there had been no adverse events regarding its compounded sterile products in the last twelve months. Inspector J.F. documented in his October 19, 2021, inspection report that he had reminded Respondent of the requirements of mandatory reporting, including the reporting of adverse events, recalls, and complaints. Inspector J.F. notified Respondent that the acts were in violation of Code sections 4301, subdivision (g), 4127.2, subdivision (f), and 4301, subdivision (c).

**Written Notice #7**

65. Inspector J.F. found that Respondent's lyophilized product, Sermorelin 9mg., was labeled as a multi-dose vial. Inspector J.F. also found antimicrobial effectiveness testing had not

[1] An intramuscular (IM) injection is a technique used to deliver a medication deep into the muscles. This allows the medication to be absorbed into the bloodstream quickly.

been completed as part of stability testing, which considers the possible diluent(s) used. Sermorelin is not directly formulated with a preservative, and it is unknown whether this product has inherent antimicrobial effectiveness properties making it suitable for multi-dose label claims. Respondent's label does not specify the required diluent(s) for use. Respondent only completed method suitability for its multi-dose product, SB4. Preservative effectiveness had not been demonstrated, and test results were pending. This is a repeat violation. Inspector J.F. notified Respondent that it was in violation of CCR section 1751.2, subdivision (b).

**Written Notice #8**

66. Respondent holds a Food and Drug Administration (FDA) 503B registration for an outsourcing facility. Inspector J.F. found that Respondent's Storage Instructions leaflets, as well as other informational material, that generally accompany Respondent's product shipments into California, represent that Respondent is "A 503B Outsourcing Facility". Respondent does not hold a license as a nonresident outsourcing facility in the State of California. This is a repeat violation. Inspector J.F. notified Respondent that it was in violation of Code section 4129.2, subdivision (a).

**Written Notice #10**

67. Inspector J.F. found that Respondent's testosterone injection, Lot #J24014, compounded on October 14, 2021, with a BUD of October 14, 2022, failed to include a controlled substance designation on the label. Inspector J.F. notified Respondent that it was in violation of Code section 4301, subdivision (j).

**Written Notice #11**

68. Inspector J.F. found that on or about April 26, 2022, Respondent recalled all lots produced prior to March 1, 2022. Respondent's SOP, *Recall of Compounded Product,* states, in pertinent part, that, "the states that received the products from the affected lots must be notified immediately or within 12 hours of product being deemed as a recall, whichever is sooner." The initial recall notification provided to the Board did not include the recall of all products. Inspector J.F. notified Respondent that it was in violation of Code section 4127.2, subdivision (e)(3).

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**Written Notice #12**

69. Respondent had a Central Fill agreement with Mint Pharmacy and Skin Clinic, (NRP 1968), located at 1201 US HWY 1 STE# 305C, North Palm Beach, Florida. On or about June 8, 2022, Mint pharmacy changed its location to 7960 Central Industrial Dr. STE 120, West Palm Beach, Florida (NRP 2728). On or about June 8, 2022, Respondent began shipping compounded products to 7960 Central Industrial Dr. STE 120, West Palm Beach, Florida (new location). On or about June 20, 2022, Respondent began shipping compounded sterile products for injection to the new location. A new Central Fill agreement was not executed until August 2, 2022, during the Board's onsite inspection. The Board was not notified within 30 days of commencing central fill activities with NRP 2728. This is a repeat violation. Inspector J.F. notified Respondent that it was in violation of Code section 4123.

**Written Notice #13**

70. Inspector J.F. concluded that Respondent's quality assurance plan was inadequate in that he found that not all integral units produced by Respondent in its aseptic process simulation were properly incubated. Inspector J.F. found that media fill lots APS2-A10-22 and APS2-B017-22 failed to incubate a total of 72 vials for 14 days. Samples were prematurely sent to the contract lab for growth promotion testing. Inspector J.F. notified Respondent that it was in violation of CCR section 1735.8, subdivision (b).

