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 OAH No. 2016120077 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER (DENNIS AKIRA AMANO ONLY)**

DECISION AND ORDER

The attached Stipulated Surrender of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on May 25, 2017.

It is so ORDERED on April 25, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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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 K. Herold (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by

Xavier Becerra, Attorney General of the State of California, by Desiree I. Kellogg, Deputy Attorney General.

2. Respondent Dennis Akira Amano is represented in this proceeding by attorney Herbert L. Weinberg of Fenton Law Group, LLP, whose address is: 1990 S. Bundy Drive, Suite 777, Los Angeles, CA 90025.

3. On or about August 17, 1987, the Board issued Pharmacist License No. RPH 41015 to Dennis Akira Amano (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2018, unless renewed.

JURISDICTION

4. Accusation No. 5438 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on July 19, 2016. Respondent timely filed his Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 5438 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5438. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on his 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.

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

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 5438, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacist License.

10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest those charges.

11. Respondent agrees that his Pharmacist License is subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

12. 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 his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his 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.

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

14. 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.

15. 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:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 41015 issued to Respondent Dennis Akira Amano is revoked. However, the revocation is stayed and Respondent is placed on probation for four (4) years on the following terms and conditions.

1. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo 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, distributing, billing, or charging for any drug, device or controlled substance.

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

2. **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.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent 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.

4. **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.

5. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. **Notice to Employers**

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 5438 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, pharmacist-in-charge (including each new pharmacist-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 5438, and terms and conditions imposed

thereby. It shall be respondent's responsibility to ensure that their employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify their direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 5438 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 5438 and the terms and conditions imposed thereby. It shall be 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 acknowledgments 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, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. **No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant**

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $2,047.70. Respondent shall make said payments in a payment plan to be approved by the Board.

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.

9. **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.

10. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current 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 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.

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

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender their 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 pocket and wall 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 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, including any outstanding costs.

12. **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, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, 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.

13. **Tolling of Probation**

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist 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 practicing as a pharmacist for a minimum of 40 hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and

must further notify the board in writing within ten (10) days of the resumption of practice. 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 practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

14. **Violation of Probation**

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

15. **Completion of Probation**

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

16. **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, Pharmacy Law and the role of the Pharmacist-in-Charge. The program of remedial education shall consist of at least ten (10) hours per year of probation, fifty (50) percent shall be in-person at respondent's own expense. 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 their 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.

17. **Supervised Practice**

During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and their license shall be automatically suspended until a supervisor is approved by the board or its designee. At the outset of probation, the practice supervisor shall agree to and shall supervise respondent utilizing Daily Review—the supervisor shall review respondent's daily activities within 24 hours.

Thereafter, should a change in supervision be required, the Board or its designee shall have the discretion to choose from the following supervision levels:

Continuous – At least 75% of a work week

Substantial - At least 50% of a work week

Partial - At least 25% of a work week

Within thirty (30) days of the effective date of this decision, respondent shall have their

supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number 5438 and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that their employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

If respondent changes employment, it shall be the respondent's responsibility to ensure that their employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have their new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number 5438 and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and their license shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

Within ten (10) days of leaving employment, respondent shall notify the board in writing.

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 controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, 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.

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

18. **No Ownership of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, or serve 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 shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

19. **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.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it will have on my Pharmacist License. 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: 3/31/17

DENNIS AKIRA AMANO
Respondent

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

DATED: 3/31/2017

HERBERT L. WEINBERG
Attorney for Respondent

ENDORSEMENT

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

DATED: 4/3/17

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General

DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 5438

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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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