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

In the Matter of the First Amended Accusation Against: **DE VERA, INC.** **DBA ECOMPOUNDING PHARMACY;** 21250 Califa Street, Suite 109 Woodland Hills, CA 91367 Pharmacy Permit No. PHY 50194 Sterile Compounding Permit No. LSC 99618 and **PIERRE PELAYO NARVADES** 20364 Lander Drive Woodland Hills, CA 91364 Original Pharmacist License No. RPH 46866 Respondents.	Case No. 4534 OAH No. 2013110165

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 on October 1, 2014.

It is so ORDERED on September 24, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
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Board President

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In the Matter of the First Amended Accusation Against: **DE VERA, INC.** **DBA ECOMPOUNDING PHARMACY;** 21250 Califa Street, Suite 109 Woodland Hills, CA 91367 Pharmacy Permit No. PHY 50194 Sterile Compounding Permit No. LSC 99618 and **PIERRE PELAYO NARVADES** 20364 Lander Drive Woodland Hills, CA 91364 Original Pharmacist License No. RPH 46866 Respondents.	Case No. 4534 OAH No. 2013110165 **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. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Gillian E. Friedman, Deputy Attorney General.

2. Respondents De Vera, Inc. dba Ecompounding Pharmacy and Pierre Pelayo Narvades ("Respondents") are represented in this proceeding by attorney Herbert L. Weinberg, Esq., whose address is: McGuire Woods LLP, 1800 Century Park East, 8th Fl., Los Angeles, California 90067.

3. On or about March 7, 1994, the Board of Pharmacy issued Pharmacist License Number RPH 46866 to Pierre Pelayo Narvades. The Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on September 30, 2015, unless renewed.

4. On or about January 21, 2010, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 50194 to De Vera, Inc. dba Ecompounding Pharmacy with the address of record of 21250 Califa Street, Suite 109, Woodland Hills, California 91367 (Respondent Ecompounding Pharmacy). Since on or about January 21, 2010, Respondent Narvades has served and/or been reflected in Board records as the President and Pharmacist in Charge (PIC) for Respondent Ecompounding Pharmacy. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 4534 and will expire on January 1, 2015, unless renewed.

5. On or about July 7, 2010, the Board of Pharmacy issued Sterile Compounding Permit No. LSC 99618 to De Vera, Inc. dba Ecompounding Pharmacy; Pierre Pelayo Narvades. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 4534. It expired on January 1, 2013 and has not been renewed.

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JURISDICTION

6. First Amended Accusation No. 4534 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondents. The Accusation and all other statutorily required documents were properly served on Respondents on October 18, 2013. Respondents timely filed their Notice of Defense contesting the Accusation. A First Amended Accusation was subsequently filed and served on Respondents.

7. A copy of First Amended Accusation No. 4534 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

8. Respondents have carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 4534. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

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

10. Respondents voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

11. Respondents admits the truth of each and every charge and allegation in First Amended Accusation No. 4534.

12. Respondents agrees that their Pharmacist License, Pharmacy Permit and Sterile Compounding Permit are subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

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

15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

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

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DISCIPLINARY ORDERS

IT IS HEREBY ORDERED as follows:

Sterile Compounding Permit

1. That Respondents De Vera, Inc. dba Ecompounding Pharmacy and Pierre Pelayo Narvades surrender Sterile Compounding Permit No. LSC 99618 as of the effective date of this decision. Respondents shall relinquish any indicia of licensure within ten (10) days of the effective date of this decision.

2. The surrender of Respondents' permit and the acceptance of the surrendered permit by the Board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of Respondents' license history with the Board.

3. Respondents understand and agree that if an application for a Sterile Compounding Permit or a petition for reinstatement of the Sterile Compounding Permit is filed in the State of California, the Board shall treat it as a new application for licensure.

4. Respondents may not apply for a Sterile Compounding Permit from the Board for three years from the effective date of this decision. Respondents stipulate that should they apply for a Sterile Compounding Permit on or after the effective date of this decision, all allegations set forth in the First Amended Accusation shall be deemed to be true, correct and admitted by Respondents when the Board determines whether to grant or deny the application. Respondents shall satisfy all requirements applicable to the Sterile Compounding Permit as of the date the application is submitted to the Board . Respondents are required to report this surrender as disciplinary action.

5. Respondents stipulates that should they apply for a Sterile Compounding Permit from the Board on or after the effective date of this Decision, the investigation and prosecution costs in Pharmacy Board number 4534, that remain unpaid, shall be paid to the Board prior to issuance of the new license.

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Original Pharmacy Permit Number PHY 50194

6. **IT IS FURTHER ORDERED** that Pharmacy Permit No. PHY 50194 issued to De Vera, Inc. dba Ecompounding Pharmacy with Pierre Pelayo Narvades as the President and Pharmacist in Charge (PIC) is revoked. However, the revocation is stayed and Respondent De Vera, Inc. dba Ecompounding Pharmacy is placed on probation for five (5) years on the following terms and conditions.

7. **Obey All Laws** Respondent owner shall obey all state and federal laws and regulations. Respondent owner 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
- ☐ an arrest or issuance of a criminal complaint for violation of any state or federal law
- ☐ a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- ☐ a conviction of any crime
- ☐ discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

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

8. **Report to the Board**

Respondent owner 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 owner 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 .

9. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent owner shall appear in person 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.

10. **Cooperate with Board Staff**

Respondent owner shall 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 his or her probation. Failure to cooperate shall be considered a violation of probation.

11. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondents De Vera, Inc. dba Ecompounding Pharmacy and Pierre Pelayo Narvades are jointly and severally liable to pay to the Board its costs of investigation and prosecution in the amount of $38,437.50. Respondents may be permitted to make payments under a payment plan approved by the Board, provided that payment in full is received no later than 48 months after the effective date of the decision and order. There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by Respondent owner shall not relieve respondent of his/its responsibility to reimburse the Board its costs of investigation and prosecution.

12. **Probation Monitoring Costs**

Respondent owner shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. 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.

13. **Status of License**

Respondent owner shall, at all times while on probation, maintain current licensure with the Board . If respondent owner submits an application to the Board , and the application is approved, for a change of location, change of permit or change of ownership, the Board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the Board . Failure to maintain current licensure shall be considered a violation of probation.

If respondent license 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.

