XAVIER BECERRA
Attorney General of California
THOMAS L. RINALDI
Supervising Deputy Attorney General
EMILY Y. WADA
Deputy Attorney General
State Bar No. 241845
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-8944
Facsimile: (213) 897-2804
E-mail: Emily.Wada@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against: **PACIFIC HEALTHCARE INC. DBA B&B PHARMACY, JANE E. HYUN, HYUN JOON RO, OWNERS** 10244 Rosecrans Ave. Bellflower, CA 90706 Original Permit No. PHY 50799 Sterile Compounding Permit No. LSC 99714, **SUZY MICHEL MORKOS** 6222 Forester Dr. Huntington Beach, CA 92648 Pharmacist License No. RPH 47817 Respondents.	Case No. 6022 **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 December 22, 2011, the Board of Pharmacy issued Original Permit Number PHY 50799 to Pacific Healthcare Inc., dba B&B Pharmacy, Jane E. Hyun, Hyun Joon Ro ("B&B Pharmacy"). The Original Permit expired on April 15, 2016, and has not been renewed.

///

///

3. On or about January 31, 2012, the Board of Pharmacy issued Sterile Compounding Permit Number LSC 99714 to B&B Pharmacy. The Sterile Compounding Permit expired on August 26, 2015, and has not been renewed.

4. On or about March 8, 1995, the Board of Pharmacy issued Pharmacist License Number RPH 47817 to Suzy Michel Morkos ("Morkos"). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2018, unless renewed. Morkos has been the Pharmacist-in-Charge of B&B Pharmacy since May 1, 2015.

JURISDICTION

5. 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.

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

7. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law, Business and Professions Code, § 4000, *et seq.*, and the Uniform Controlled Substances Act, Health and Safety Code, § 11000, *et seq.*

8. Section 4300.1 of the Business and Professions Code ("Code") states:

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

STATUTORY PROVISIONS

9. Health and Safety Code section 111330 provides that, "Any drug or device is misbranded if its labeling is false or misleading in any particular."

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

11. Section 4059.5, subdivision (e), provides, in pertinent part, that:

> (e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. . . .

12. Section 4113, subdivision (c), provides that, "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."

13. Section 4169, subdivision (a)(3), of the Code provides that:

> (a) A person or entity shall not do any of the following:
> . . . .
> (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code. . . .

14. Section 4301, subdivision (o), provides, that:

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

15. Section 4307 provides, in relevant part, that:

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

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

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

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

REGULATORY PROVISIONS

16. California Code of Regulations, title 16, section 1735.2, provides, in pertinent part, that:

(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.

17. California Code of Regulations, title 16, section 1735.6, subdivision (b), provides that, "Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications."

18. California Code of Regulations, title 16, section 1751.4, subdivision (d), provides that:

Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

19. California Code of Regulations, title 16, section 1751.7, subdivision (c), provides 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.

OTHER PROVISIONS

20. Arizona Administrative Code section R4-23-607, subdivision (A)(1), provides that:

> A. Permit. A person who is not a resident of Arizona shall not sell or distribute any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona without:
>
> 1. Processing a current Board-issued nonresident pharmacy permit, nonresident manufacturer permit, nonresident full-service or nonprescription drug wholesale permit, or nonresident nonprescription drug permit;

COST RECOVERY

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

FIRST CAUSE FOR DISCIPLINE

(Failure to Clean)

Against Respondents B&B Pharmacy and Morkos

22. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under California Code of Regulations, title 16, section 1751.4, subdivision (d), in that all of the exterior workbench surfaces and other hard surfaces in the designated sterile compounding area of the pharmacy had not been disinfected on a weekly basis according to the pharmacy's own cleaning logs.

///

///

SECOND CAUSE FOR DISCIPLINE

(Misbranded Drugs)

Against Respondents B&B Pharmacy and Morkos

23. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under Code section 4169, subdivision (a)(3), and Health and Safety Code sections 111330 and 111440 on the grounds that they manufactured, sold, delivered, held, and/or offered for sale misbranded drugs. The circumstances are as follows:

24. On or around October 27, 2015, Morkos provided pharmacy documents to a Board inspector that showed several lots of compounded drug products had been assigned improper beyond-use-dates ("BUDs"). For example, pharmacy documents showed that Lot No. 06022015@4 of Papaverine HCL Injection 33mg/mL Solution had been given a BUD of May 27, 2016, but one of its components, Lot No. C162544 of Chlorobutanol NF Anhydrous, had an earlier BUD of November 16, 2015. As another example, pharmacy documents showed that Lot No. 06302015@6 of Phentolamine 20mg/mL Injectable had been given a BUD of June 24, 2016, but one of its components, Lot No. 111930/K of Phentolamine Mesylate USP Powder had an earlier BUD of April 1, 2016. As yet another examine, pharmacy documents showed that Lot No. 05062015@12 of Alprostadil Alcohol Stock 500mcg/mL Solution had been given a BUD of April 30, 2016, but one of its components, Lot No. 98231/D of Alprostadil USP Powder had an earlier BUD of March 31, 2016.

