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

In the Matter of the Accusation Against: **FRIENDLY HILLS MEDICAL CENTER, DBA FRIENDLY HILLS UNITED DRUGS** **15141 East Whittier Boulevard, Suite 115** **Whittier, CA 90603** **Pharmacy Permit No. PHY 40712** **DENNIS AKIRA AMANO** **5076 Avenida De Los Reyes** **Yorba Linda, CA 92886** **Pharmacist License No. RPH 41015** Respondents.	Case No. 5438 **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 5, 2005, the Board of Pharmacy issued Pharmacy Permit Number PHY 40712 to Friendly Hills Medical Center, doing business as Friendly Hills United Drugs with Dennis Akira Amano designated as the Pharmacist-in-Charge (Respondent Friendly Hills United

Drugs). The Pharmacy Permit expired on October 25, 2014 and was cancelled on January 23, 2015.

3. On or about August 17, 1987, the Board of Pharmacy issued Pharmacist License Number RPH 41015 to Dennis Akira Amano (Respondent Dennis Amano). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2016, unless renewed.

JURISDICTION

4. 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.

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

6. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

7. Section 4300.1 of the 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

8. Section 4022 of the Code states:

> "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:
>
> (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
>
> (b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____," "Rx only," or words of similar import,

the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

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

9. Section 4033, subdivision (a)(1) of the Code defines the term "manufacturer" as "every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."

10. Section 4113, subdivision (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.

11. Section 4301 of the Code states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not 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.

. . . .

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

13. Health and Safety Code section 111430 provides 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.

14. 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.

15. Health and Safety Code section 111450 provides that it is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

16. Health and Safety Code section 111615 provides that no person shall manufacture any drug or device in this state unless he or she has a valid license from the Department of Public Health.

REGULATORY PROVISIONS

17. Title 16, California Code of Regulations, section 1735 (a) states in pertinent part:

> "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
>
> (1) Altering the dosage form or delivery system of a drug
>
> (2) Altering the strength of a drug
>
> (3) Combining components or active ingredients
>
> (4) Preparing a drug product from chemicals or bulk drug substances
>
> . . . .

18. Title 16, California Code of Regulations, sections 1735.2 (d) and (j) states:

> (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) 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.
>
> . . . .
>
> (j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies

developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. (02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

. . . .

19. Title 16, California Code of Regulations, section 1735.3 (a) states:

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

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

(7) A pharmacy assigned reference or lot number for the compounded drug product.

(8) The expiration date of the final compounded drug product.

(9) The quantity or amount of drug product compounded.

20. Title 16, California Code of Regulations, section 1735.4 (a) states:

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).

21. Title 16, California Code of Regulations, section 1735.5 states:

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedures manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

(c) The policy and procedure manual shall include the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual

(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product;

(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on those procedures as part of the staff training and competency evaluation process.

(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

22. Title 16, California Code of Regulations, section 1735.6(a):

Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) f facilities or equipment.

23. Title 16, California Code of Regulations, sections 1735.7 (a) and (b) states:

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that the pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

. . . .

24. Title 16, California Code of Regulations, section 1735.8 states:

(a) Any pharmacy engaged in compounding shall maintain, as part of its written

policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

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

(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

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

COST RECOVERY

25. 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.

FACTUAL ALLEGATIONS

26. From March 3, 1995 through January 23, 2015, Respondent Dennis Amano was the Pharmacist-in-Charge of Respondent Friendly Hills United Drugs. Respondents compounded non-sterile drug products, along with dispensing controlled substances.

27. Respondents received and held a 540 ml bottle of Gabapentin 10mg/ml suspension compounded by another pharmacy which was not duly registered with the Secretary of Health, Education and Welfare of the United States or did not have a valid license from the Department of Public Health.

28. Respondents compounded drugs utilizing master formulas which lacked all required elements, including expiration dating requirements, equipment to be used, processes and procedures used to prepare compounded drug products, quality review steps and post compounding processes or procedures.

29. Respondents did not complete a compounding self-assessment. They also failed to maintain full and complete compounding logs, policies and procedures for compounding drugs and training staff engaged in compounding drugs, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug products and a quality assurance plan or a recall plan for compounded drug products.

30. Respondents also failed to perform qualitative and quantitative analysis of the integrity, potency, quality and labeled strength of compounded drug products. They also did not label compounded drugs with all principal active ingredients.