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

Following the effective date of this decision, should respondent owner discontinue business, respondent owner 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 owner 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 owner shall further submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer. Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area 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 owner shall provide a copy of the written notice to the Board . For the purposes of this provision, "ongoing patients" means those 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 owner may not apply for any new licensure from the Board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board .

Respondent owner further stipulates that he or she shall reimburse the Board for its costs of investigation and prosecution prior to the acceptance of the surrender.

15. **Notice to Employees**

Respondent owner 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 owner 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 owner 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 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.

16. **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 any 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.

17. **Posted Notice of Probation**

Respondent owner shall prominently post a probation notice provided by the Board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner 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.

Failure to post such notice shall be considered a violation of probation.

18. **Violation of Probation**

If a respondent owner has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over respondent license, 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 owner violates probation in any respect, the Board , after giving respondent owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. 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.

19. **Completion of Probation**

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

20. **Separate File of Records for Compounding**

Respondent owner shall maintain and make available for inspection a separate file of all compounded preparations. The file shall be in compliance with California Code of Regulations

section 1735.3, subdivision (a). The master formula records shall include at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

(5) Process and/or procedure 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.

File shall contain disposition records for all compounded preparations.

Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

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Pharmacist License Number RPH 46866 to Pierre Pelayo Narvades

21. **IT IS HEREBY ORDERED** that Pharmacist License Number RPH 46866 issued to Pierre Pelayo Narvades is revoked. However, the revocation is stayed and Respondent Pierre Pelayo Narvades is placed on probation for five (5) years on the following terms and conditions.

22. **Suspension**

As part of probation, Respondent's pharmacist license is suspended from the practice of pharmacy for 60 days beginning the effective date of this decision.

During suspension, Respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the Board , or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the Board , or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the Board .

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

23. **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

- ☐ an arrest or issuance of a criminal complaint for violation of any state or federal law
- ☐ a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- ☐ a conviction of any crime
- ☐ discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

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

24. **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 .

25. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the Board or its designee, upon request 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.

26. **Cooperate with Board Staff**

Respondent shall 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 their probation. Failure to cooperate shall be considered a violation of probation.

27. **Notice to Employers**

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 4534 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause their direct supervisor, designated representative-in-charge (including each new designated representative-in-charge employed during respondent's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4534 and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that their employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the Board .

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify their direct supervisor, designated representative-in-charge and owner at each entity licensed by the Board of the terms and conditions of the decision in case number 4534 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause their direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that they has read the decision in case number 4534 and the terms and conditions imposed thereby. It shall be the respondent's responsibility to ensure that their employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the Board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time,

part-time, temporary or relief service or pharmacy management service as a designated representative or in any position for which a designated representative license is a requirement or criterion for employment, whether the Respondents are considered an employee or independent contractor or volunteer.

28. **No Being Designated Representative-in-Charge, except as designated below.**

During the period of probation, respondent shall not be the designated representative-in-charge of any entity licensed by the Board unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

29. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondents De Vera, Inc. dba Ecompounding Pharmacy and Pierre Pelayo Narvades are jointly and severally liable to pay to the Board its costs of investigation and prosecution in the amount of $38,437.50. Respondents may be permitted to make payments under a payment plan approved by the Board, provided that payment in full is received no later than 48 months after the effective date of the decision and order. There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of their responsibility to reimburse the Board its costs of investigation and prosecution.

30. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. 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.

31. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current designated representative license with the Board , including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of

probation.

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

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

Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender their designated representative 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. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the Board .

Upon acceptance of the surrender, respondent shall relinquish their designated representative license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license, permit, or registration from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board .

33. **Notification of a Change in Name, Residence Address, Mailing Address or Employment**

Respondent shall notify the Board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving and the address of the new employer, supervisor and owner and work schedule, if known. Respondent shall further notify the Board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.

Failure to timely notify the Board of any change in employer(s), name(s), address(es), or

phone number(s) shall be considered a violation of probation.

34. **Tolling of Probation**

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a designated representative in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease working as a designated representative for a minimum of 40 hours in California, respondent must notify the Board in writing within ten (10) days of cessation of work and must further notify the Board in writing within ten (10) days of the resumption of work. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of work" means any calendar month during which respondent is not working as a designated representative for at least 40 hours as a designated representative as defined by Business and Professions Code section 4053.

"Resumption of work" means any calendar month during which respondent is working as a designated representative for at least 40 hours as a designated representative as defined by Business and Professions Code section 4053.

35. **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 automatically be extended until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

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. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. 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.

36. **Completion of Probation**

Upon written notice by the Board indicating successful completion of probation, respondent's designated representative license will be fully restored.

37. **Consultant for Owner or Pharmacist-In-Charge**

During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the Board . Respondent may be a pharmacist-in-charge. However, if during the period of probation respondent serves as a pharmacist-in-charge, respondent shall retain an independent consultant at his or her own expense who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the Board and whose name shall be submitted to the Board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

38. **Restricted Practice**

Respondent shall not prepare, oversee or participate in the preparation of sterile products during the first three (3) years of probation. Respondent must complete a preapproved compounding course before resuming practice. Respondent shall submit proof satisfactory to the Board of compliance with this term of probation. Failure to abide by this restriction or to timely

submit proof to the Board of compliance therewith shall be considered a violation of probation.

39. **Community Services Program**

Within sixty (60) days of the effective date of this decision, respondent shall submit to the Board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least 60 hours per year for the period of probation. Within thirty (30) days of Board approval thereof, respondent shall submit documentation to the Board demonstrating commencement of the community service program. A record of this notification must be provided to the Board upon request. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

40. **Remedial Education**

Within sixty (60) days of the effective date of this decision, respondent shall submit to the Board or its designee, for prior approval, an appropriate program of remedial education related to compounding drug products. The program of remedial education shall consist of at least 10 units/per year at respondent's own expense. Respondent must have completed the first 10 units prior to resuming practice. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the Board , is provided to the Board or its designee.

Following the completion of each course, the Board or its designee may require the respondent, at his or her own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the Board in the same subject area.

///

41. **No New Ownership of Licensed Premises**

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the Board . If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the Board , respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

42. **Separate File of Records**

Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

43. **Separate File of Records for Compounding**

Respondent owner shall maintain and make available for inspection a separate file of all compounded preparations. The file shall be in compliance with California Code of Regulations section 1735.3, subdivision (a). The master formula records shall include at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

(5) Process and/or procedure 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.