THIRD CAUSE FOR DISCIPLINE

(Failure to Use Equipment In Accordance With Manufacturer's Specifications)

Against Respondents B&B Pharmacy and Morkos

25. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under California Code of Regulations, title 16, section 1735.6, subdivision (b), on the grounds that they used certain equipment outside of the manufacturers' specifications to compound drugs. Specifically, Respondents used a Sharp convection microwave model R-390Ak/R-930AW and an Emerson 900W microwave oven model number MW8889SB during the compounding process to sterilize glassware or heat non-sterile drug preparations although both microwaves are only intended for household use.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Prepare Master Formulas)

Against Respondents B&B Pharmacy and Morkos

26. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under California Code of Regulations, title 16, section 1735.2, subdivision (d), on the grounds that they compounded drug products without complete written master formulas. The circumstances are as follows:

27. On or around October 27, 2015, Morkos provided pharmacy documents to a Board inspector that showed several lots of compounded drug products did not have complete written master formulas. For example, there were no formula instructions or compounding steps to prepare Lot No. 05062015@12 of Alprostadil Alcohol Stock 500mcg/mL Solution, Lot No. 06022015@4 of Papaverine HCL Injection 33mg/mL Solution, and Lot No. 08032015@2 of Papaverine+PGE1+Phentolamine Injection 30mg:20mcg/mL Injectable. As another example, the only formula instructions or compounding steps for Lot No. 06182013@16 of Papaverine+PGE1+Phentolamine Injection 30mg:20mcg/mL Injectable was to "combine all ingredients in sterile vial and seal."

FIFTH CAUSE FOR DISCIPLINE

(Failure to Assign Valid Beyond Use Dates)

Against Respondents B&B Pharmacy and Morkos

28. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under California Code of Regulations, title 16, section 1735.2, subdivision (h), on the grounds that they assigned improper BUDs to compounded drug products without the appropriate supporting stability analyses. Complainant refers to and hereby incorporates the allegations contained within paragraph 24, above, as though fully set forth herein.

///

///

SIXTH CAUSE FOR DISCIPLINE

(Failure to Have Valid Sterility Testing)

Against Respondents B&B Pharmacy and Morkos

29. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under California Code of Regulations, title 16, section 1751.7, subdivision (c), on the grounds that they failed to obtain end product testing for sterility and/or pyrogens on all compounded drug products. Specifically, Respondents failed to send a compliant sample size for sterility and pyrogens testing on Lot No. 06022015@4 of Papaverine HCL Injection 33mg/mL Solution, Lot No. 06302015@6 of Phentolamine 20mg/mL Injectable, and Lot No. 05062015@12 of Alprostadil Alcohol Stock 500mcg/mL Solution, and, therefore, had no documented end product testing on those lots.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

Against Respondents B&B Pharmacy and Morkos

30. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under Code section 4301, subdivision (o), on the grounds that they violated, either directly or indirectly, or assisted in or abetted the violation of another state's laws and regulations governing pharmacies. The circumstances are as follows:

31. Between March 2012 and September 2015, Respondents prepared and shipped compounded drug products to an individual in Arizona on at least nine occasions. However, B&B Pharmacy did not have a nonresident permit under Arizona Administrative Code section R4-23-607, subdivision (A)(1), to sell or distribute drugs in Arizona.

EIGHTH CAUSE FOR DISCIPLINE

(Unlicensed Shipping to Arizona)

Against Respondents B&B Pharmacy and Morkos

32. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under Code section 4059.5, subdivision (e), on the grounds that they transferred, sold, and/or delivered a dangerous drug to a person in Arizona without complying with all of the laws of the states of California and Arizona before doing so. Complainant refers to and hereby incorporates the allegations contained within paragraph 31, above, as though fully set forth herein.

OTHER MATTERS

33. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number

PHY 50799 issued to Respondent B&B Pharmacy, then Respondent B&B Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50799 is placed on probation or until Pharmacy Permit Number PHY 50799 is reinstated if it is revoked.

34. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50799 issued to Respondent B&B Pharmacy while Jane E. Hyun and/or Hyun Joon Ro, Pharmacist License Number RPH 64426, have been officers and/or owners and had knowledge or knowingly participated in any conduct for which the licensee was disciplined, then Jane E. Hyun and/or Hyun Joon Ro shall be prohibited from serving as managers, administrators, owners, members, officers, directors, associates, or partners of a licensee for five years if Pharmacy Permit Number PHY 50799 is placed on probation or until Pharmacy Permit Number PHY 50799 is reinstated if it is revoked.

DISCIPLINARY CONSIDERATIONS

35. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that, on or around August 13, 2012, Respondent B&B Pharmacy was issued Citation No. CI 2011 50984 for violating Business and Professions Code section 4169, subdivision (a)(4) [purchase, trade, sell, or transfer dangerous drugs or devices after or beyond use date on label], in the amount of $750, and California Code of Regulations, title 16, section 1751.7, subdivision (a)(4) [written justification of the chosen expiration date for compounded sterile injectable products], in the amount of $500. Specifically, on or around January 6, 2012, during an inspection of the pharmacy, it was discovered that B&B Pharmacy dispensed Amlodipine 5mg beyond its labeled expiration date on multiple occasions between December 22, 2011, and January 6, 2012. It was also discovered that B&B Pharmacy did not have written justification for the chosen expiration dates printed on the logged formula worksheets and stock bottle labels for Apomorphine HCL 6mg/ml, dated November 2, 2011, and Baclofen Intrathecal 1mg/ml, dated November 16, 2011, and that the chosen expiration dates did not correlate to the pharmacy's master formulas.

36. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that, on or around March 22, 2013, Respondent B&B Pharmacy was issued Citation No. CI 2011 51974 for violating Health and Safety Code section 11162.1, subdivision (a) [prescription forms for controlled substances; requirements], in the amount of $5,000. Specifically, between March 26, 2012, and June 23, 2012, B&B Pharmacy dispensed the following prescriptions for controlled substances that were not printed in compliance with California security form requirements:

Dates	Drugs
6/23/12	Hydrocodone/acetaminophen (APAP) 5/500 #60
3/26/12	Carisoprodol 350mg #90
3/26/12	Alprazolam 5mg #60
3/26/12	Zolpidem 10mg #0
3/26/12	Hydrocodone (APAP) 10/325/ #60
3/26/12	Lorazepam 1mg #30
3/26/12	Hydrocodone (APAP) 10/325mg #60

37. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that, on or around June 13, 2014, Respondent B&B Pharmacy was issued a letter of admonishment pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California, including: (i) Business and Professions Code section 4315 and 4115, subdivision (f)(1) [ratio of pharmacists to pharmacy technicians]; (ii) California Code of Regulations, title 16, section 1751.7, subdivision (a)(4) [written justification on the chosen expiration date for compounded sterile injectable products]; (iii) California Code of Regulations, title 16, section 1751, subdivision (c) [batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subjected to documented end product testing and quarantined]; (iv) California Code of Regulations, title 16, section 1735.8, subdivision (c) [compounding quality assurance requires reports on integrity, potency, and quality]; (v) California Code of Regulations, title 16, sections 1735.6, subdivisions (b) and (c), 1735.5, subdivision (c), and 1735.3, subdivision (a)(7)

[compounding facilities and equipment, compounding policies and procedures, and records of compounded drug products], (vi) Business and Professions Code section 4169, subdivision (a)(3), in conjunction with California Code of Regulations, title 16, section 1735.2, subdivision (f) [prohibited to purchase, trade, sell, or transfer dangerous drugs that a person knows or reasonably should know are misbranded; pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a drug until it is dispensed]. Specifically, on or around October 9, 2012, during an inspection of the pharmacy, multiple violations of pharmacy law were observed under the aforementioned laws.

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 Original Permit Number PHY 50799, issued to Pacific Healthcare Inc., dba B&B Pharmacy, Jane E. Hyun, Hyun Joon Ro;

2. Revoking or suspending Sterile Compounding Permit Number LSC 99714, issued to Pacific Healthcare Inc., dba B&B Pharmacy, Jane E. Hyun, Hyun Joon Ro;

3. Revoking or suspending Pharmacist License Number RPH 47817, issued to Suzy Michel Morkos;

4. Prohibiting Jane E. Hyun from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee for five years if Pharmacy Permit Number PHY 50799 is placed on probation or until Pharmacy Permit Number PHY 50799 is reinstated if it is revoked.

5. Prohibiting Hyun Joon Ro, Pharmacist License Number RPH 64426, from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee for five years if Pharmacy Permit Number PHY 50799 is placed on probation or until Pharmacy Permit Number PHY 50799 is reinstated if it is revoked.

6. Ordering B&B Pharmacy and Suzy Michel Morkos 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,

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

DATED: 6/30/17

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

LA2016602903
52342545.doc