FIRST CAUSE FOR DISCIPLINE

(Held Misbranded Drugs)

31. Respondents are subject to disciplinary action under Code section 4301(j) for violating statutes regulating controlled substances and dangerous drugs and state laws governing pharmacy, in that Respondents held a misbranded drug, as defined by Health & Safety Code section 111330 and 111430 in violation of Health and Safety Code section 111440, as set forth in paragraphs 26 through 30, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Received Misbranded Drugs)

32. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating statutes regulating controlled substances and dangerous drugs and state laws governing pharmacy, in that Respondents received a misbranded drug, as defined by Health & Safety Code sections 111330 and 111430 in violation of Health and Safety Code section 111450, as set forth in paragraphs 26 through 30, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Inadequate Record-Keeping)

33. Respondents are subject to disciplinary action under Code section 4301(o) for violating Pharmacy Law and regulations, as set forth in paragraphs 26 through 30, which are incorporated herein by reference and as described below:

a. **California Code of Regulations, title 16, section 1735.7(a)**: Failure to maintain training records for compounding staff.

b. **California Code of Regulations, title 16, section 1735.5(a)**: Failure to maintain current written policies and procedures for compounding.

c. **California Code of Regulations, title 16, section 1735.5(b)**: Failure to review policy and procedures manual on an annual basis and update it.

d. **California Code of Regulations, title 16, section 1735.6(a)**: Failure to maintain written documentation of facilities and equipment for compounding.

e. **California Code of Regulations, title 16, section 1735.5(c)(3)**: Failure to maintain policies and procedures regarding facilities and equipment cleaning, maintenance, and operation and facilities and equipment necessary for safe and accurate compounded drug products.

f. **California Code of Regulations, title 16, section 1735.5(c)(4)** : Failure to produce and maintain documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

g. **California Code of Regulations, title 16, section 1735.5(c)(5)** : Failure to produce and maintain documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

h. **California Code of Regulations, title 16, section 1735.3**: Failure to produce and maintain complete records or any records of compounded drugs, including failing to record the lot number, the expiration date of all components, the pharmacist who verified the compounded drugs and the identity of the pharmacy staff who compounded the drug product.

i. **California Code of Regulations, title 16, section 1735.7(b)**: Failure to produce and maintain written documentation sufficient to demonstrate pharmacy personnel have the skills and training necessary to complete compounding, an on-going competency evaluation process and the training completed by pharmacy personnel.

j. **California Code of Regulations, title 16, section 1735.8(a)-(c)**: Failure to produce and maintain a written quality assurance plan to monitor and ensure the integrity,

potency, quality and labeled strength of compounded drug products and the qualitative and quantitative analysis of the integrity, potency, quality and labeled strength of compounded drug products.

k. **California Code of Regulations, title 16, sections 1735.5 (c)(2) and 1735.8 (d)**: Failure to produce and maintain a recall plan for compounded drug products and procedures if any compounded drug products are discovered to be below minimum standards for integrity, potency, quality or labeled strength.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Label Drug With All Active Ingredients)

34. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, section 1735.4(a), in that they did not label the compounded drug products with all active ingredients, as set forth in paragraphs 26 through 30, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Complete Compounding Self-Assessment Form)

35. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violating California Code of Regulations, title 16, section 1735.2(j), in that Respondents did not complete a self-assessment form prior to compounding drug products, as set forth in paragraphs 26 through 30, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Master Formulas)

36. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violating California Code of Regulations, title 16, section 1735.2(d), in that Respondents did not prepare master formulas which contained all required elements, including expiration dating requirements, active and inactive ingredients to be used and processes and/or procedures used to prepare compounded drug products, as set forth in paragraphs 26 through 30, which are incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

37. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct in that they engaged in the activities described in paragraphs 26 through 30 above, which are incorporated herein by reference.

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 Pharmacy Permit Number PHY 40712 issued to Friendly Hills Medical Center, doing business as Friendly Hills United Drugs;

2. Revoking or suspending Pharmacist License Number RPH 41015 issued to Dennis Akira Amano;

3. Ordering Friendly Hills Medical Center, doing business as Friendly Hills United Drugs and Dennis Akira Amano 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

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

DATED: 7/19/16

Virginia Herold

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

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