File shall contain disposition records for all compounded preparations.

Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

44. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the Board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the Board or its designee within five days after completing the course.

45. **Tolling of Suspension**

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

Respondent must notify the Board in writing within ten (10) days of departure, and must further notify the Board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not return to work until notified by the Board that the period of suspension has been satisfactorily completed.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Herbert L. Weinberg, Esq. I understand the stipulation and the effect it will have on my Pharmacy Permit, Pharmacist License and Sterile Compounding Permit.

///

///

I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 7/28/14

DE VERA, INC. DBA ECOMPOUNDING PHARMACY by PIERRE PELAYO NARVADES
Its President/Pharmacist in Charge
Respondent

DATED:	7/22/14	PIERRE PELAYO NARVADES Respondent

I have read and fully discussed with Respondent De Vera, Inc. dba Ecompounding Pharmacy; Pierre Pelayo Narvades the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED:

Herbert L. Weinberg, Esq.,
McGuire Woods LLP
Attorneys for Respondent

ENDORSEMENT

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

Dated:

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
MARC D. GREENBAUM
Supervising Deputy Attorney General

GILLIAN E. FRIEDMAN
Deputy Attorney General
Attorneys for Complainant

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DATED: _____

DE VERA, INC. DBA ECOMPOUNDING PHARMACY by PIERRE PELAYO NARVADES
Its President/Pharmacist in Charge
Respondent

DATED:			
			PIERRE PELAYO NARVADES Respondent

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DATED: 7/23/2014

Herbert L. Weinberg, Esq.,
McGuire Woods LLP
Attorneys for Respondent

ENDORSEMENT

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Dated:

Respectfully submitted,

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MARC D. GREENBAUM
Supervising Deputy Attorney General

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Its President/Pharmacist in Charge
Respondent

DATED:			
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DATED: _____

Herbert L. Weinberg, Esq.,
McGuire Woods LLP
Attorneys for Respondent

ENDORSEMENT

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Respectfully submitted,

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GILLIAN E. FRIEDMAN
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 4534

KAMALA D. HARRIS
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MARC D. GREENBAUM
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GILLIAN E. FRIEDMAN
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State Bar No. 169207
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Attorneys for Complainant

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

In the Matter of the First Amended Accusation Against: **DE VERA, INC.** **DBA ECOMPOUNDING PHARMACY;** 21250 Califa Street, Suite 109 Woodland Hills, CA 91367 Pharmacy Permit No. PHY 50194 Sterile Compounding Permit No. LSC 99618 and **PIERRE PELAYO NARVADES** 20364 Lander Drive Woodland Hills, CA 91364 Original Pharmacist License No. RPH 46866 Respondents.	Case No. 4534 **FIRST AMENDED ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about March 7, 1994, the Board of Pharmacy issued Pharmacist License Number RPH 46866 to Pierre Pelayo Narvades. The Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on September 30, 2015, unless renewed.

3. Since on or about January 21, 2010, Respondent Narvades has served and/or been reflected in Board records as the President and Pharmacist in Charge (PIC) for Respondent Ecompounding Pharmacy.

4. On or about January 21, 2010, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 50194 to De Vera, Inc. dba Ecompounding Pharmacy with the address of record of 21250 Califa Street, Suite 109, Woodland Hills, California 91367 (Respondent Ecompounding Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2014, unless renewed.

5. On or about July 7, 2010, the Board of Pharmacy issued Sterile Compounding Permit Number LSC 99618 to De Vera, Inc. dba Ecompounding Pharmacy. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein. The Board received a discontinuance of business on January 18, 2012.

JURISDICTION

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

STATUTORY AND REGULATORY PROVISIONS

7. Section 4300 of the Code states, in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

8. Section 4301 of the Code provides, in pertinent part, that the Board shall take action against any holder of a license who is guilty of "unprofessional conduct," defined to include, but not be limited to, any of the following:

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

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

9. Section 4081 of the Code states:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

"(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

. . . . .

10. Section 4077 of the Code states, in pertinent part, that except as provided in subdivisions (b) and (c) of this section, no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

11. Section 4113 (c) of the Code states, "The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

12. Section 118, subdivision (b), of the Code provides that the suspension/ expiration/surrender/cancellation of a license shall not deprive the Board/Registrar/Director of

jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

13. Section 1735.2 of the California Code of Regulations, states in pertinent part:

. . . . .

"(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Inactive ingredients to be used.

(3) Process and/or procedure used to prepare the drug.

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

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

(6) Expiration dating requirements..

. . .

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

14. Section 1735.3 subdivision (a) (1) of the California Code of Regulations, states that:

"For each compounded drug product, the pharmacy records shall include:

(1) The master formula record...."

15. Section 1735.4 of the California Code of Regulations, states in pertinent part:

"(a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).

. . . .

"(c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date."

16. Section 1735.6 subdivision (b) of the California Code of Regulations, states:

. . . .

"(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications."

17. California Code of Regulations, title 16, section 1751.1, subdivision (a), requires that pharmacies compounding sterile injectable drug products for future use keep, in addition to those records required by section 1735.3, records indicating the name, lot number, amount, and date on which products were provided to a prescriber. Subdivision (c) requires that these records be kept and maintained in the pharmacy in a readily retrievable form for at least three years.

18. California Code of Regulations, Title 16, section 1751.2, subdivision (b), provides:

"In addition to existing labeling requirements, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

. . .

"(b) Name and concentrations of ingredients contained in the sterile injectable product. . . ."

19. Section 1751.7 subdivision (c) of the California Code of Regulations, states that:

. . . .

"Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens."