**Written Notices #s 14 and 16**

71. Inspector J.F. found that the inactive ingredient "BHT" was not listed on the master formula for compounding formula ID# 7409 for Benzocaine/Lidocaine/Tetracaine (BLT) 20/4/5, a cream. The equipment required for trituration, mixing, pouring, and measuring was not defined in Respondent's master formula. Quality reviews were not described and adequacy of mixing was not documented.

72. Customer complaint CC-2022-011 documented a complaint of product separation for BLT, Lot #210130. The compounding technician for that product acknowledged that separation was "caused by not leaving mix spin for a while." The product was not recalled from other customers who received the same batch. Inspector J.F. found that other steps for compounding

formula ID #7409 were also not followed as required. Specifically, BHT, pluronic acid and polysorbate were required ingredients for formula ID #7409, but were not added. Inspector J.F. reviewed Respondent's March 15, 2022, compounding of formula ID# 7409, and confirmed that there were no changes to the master formula's essential compounding steps and no preventative action was taken to prevent reoccurrence of inadequate mixing. This is a repeat violation.

73. Inspector J.F. found that the master formulation and compounding logs for compounding formula ID #6924, lots K210219, K210202, compounded on November 29, 2021, and November 2, 2021, respectively, for minoxidil/fluocinolone/retinoic acid 5/0.01/0.01% called for the addition of vitamin E liquid, which was not added. Further, the final packaging requirements were not described and the final packout quantity for lot K210202 was unclear. Lastly, the labels did not include the compounding date.

74. Inspector J.F. found that the master formulation for Sermorelin 9mg formula ID# 5679 calls for 18 grams of API; however, the pharmacy routinely added a 10% overage without documenting an explanation for doing so.

75. Inspector J.F. notified Respondent that the acts set forth in paragraphs 71 through 74 above were in violation of Code section 4169, subdivision (a)(2) and CCR section 1735.2, subdivision (c).

**Written Notice #17**

76. Inspector J.F. found that Respondent's SOPs addressing hand hygiene did not require persistent activity hand sanitizer and that Respondent did not have a related competency assessment. Respondent's competency assessment for hand hygiene also did not evaluate operators for use of a nail pick to remove debris or the application of a waterless surgical scrub with persistent activity. Inspector J.F. notified Respondent that it was in violation of CCR section 1751.6, subdivision (e)(1)(F).

## FIRST CAUSE FOR DENIAL OF APPLICATION

**(Failure to Maintain Written Policies and Procedures for Compounding)**

77. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional

conduct as defined by Code section 4301, subdivision (o). Specifically, Respondent failed to follow its written policies and procedures, in violation of CCR section 1735.5, subdivision (a), as follows:

a. Respondent's employee, L.S., admitted that he signed that a specific task was completed at a specific date when, in fact that task had not been completed on that date, contrary to Respondent's SOPs, as set forth in paragraph 56, above.

b. Respondent's employee, L.S., admitted that he entered initials of other employees on environmental monitoring forms without personally performing the task for which the initials were entered, contrary to Respondent's SOPs, as set forth in paragraph 56, above.

c. On or about April 1, 2022, Respondent verified that Lot APS-A10-22 met Respondent's finished product specifications for quality assurance when, in fact, Respondent's specifications had not been followed, as set forth in paragraph 57, above.

d. On or about April 6, 2022, Respondent verified that Lot APS-B017-22 met Respondent's finished product specifications for quality assurance when, in fact, Respondent's specifications had not been followed, as set forth in paragraph 58 above.

**SECOND CAUSE FOR DENIAL OF APPLICATION**

**(Failure to Maintain United States Pharmacopeia-National Formulary Compounding Standards)**

78. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivision (o). Specifically, Respondent failed to follow United States Pharmacopeia-National Formulary (USP-NF) compounding standards in, violation of Code section 4126.8, as set forth in paragraph 60, above. To wit:

a. Respondent's labels for packaging and shipping procedures for compounded sterile products requiring frozen storage conditions indicating that the compound is to be stored frozen (-10C to -25C/-13º to 14ºF) is incongruent with Respondent's procedure, which states that temperature sensitive compounded preparations must be maintained at a temperature of <8C for the entire duration of the transit.

b. Respondent failed to describe adequately box sizes for shipping.

c. Respondent failed to ensure adequate temperature control for shipped frozen product.

