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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)(l-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 Cl 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 Cl 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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