COST RECOVERY

20. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of

the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Failure to Prepare Master Formula Prior to Compounding)

[Respondents Ecompounding Pharmacy and PIC Narvades]

21. Respondents Ecompounding Pharmacy and PIC Narvades are subject to disciplinary action for unprofessional conduct under section(s) 4301, 4301(j), 4301(o), and 4113(c) of the Code, and California Code of Regulation, title 16, sections 1735.2(d) and 1751.1, in that Respondents were unable to produce or retrieve adequate compounding records for batches of compounded drug products. The circumstances are as follows:

22. During an investigation at Ecompounding Pharmacy on or about December 4, 2012, Respondent PIC Narvades was unable to produce compounding worksheets and written master formulas that had been prepared prior to the compounding of batches of drugs including the following:

a. eight (8) batches of L-carnitine 250 mg/ml,

b. six (6) batches of methylcobalamin 1000 mcg/ml,

c. three (3) batches of testosterone propionate 100 mg/ml,

d. four (4) batches testosterone propionate 50 mg/ml; and

e. thirteen (13) batches of HCG* 1000 U/ml.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Lacking Master Formula For Compounded Products)

[Respondents Ecompounding Pharmacy and PIC Narvades]

23. Respondents Ecompounding Pharmacy and PIC Narvades are subject to disciplinary action for unprofessional conduct under section 4301, subdivisions (j) and (o), in conjunction with section 4081, subdivisions (a) and (b) and California Code of Regulations section 1735.3(a) and 1751.1 in that for each compounded drug product, the pharmacy records required to be maintained shall include the master formula record.

24. During an investigation at Ecompounding Pharmacy on or about December 4, 2012, Respondent PIC Narvades was unable to produce proper master formulas for drug products that were compounded.

25. Specifically, the deficiencies included that the written master formulas that were produced by Respondents were for a different strength then the compounds being made and/or the master formula was for a preservative free product, however Respondent added preservatives (benzyl alcohol). The batches reviewed included the following:

a. eight (8) batches of L-carnitine 250mg/ml,

b. six (6) batches of methylcobalamin 1000 mcg/ml,

c. three (3) batches of testosterone propionate 100 mg/ml,

d. four (4) batches testosterone propionate 50mg/ml; and

e. thirteen (13) batches of HCG* 1000U/ml.

26. Additionally, the compounding worksheets did not provide "step by step" instructions for compounding the products. Instead, the equipment and compounding procedures that were documented on the worksheets appeared to have been copied from the master formula. Moreover, some of the equipment documented on the worksheets as having been used was not, however, owned by Respondent Ecompounding Pharmacy.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Failure To Quarantine And Complete End-Product Testing)

[Respondents Ecompounding Pharmacy and PIC Narvades]

27. Respondents Ecompounding Pharmacy and PIC Narvades are subject to discipline under section(s) 4301, 4301(j), 4301(o), and 4113(c) of the Code, and California Code of Regulations, title 16, section 1751.7, subdivision (c), in that Respondents failed to quarantine and adequately conduct end-product testing. The circumstances are as follows:

28. During an investigation at Respondent Ecompounding Pharmacy on or about December 4, 2012, Respondents produced batch produced injectable drug products compounded from one or more non-sterile ingredients that did not have appropriate end-product testing for sterility and pyrogens. Documentation on the batch produced non-sterile to sterile compounding

worksheets indicated the compounded products were being dispensed to multiple patients and for office use before the 14-day period and before Respondent Ecompounding Pharmacy could receive appropriate results for sterility.

29. Respondents further failed to conduct pyrogen testing for the non-sterile to sterile batch produced compounded products, which included eight (8) batches of L-carnitine 250 mg/ml, six (6) batches of methylcobalamin 1000 mcg/ml, three (3) batches of testosterone propionate 100 mg/ml, four (4) batches testosterone propionate 50mg/ml, and thirteen (13) batches of HCG* 1000U/ml.

FOURTH CAUSE FOR DISCIPLINE

(Inappropriate Equipment Used In Sterile Compounding)

[Respondents Ecompounding Pharmacy and PIC Narvades]

30. Respondents Ecompounding Pharmacy and PIC Narvades are subject to disciplinary action under sections 4301, 4301(j), 4301(o), and 4113(c) and California Code of Regulations, title 16, section 1735.6 subdivision (b) in that inappropriate equipment was used to compound drug products. The circumstances are as follows:

31. During an investigation at Ecompounding Pharmacy on or about December 4, 2012, PIC Narvades identified a euro-pro toaster as his "dry heat sterilizer." At the time of the inspection, the toaster appeared to be used to "sterilize" 10 ml amber vials with the settings on convection bake and 250°F. Intertek, the manufacturer for the toaster noted that the product was for "house hold use only." According to the user's manual for the euro-pro toaster oven model TO176, the product was manufactured solely for use in cooking/toasting food items and not intended for the use as a sterilization oven for compounding equipment.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Inappropriate labeling of compounded drug products)

[Respondents Ecompounding Pharmacy and PIC Narvades]

32. Respondents Ecompounding Pharmacy and PIC Narvades are subject to discipline under section(s) 4301, 4301(j), 4301(o), and 4113(c) of the Code, and California Code of Regulations, title 16, section 1735.4 subdivision (c) for failure to list the names of the active

ingredients, concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date on the label.

33. The circumstances are that during the inspection of Respondent Ecompounding Pharmacy by the Board inspectors on December 4, 2012, no expiration dates were found on the following vials:

Number of Vials Found	Drug
2	L-arginine 100mg/ml 30ml
3	carnitine (1) NP 250mg/ml 30ml
3	MIC w/Vit B-12 30ml
2	Nandrolone Deca (GS) 300mg/ml 10ml
9	Testosterone cypionate 200mg/ml 10ml,
3	Testosterone propionate 50mg/ml 10ml,
3	Testosterone propionate 100ml/ml 10ml
1	Testosterone USP 100 ml/ml 10 ml
6	Methylcobalamin 1000mcg/ml 30ml

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

[Respondent PIC Narvades]

34. Respondent PIC Narvades is subject to disciplinary action under section 4306.5 subdivision (a) in that he engaged in unprofessional conduct while working as the Pharmacist in Charge at Ecompounding Pharmacy located in Woodland Hills, California where he failed to

exercise or implement his best professional judgment. The circumstances are described more fully below:

35. Respondent PIC Narvades allowed the extension of the beyond use date (BUD) for HCG* 1,000U/ml without proper written justification.

36. Respondent PIC Narvades failed to perform the bubble test to confirm the proper function of the filter when using it to sterilize injectable dangerous drugs. The bubble test is the industry standard and master formulas require this standard of practice to ensure the integrity of the filter.

37. Respondent PIC Narvades improperly permitted a consumer home use toaster oven to be used to "sterilize" vials for sterile injectables.