**THIRD CAUSE FOR DENIAL OF APPLICATION**

**(Omission of Licensee's Name on Label)**

79. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivision (o). Specifically, as set forth above in paragraph 62, Respondent's drug product labels identified the pharmacy as "Olympia Pharmaceuticals", when, in fact, Respondent's licensed name is "Olympia Pharmacy", in violation of CCR 1735.4, subdivision (a)(1).

**FOURTH CAUSE FOR DENIAL OF APPLICATION**

**(False Certification/Documentation of Facts)**

80. Respondent's application for renewal is subject to denial pursuant to Code section 4301, subdivision (g), on the grounds that it engaged in unprofessional conduct by knowingly making or signing a certificate or other document that falsely represents the existence or nonexistence of a state of facts. To wit:

a. As set forth above in paragraph 63, Respondent released compounded sterile drug product without a pharmacist's final signature, contrary to its assurances to the Board that its compounded sterile drug batches would be reviewed and signed by a member of its Quality Unit as well as a pharmacist prior to release.

b. As set forth above in paragraph 64, Respondent stated to the Board that it had no adverse events regarding its compounded sterile products. In fact, on or about April 26, 2022, Respondent was notified of a customer's complaint describing anaphylaxis and subsequent hospitalization after use of a drug compounded by Respondent.

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**FIFTH CAUSE FOR DENIAL OF APPLICATION**

**(Labeling Requirements – Inappropriate Instructions for Storage, Handling, Administration)**

81. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivision and (o). Specifically, as set forth above in paragraph 65, Respondent failed to demonstrate that multi-dose vials used for Sermorelin and SB4 were suitable for multi-dose label claims, in violation of CCR 1751.2, subdivision (b).

**SIXTH CAUSE FOR DENIAL OF APPLICATION**

**(Unlicensed Activity - Outsourcing)**

82. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivision (o). Specifically, as set forth above in paragraph 66, Respondent represented to California consumers that it is a 503B outsourcing facility. Respondent does not hold a license as a non-resident outsourcing facility in the State of California, in violation of Code section 4129.2, subdivision (a).

**SEVENTH CAUSE FOR DENIAL OF APPLICATION**

**(Improper Labeling of a Controlled Substance)**

83. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivision (o). Specifically, as set forth above in paragraph 72, Respondent failed to label testosterone as a controlled substance, in violation of 21 CFR 1302.03.

**EIGHTH CAUSE FOR DENIAL OF APPLICATION**

**(Failure to Provide Board with Timely Notice of Recall)**

84. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivision (o). Specifically, as set forth above in

paragraph 68, Respondent failed to provide the Board within twelve hours of its notice of recall for a sterile drug product that it compounded and shipped into California, in violation of Code section 4127.2, subdivision (e)(3).

**NINTH CAUSE FOR DENIAL OF APPLICATION**

**(Failure to Provide Board with Notice of Contract to Compound Drug for Parenteral Therapy)**

85. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivision (o). Specifically, as set forth above in paragraph 69, Respondent failed to notify the Board, within 30 days of commencing compounding a drug for another pharmacy for parenteral therapy, of its contract with that pharmacy to do so, in violation of Code section 4123.

**TENTH CAUSE FOR DENIAL OF APPLICATION**

**(Quality Assurance Plan – Written Procedures)**

86. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivision (o). Respondent failed to ensure the adequacy of its compounding processes, in violation of CCR section 1735.8, subdivision (b). Specifically, as set forth above in paragraph 70, Respondent failed to adequately incubate for aseptic conditions and failed to have a pre-defined set of compounding instructions for its aseptic process simulation.