38. Respondent PIC Narvades permitted dangerous drugs to be compounded without proper master formulas.

39. Respondent PIC Narvades failed to quarantine batches of non-sterile to sterile compounds to conduct end product testing.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct- Fraud/Misrepresentation)

[Respondent PIC Narvades]

40. Respondent PIC Narvades is subject to disciplinary action under section 4301 subdivision (g) and California Code of Regulations 1735.2 in that he engaged in unprofessional conduct while working at the Pharmacist in Charge at Ecompounding Pharmacy located in Woodland Hills, California where Respondents knowingly made and/or signed a certificate or other document that falsely represented the existence or nonexistence of a state of facts. The circumstances are described more fully below:

41. The circumstances are that during the written self-assessment of Ecompounding Pharmacy dated November 12, 2012; PIC Narvades willingly signed and initialed each page of his self assessment, representing Ecompounding Pharmacy to be compliant with all applicable laws and regulations. The self assessment was presented to the Board during the inspection on

December 4, 2012. Such representation, included in the self assessment, was false and untrue as to at least the following four regulations:

a. PIC Narvades falsely marked "yes" to the assessment question as to whether the pharmacy does not compound medication until it has prepared a written master formula that includes the flowing elements: (1) Active ingredients to be used. (2) Inactive ingredients to be used. (3) Process and/or procedure used to prepare the drug. (4) Quality reviews required at each step in preparation of the drug. (5) Post-compounding process or procedures required, if any. (6) Expiration dating requirements. In fact, a violation of CCR 1735.2(d)(1-6) was found as described more fully above.

b. PIC Narvades falsely marked "yes" to the assessment question as to whether "Compounded drug products are given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. The 'beyond use date' of the compounded drug product does not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist." In fact, a violation of CCR 1735.2(h) was found as described more fully above.

c. PIC Narvades falsely marked "yes" to the assessment question as to whether "Drug products compounded into unit dose containers that are too small or otherwise impractical for full compliance with the requirements of [a] and [b] are labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, -pharmacy reference or lot number, and expiration date." In fact, a violation of CCR 1735.4(c) was found as described more fully above.

d. PIC Narvades falsely marked "yes" to the assessment question as to whether "batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogen and are

quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. In fact, a violation of CCR 1751.7(c) was found as described more fully above.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct- Excessive Furnishing To A Prescriber)

[Respondents PIC Narvades and Ecompounding

42. Respondents PIC Narvades and Ecompounding are subject to disciplinary action under section 4052 subdivision (a) and California Code of Regulations CCR 1735.2(c) in that he engaged in unprofessional conduct while working as the Pharmacist in Charge at Ecompounding Pharmacy located in Woodland Hills, California. Specifically, while Respondents may (1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber. Such amount is reasonable where it (1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and (3) for any individual prescriber and for all prescribers taken as a whole, 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 product. Instead, Respondents furnished compounded drugs which exceeded a reasonable quantity as follows:

43. The circumstances are that during an inspection by Board inspectors on December 4, 2012, the files and records of Respondents PIC Narvades and Ecompounding indicated that Respondents furnished to prescribers and clinics more than a reasonable quantity of compounded medications. Specifically, Respondent's exceeded a reasonable quantity of 72-hours supply for at home use, where the actual medications furnished were for 30 days. Additionally, Respondent PIC Narvades knew the prescribers were dispensing these products for the patients to use at home.

a. Such medications, include an extensive list. As an example, but not limited to the following: Thyroid Porcine, Testosterone 20% Cream, Testosterone Cypionate 200mg/ml oil injectable; the Progesterone 100mg/gm with Melatonin 3mg/gm topical, Progesterone 100 mg SR

caps; Bi-Est Cream 50:50 8mg/gm. Cream; Hydrocortisone 20mg SR Capsule; Tretinoin 0.05% HQ 4% Fluocinolone 0.01% Cream; and cyanocobalamin 1000mcg/ml injectable.

44. Additionally, compounded medications furnished by Ecompounding exceeded a reasonable quantity by drug, which included, but are not limited to the following: Bi-Est Cream; Bi-Est 50:50; Firm and Fade (HQ 4%) LT Cream; Hydrocortisone 10 mg SR Capsule; and Hydroquinone (LT) 6% Cream.

45. Moreover, compounded medications furnished by Ecompounding exceeded a reasonable quantity by patient/clinic , which included, but are not limited to the following: Dr. E.M was furnished 179 units; EC Medical Group was furnished 48 units; Evol Medical Spa was furnished 19 units; Skin Physicians and Surgeons was furnished18 units; and Pacific Center for Plastic Surgery was furnished 11 units.

46. Additionally, compounded medications furnished by Ecompounding that exceeded a reasonable quantity included, but are not limited to the following: Bi-Est creams, Bi-Est capsules, Firm and Fade creams, Hydrocortisone capsules, and Hydroquinone creams. Medication totals included, but are not limited to, the following: troche (each) 240 units; cream (gm) 48,790 units; capsule (each) 17,760 units and injectables (mls) 4,631 units.

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct- Unlicensed Repackaging and Manufacturing)

[Respondents PIC Narvades and Ecompounding]

47. Respondents PIC Narvades and Ecompounding are subject to disciplinary action for violations of section 4033 subdivision (a)(l) and the Sherman Food, Drug and Cosmetic law Chapter 6, Article 6 commencing with Section 111615) in that by compounding certain drugs, Respondents engaged in the "manufacture" of a drug or device in California without a valid license from the Department of Health, Education and Welfare of the United States.

48. The circumstances are that Respondents Ecompounding and PIC Narvades manufactured approximately 240 "compounded" troche, 48,00 gms of "compounded" cream, 17,000 "compounded" capsules, 4,600 mls of "compounded" injectables and repackaged 13,300 tablets and furnished them directly to the consumer without licensure as a manufacture.

TENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct- Manufacturing and Selling misbranded drugs)

[Respondents PIC Narvades and Ecompounding]

49. Respondents PIC Narvades and Ecompounding are subject to disciplinary action for violations of section 4033 subdivision (a)(l) and Health and Safety Code sections 111430 and 111440, which states that 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 and accordingly, that the sale and delivery of such misbranded drugs is a violation. Respondent Ecompounding is not registered as a manufacturer. Accordingly, all items furnished in excess of reasonable quantity or repackaged constitute misbranded drugs, the sale of which is a violation .

50. The circumstances are that Respondents Ecompounding and PIC Narvades manufactured approximately 240 "compounded" troche, 48,00 gms of "compounded" cream, 17,000 "compounded" capsules, 4,600 mls of "compounded" injectables and repackaged 13,300 tablets and furnished them directly to the consumer without licensure as a manufacturer.

ELEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct- Prohibited Act)

[Respondents PIC Narvades and Ecompounding]

51. Respondents PIC Narvades and Ecompounding are subject to disciplinary action for violations of section 4169 subdivision (a) and Health and Safety Code sections 111335 and 111440 for its unlawful purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded.

52. The circumstances are that Respondents Ecompounding and PIC Narvades manufactured approximately 240 misbranded troche, 48,00 gms of misbranded cream, 17,000 misbranded capsules, 4,600 mls of misbranded injectables and repackaged 13,300 tablets and furnished them directly to the consumer without licensure as a manufacturer.

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TWELFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct- Failure To Properly Invoice)

[Respondents PIC Narvades and Ecompounding]

53. Respondents PIC Narvades and Ecompounding are subject to disciplinary action under Code of Federal Regulations (CFR) section 1304.22 subdivision (c) for furnishing 31 controlled medications without providing invoices and maintaining records which included registration number of the person to whom the containers were distributed. Said medications were distributed to Dr. E.M between June 2010 and November 2012.

THIRTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct- Unlawful Advertising And Promotion Of Compounded Medications)

[Respondents PIC Narvades and Ecompounding]

54. Respondents PIC Narvades and Ecompounding are subject to disciplinary action under Code section 651(a) and 21 U.S.C. section 353a subdivision (c) in the Respondent Ecompounding's promotional and advertising documents showed unlawful advertising of at least 13 different compounded medications.

FOURTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct- Failure To Implement Corresponding Responsibility)

[Respondents PIC Narvades and Ecompounding]

55. Respondents PIC Narvades and Ecompounding are subject to disciplinary action under Code section 4301 subdivision (d) and Health and Safety Code section 11153 subdivision (a) in that Respondent had a corresponding responsibility for proper prescribing and dispensing of controlled substances. Specifically, Respondent Ecompounding dispensed 15 prescriptions (10 prescriptions for 600 tablets of Amphetamine Salt Combo 30mg, 2 prescriptions for 120 tablets of Amphetamine Salt Combo 20mg, 2 prescriptions for 120 tablets of Dextroamphetamine 30mg Tab, and 1 prescription for 120 tablets of Oxandrolone 2.5 tablet) written by Dr. E.M. that lacked legitimate medical purpose.

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DISCIPLINE CONSIDERATIONS

56. To determine the level of discipline, if any, to be imposed on PIC Narvades, Complainant further alleges that:

a. On or about September 21, 2010, Citation Number CI 2010 45835 was issued against Pierre Pelayo Narvades, RPH 46866 for a violation of *Bus. & Prof. Code* § 4081 subd. (a) and California Code of Regulations Title 16, § 1718 [Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined.] The circumstances were that between 1/19/2010 and 2/17/2010, while Respondent Narvades was pharmacist-in-charge of Medpro Pharmacy located at 7129 W. Sunset Blvd, Los Angeles, CA 90046, PIC Narvades did not dispense certain medication to the patients resulting in a lack of complete accountability in inventory. A fine of $3,500 was issued by the Board.

b. On or about June 24, 2009, Citation Number CI 2008 40615 was issued against Pierre Pelayo Narvades, RPH 46866 for a violation of California Code of Regulations, title 16, § 1714 subd (d) [Operational standards and security; pharmacist responsible for pharmacy security] and Bus. & Prof. Code§ 4104 [Procedures to take action when licensed individual is impaired or known to have diverted or used drugs; Written policies; Report; Immunity.] The circumstances are that non-pharmacist Felix Lyubovny was in possession of the key for the licensed area of Medpro Pharmacy, PHY 48193 and not PIC Narvades.

c. Additionally, on December 5, 2008, during an inspection of Medpro Pharmacy, PIC Narvades, told the Board Inspector that he did not have operational standards and security policies.

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 Pharmacist License Number RPH 46866 to Pierre Pelayo Narvades;

2. Revoking or suspending Pharmacy Permit Number PHY 50194, issued to De Vera, Inc. dba Ecompounding Pharmacy;

3. Revoking or suspending Sterile Compounding Permit Number LSC 99618, issued to De Vera, Inc. dba Ecompounding Pharmacy;

4. Ordering Ecompounding Pharmacy to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: 2/19/14

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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

In the Matter of the Accusation Against: **DE VERA, INC.** **DBA ECOMPOUNDING PHARMACY;** 21250 Califa Street, Suite 109 Woodland Hills, CA 91367 Pharmacy Permit No. PHY 50194 Sterile Compounding Permit No. LSC 99618 and **PIERRE PELAYO NARVADES** 20364 Lander Drive Woodland Hills, CA 91364 Original Pharmacist License No. RPH 46866 Respondents.	Case No. 4534 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about March 7, 1994, the Board of Pharmacy issued Pharmacist License Number RPH 46866 to Pierre Pelayo Narvades. The Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on September 30, 2013, unless renewed.

3. Since on or about January 21, 2010, Respondent Narvades has served and/or been reflected in Board records as the President and Pharmacist in Charge (PIC) for Respondent Ecompounding Pharmacy.

4. On or about January 21, 2010, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 50194 to De Vera, Inc. dba Ecompounding Pharmacy with the address of record of 21250 Califa Street, Suite 109, Woodland Hills, California 91367 (Respondent Ecompounding Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2014, unless renewed.

5. On or about July 7, 2010, the Board of Pharmacy issued Sterile Compounding Permit Number LSC 99618 to De Vera, Inc. dba Ecompounding Pharmacy. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and expired on January 1, 2013.

JURISDICTION

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

STATUTORY AND REGULATORY PROVISIONS

7. Section 4300 of the Code states, in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

8. Section 4301 of the Code provides, in pertinent part, that the Board shall take action against any holder of a license who is guilty of "unprofessional conduct," defined to include, but not be limited to, any of the following:

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(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.

9. Section 4081 of the Code states:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

"(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

. . . . .