**ELEVENTH CAUSE FOR DENIAL OF APPLICATION**

**(Written Master Formula)**

87. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivision (o). Specifically, Respondent failed to prepare a written master formula adequate for compounding, in violation of CCR section 1735.2, subdivision (e), as follows:

a. As set forth above in paragraph 71, Respondent's master formulation for compound formula ID #7409 for BLT 20/4/5 was inadequate, to wit:

i. "BHT" was not listed on the master formula.

ii. Equipment required for trituration, mixing, pouring, and measuring was not defined in its SOPs.

iii. Quality reviews were not described.

iv. Adequacy of mixing was not documented.

b. As set forth above in paragraph 73, Respondent's master formulation for compound formula ID #6924, lot #K210219, compounded on or about November 29, 2021, and lot #K210202, compounded on or about November 2, 2021, was inadequate, to wit:

i. The addition of vitamin E liquid was not added, contrary to the mixing directions.

ii. The final packout quantity could not be determined for lot K210202.

iii. The labels were missing the compounding date.

c. As set forth above in paragraph 74, Respondent's master formulation for compound formula Sermorelin 9 mg. formula, ID# 5679 called for 18 grams of Active Pharmaceutical Ingredient (API); however, the pharmacy routinely added a 10% overage without documenting an explanation for doing so.

**TWELFTH CAUSE FOR DENIAL OF APPLICATION**

**(Adverse Effects Reporting)**

88. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivision (o). Specifically, as set forth in paragraph 64, above, Respondent failed to notify the Board within twelve hours of an adverse drug reaction for anaphylaxis of a patient resulting from use of a drug compounded by Respondent, in violation of Code section 4127.2, subdivision (f).

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**THIRTEENTH CAUSE FOR DENIAL OF APPLICATION**

**(Failure to Maintain Quality of Compounded Sterile Preparations)**

89. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivision (o), in that Respondent violated pharmacy law. Specifically, Respondent violated CCR section 1735.2, subdivision (g), in that, as set forth in paragraph 75, above, Respondent compounded Lot #210130, a BLT cream preparation, which Respondent knew to have a compounding error and for which compounding steps were unclear, resulting in separation.

**FOURTEENTH CAUSE FOR DENIAL OF APPLICATION**

**(Adulterated Preparation)**

90. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivision (o), in that Respondent violated statutes regulating dangerous drugs and pharmacy law. Specifically, as set forth in paragraph 75, above, Respondent compounded and furnished Lot #210130, a BLT cream preparation, which was, or may have been, contaminated with filth, putrid, or decomposed substances, and was therefore adulterated pursuant to Health & Saf. Code sections 111250, 111255, and/or 21 USCA 351, subdivision (a), in violation of Code section 4169, subdivision (a)(2), Health & Saf. Code section 111295, and 21 USCA section 331, subdivision (a).

**FIFTEENTH CAUSE FOR DENIAL OF APPLICATION**

**(Training and Evaluation of Compounding Staff – Hand Hygiene)**

91. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivisions (o). Specifically, as set forth above in paragraph 76, Respondent failed to include proper hand hygiene in its SOPs/written program of training and its evaluation of the hand hygiene of staff, in violation of CCR section 1751.6, subdivision (e)(1)(F).

**SIXTEENTH CAUSE FOR DENIAL OF APPLICATION**

**(Gross Negligence)**

92. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivision (c). Specifically, Respondent committed gross negligence when it erroneously concluded that methionine caused a customer's anaphylactic reaction, as set forth in paragraph 64, above.

**SEVENTEENTH CAUSE FOR DENIAL OF APPLICATION**

**(Compounding and Furnishing Misbranded Drugs)**

93. Respondent's application for renewal is subject to denial pursuant to Code section 4300 and Code section 4127.2, subdivision (c), on the grounds that it engaged in unprofessional conduct as defined by Code section 4301, subdivision (o). Specifically, Respondent violated Code section 4169, subdivision (a), and Health & Safety Code sections 111330, 111335, and 111445, in that it sold or transferred dangerous drugs that it knew, or should have known were misbranded, in that it failed to meet predefined specifications, failed to follow USP-NF compounding standards, failed to meet labeling requirements, lacked sterility assurance, failed to maintain quality of its CSPs, and compounded adulterated CSPs, and as set forth above in paragraphs 77-79, 81, 83, 86, 87, 89, 90, and 91.

**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. Denying the renewal application of Olympia Pharmacy for a Non-Resident Sterile Compounding License; and,

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

DATED: 12/16/2022

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2022.12.16 12:30:15 -08'00'

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

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