10. Section 4077 of the Code states, in pertinent part, that except as provided in subdivisions (b) and (c) of this section, no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

11. Section 4113 (c) of the Code states, "The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

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12. Section 118, subdivision (b), of the Code provides that the suspension/ expiration/surrender/cancellation of a license shall not deprive the Board/Registrar/Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

13. Section 1735.2 of the California Code of Regulations, states in pertinent part:

. . . . .

"(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Inactive ingredients to be used.

(3) Process and/or procedure used to prepare the drug.

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

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

(6) Expiration dating requirements..

. . .

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

14. Section 1735.3 subdivision (a) (1) of the California Code of Regulations, states that:

"For each compounded drug product, the pharmacy records shall include:

(1) The master formula record...."

15. Section 1735.4 of the California Code of Regulations, states in pertinent part:

"(a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).

. . . .

"(c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date."

16. Section 1735.6 subdivision (b) of the California Code of Regulations, states:

. . . .

"(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications."

17. California Code of Regulations, title 16, section 1751.1, subdivision (a), requires that pharmacies compounding sterile injectable drug products for future use keep, in addition to those records required by section 1735.3, records indicating the name, lot number, amount, and date on which products were provided to a prescriber. Subdivision (c) requires that these records be kept and maintained in the pharmacy in a readily retrievable form for at least three years.

18. California Code of Regulations, Title 16, section 1751.2, subdivision (b), provides:

"In addition to existing labeling requirements, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

. . .

"(b) Name and concentrations of ingredients contained in the sterile injectable product. . . ."

19. Section 1751.7 subdivision (c) of the California Code of Regulations, states that:

. . . .

"Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens."

COST RECOVERY

20. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Failure to Prepare Master Formula Prior to Compounding)

[Respondents Ecompounding Pharmacy and PIC Narvades]

21. Respondents Ecompounding Pharmacy and PIC Narvades are subject to disciplinary action for unprofessional conduct under section(s) 4301, 4301(j), 4301(o), and 4113(c) of the Code, and California Code of Regulation, title 16, sections 1735.2(d) and 1751.1, in that Respondents were unable to produce or retrieve adequate compounding records for batches of compounded drug products. The circumstances are as follows:

22. During an investigation at Ecompounding Pharmacy on or about December 4, 2012, Respondent PIC Narvades was unable to produce compounding worksheets and written master formulas that had been prepared prior to the compounding of batches of drugs including the following:

a. eight (8) batches of L-carnitine 250 mg/ml,

b. six (6) batches of methylcobalamin 1000 mcg/ml,

c. three (3) batches of testosterone propionate 100 mg/ml,

d. four (4) batches testosterone propionate 50 mg/ml; and

e. thirteen (13) batches of HCG* 1000 U/ml.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Lacking Master Formula For Compounded Products)

[Respondents Ecompounding Pharmacy and PIC Narvades]

23. Respondents Ecompounding Pharmacy and PIC Narvades are subject to disciplinary action for unprofessional conduct under section 4301, subdivisions (j) and (o), in conjunction with section 4081, subdivisions (a) and (b) and California Code of Regulations section 1735.3(a)

and 1751.1 in that for each compounded drug product, the pharmacy records required to be maintained shall include the master formula record.

24. During an investigation at Ecompounding Pharmacy on or about December 4, 2012, Respondent PIC Narvades was unable to produce proper master formulas for drug products that were compounded.

25. Specifically, the deficiencies included that the written master formulas that were produced by Respondents were for a different strength then the compounds being made and/or the master formula was for a preservative free product, however Respondent added preservatives (benzyl alcohol). The batches reviewed included the following:

a. eight (8) batches of L-carnitine 250mg/ml,

b. six (6) batches of methylcobalamin 1000 mcg/ml,

c. three (3) batches of testosterone propionate 100 mg/ml,

d. four (4) batches testosterone propionate 50mg/ml; and

e. thirteen (13) batches of HCG* 1000U/ml.

26. Additionally, the compounding worksheets did not provide "step by step" instructions for compounding the products. Instead, the equipment and compounding procedures that were documented on the worksheets appeared to have been copied from the master formula. Moreover, some of the equipment documented on the worksheets as having been used was not, however, owned by Respondent Ecompounding Pharmacy.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Failure To Quarantine And Complete End-Product Testing)

[Respondents Ecompounding Pharmacy and PIC Narvades]

27. Respondents Ecompounding Pharmacy and PIC Narvades are subject to discipline under section(s) 4301, 4301(j), 4301(o), and 4113(c) of the Code, and California Code of Regulations, title 16, section 1751.7, subdivision (c), in that Respondents failed to quarantine and adequately conduct end-product testing. The circumstances are as follows:

28. During an investigation at Respondent Ecompounding Pharmacy on or about December 4, 2012, Respondents produced batch produced injectable drug products compounded

from one or more non-sterile ingredients that did not have appropriate end-product testing for sterility and pyrogens. Documentation on the batch produced non-sterile to sterile compounding worksheets indicated the compounded products were being dispensed to multiple patients for office use before the 14-day period and before Respondent Ecompounding Pharmacy could receive appropriate results for sterility.

29. Respondents further failed to conduct pyrogen testing for the non-sterile to sterile batch produced compounded products, which included eight (8) batches of L-carnitine 250 mg/ml, six (6) batches of methylcobalamin 1000 mcg/ml, three (3) batches of testosterone propionate 100 mg/ml, four (4) batches testosterone propionate 50mg/ml, and thirteen (13) batches of HCG* 1000U/ml.

FOURTH CAUSE FOR DISCIPLINE

(Inappropriate Equipment Used In Sterile Compounding)

[Respondents Ecompounding Pharmacy and PIC Narvades]

30. Respondents Ecompounding Pharmacy and PIC Narvades are subject to disciplinary action under sections 4301, 4301(j), 4301(o), and 4113(c) and California Code of Regulations, title 16, section 1735.6 subdivision (b) in that inappropriate equipment was used to compound drug products. The circumstances are as follows:

31. During an investigation at Ecompounding Pharmacy on or about December 4, 2012, PIC Narvades identified a euro-pro toaster as his "dry heat sterilizer." At the time of the inspection, the toaster appeared to be used to "sterilize" 10 ml amber vials with the settings on convection bake and 250°F. Intertek, the manufacturer for the toaster noted that the product was for "house hold use only." According to the user's manual for the euro-pro toaster oven model TO176, the product was manufactured solely for use in cooking/toasting food items and not intended for the use as a sterilization oven for compounding equipment.

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FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Inappropriate labeling of compounded drug products)

[Respondents Ecompounding Pharmacy and PIC Narvades]

32. Respondents Ecompounding Pharmacy and PIC Narvades are subject to discipline under section(s) 4301, 4301(j), 4301(o), and 4113(c) of the Code, and California Code of Regulations, title 16, section 1735.4 subdivision (c) for failure to list the names of the active ingredients, concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date.

33. The circumstances are that during the inspection of Respondent Ecompounding Pharmacy by the Board inspectors on December 4, 2012, no expiration dates were found on the following vials:

Number of Vials Found	Drug
2	L-arginine 100mg/ml 30ml
3	carnitine (1) NP 250mg/ml 30ml
3	MIC w/Vit B-12 30ml
2	Nandrolone Deca (GS) 300mg/ml 10ml
9	Testosterone cypionate 200mg/ml 10ml,
3	Testosterone propionate 50mg/ml 10ml,
3	Testosterone propionate 100ml/ml 10ml
1	Testosterone USP 100 ml/ml 10 ml
6	Methylcobalamin 1000mcg/ml 30ml

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

[Respondent PIC Narvades]

34. Respondent PIC Narvades is subject to disciplinary action under section 4306.5 subdivision (a) in that he engaged in unprofessional conduct while working at the Pharmacist in Charge at Ecompounding Pharmacy located in Woodland Hills, California where he failed to exercise or implement his best professional judgment. The circumstances are described more fully below:

35. Respondent PIC Narvades allowed the extension of the beyond use date (BUD) for HCG* 1,000U/ml without proper written justification.

36. Respondent PIC Narvades failed to perform the bubble test to confirm the proper function of the filter when using it to sterilize injectable dangerous drugs. The bubble test is the industry standard and master formula required standard of practice on a used filter to ensure integrity of the filter.

37. Respondent PIC Narvades improperly permitted a consumer home use toaster oven to be used to "sterilize" vials for sterile injectables.

38. Respondent PIC Narvades permitted dangerous drugs to be compounded without proper master formulas.

39. Respondent PIC Narvades failed to quarantine batches of non-sterile to sterile compounds to conduct end product testing.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct- Fraud/Misrepresentation)

[Respondent PIC Narvades]

40. Respondent PIC Narvades is subject to disciplinary action under section 4301 subdivision (g) and California Code of Regulations 1735.2 in that he engaged in unprofessional conduct while working at the Pharmacist in Charge at Ecompounding Pharmacy located in Woodland Hills, California where Respondents knowingly made and/or signed a certificate or

other document that falsely represented the existence or nonexistence of a state of facts. The circumstances are described more fully below:

41. The circumstances are that during the written self-assessment of Ecompounding Pharmacy dated November 12, 2012; PIC Narvades willingly signed and initialed each page of his self assessment, representing Ecompounding Pharmacy to be compliant with all applicable laws and regulations. The self assessment was presented to the Board during the inspection on December 4, 2012. Such representation, included in the self assessment, was false and untrue as to at least the following four regulations:

a. PIC Narvades falsely marked "yes" to the assessment question as to whether the pharmacy does not compound medication until it has prepared a written master formula that includes the flowing elements: (1) Active ingredients to be used. (2) Inactive ingredients to be used. (3) Process and/or procedure used to prepare the drug. (4) Quality reviews required at each step in preparation of the drug. (5) Post-compounding process or procedures required, if any. (6) Expiration dating requirements. In fact, a violation of CCR 1735.2(d)(1-6) was found as described more fully above.

b. PIC Narvades falsely marked "yes" to the assessment question as to whether "Compounded drug products are given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. The 'beyond use date' of the compounded drug product does not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist." In fact, a violation of CCR 1735.2(h) was found as described more fully above.

c. PIC Narvades falsely marked "yes" to the assessment question as to whether "Drug products compounded into unit dose containers that are too small or otherwise impractical for full compliance with the requirements of [a] and [b] are labeled with at least the name(s) of the active

ingredient(s), concentration of strength, volume or weight, -pharmacy reference or lot number, and expiration date." In fact, a violation of CCR 1735.4(c) was found as described more fully above.

d. PIC Narvades falsely marked "yes" to the assessment question as to whether "batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogen and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. In fact, a violation of CCR 1751.7(c) was found as described more fully above.

DISCIPLINE CONSIDERATIONS

42. To determine the level of discipline, if any, to be imposed on PIC Narvades, Complainant further alleges that:

a. On or about September 21, 2010, Citation Number CI 2010 45835 was issued against Pierre Pelayo Narvades, RPH 46866 for a violation of *Bus. & Prof. Code* § 4081 subd. (a) and California Code of Regulations Title 16, § 1718 Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined. The circumstances were that between 1/19/2010 and 2/17/2010, while Respondent Narvades was pharmacist-in-charge of Medpro Pharmacy located at 7129 W. Sunset Blvd, Los Angeles, CA 90046, PIC Narvades did not dispense certain medication to the patients resulting in a lack of complete accountability in inventory. A fine of $3,500 was issued by the Board.

b. On or about June 24, 2009, Citation Number CI 2008 40615 was issued against Pierre Pelayo Narvades, RPH 46866 for a violation of California Code of Regulations, title 16, § 1714 subd (d) Operational standards and security; pharmacist responsible for pharmacy security and Bus. & Prof. Code§ 4104 Procedures to take action when licensed individual is impaired or known to have diverted or used drugs; Written policies; Report; Immunity. The circumstances are that non-pharmacist Felix Lyubovny was in possession of the key for the licensed area of Medpro Pharmacy, PHY 48193 and not PIC Narvades. Additionally, on December 5, 2008, during an inspection of Pharmacy, PIC Narvades, told the Board Inspector that he did not have operational standards and security policies.

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 Pharmacist License Number RPH 46866 to Pierre Pelayo Narvades;

2. Revoking or suspending Pharmacy Permit Number PHY 50194, issued to De Vera, Inc. dba Ecompounding Pharmacy;

3. Revoking or suspending Sterile Compounding Permit Number LSC 99618, issued to De Vera, Inc. dba Ecompounding Pharmacy;

4. Ordering Ecompounding Pharmacy to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: 6/8/13

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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