

**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**

Respondent.

Case No. 5438

**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 18, 2017.

It is so ORDERED on April 18, 2017.

BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA



By

\_\_\_\_\_  
Amy Gutierrez, Pharm.D.  
Board President

1 XAVIER BECERRA  
Attorney General of California  
2 GREGORY J. SALUTE  
Supervising Deputy Attorney General  
3 DESIREE I. KELLOGG  
Deputy Attorney General  
4 State Bar No. 126461  
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*Attorneys for Complainant*

8  
9 **BEFORE THE**  
**BOARD OF PHARMACY**  
10 **DEPARTMENT OF CONSUMER AFFAIRS**  
**STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 5438

12 **FRIENDLY HILLS MEDICAL CENTER,**  
13 **DBA FRIENDLY HILLS UNITED DRUGS**  
14 **15141 East Whittier Boulevard, Suite 115**  
**Whittier, CA 90603**

OAH No. 2016120077

**STIPULATED SURRENDER OF**  
**LICENSE AND ORDER (FRIENDLY**  
**HILLS UNITED DRUGS ONLY)**

15 **Pharmacy Permit No. PHY 40712**

16 **DENNIS AKIRA AMANO**  
17 **5076 Avenida De Los Reyes**  
**Yorba Linda, CA 92886**

18 **Pharmacist License No. RPH 41015**

19 Respondents.

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21  
22 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-  
23 entitled proceedings that the following matters are true:

24 PARTIES

25 1. Virginia K. Herold (Complainant) is the Executive Officer of the Board of Pharmacy  
26 (Board). She brought this action solely in her official capacity and is represented in this matter by  
27 Xavier Becerra, Attorney General of the State of California, by Desiree I. Kellogg, Deputy  
28 Attorney General.

1           2.     Friendly Hills Medical Center, dba Friendly Hills United Drugs (Respondent) is  
2 represented in this proceeding by attorney Herbert L. Weinberg of Fenton Law Group, LLP  
3 whose address is 1990 S. Bundy Drive, Suite 777, Los Angeles, CA 90025.

4           3.     On or about March 5, 2005, the Board issued Pharmacy Permit No. PHY 40712 to  
5 Friendly Hills Medical Center, doing business as Friendly Hills United Drugs (Respondent). The  
6 Pharmacy Permit was in full force and effect at all times relevant to the charges brought in  
7 Accusation No. 5438. It expired on October 25, 2014 and was cancelled on January 23, 2015.

8                                       JURISDICTION

9           4.     Accusation No. 5438 was filed before the (Board),, and is currently pending against  
10 Respondent. The Accusation and all other statutorily required documents were properly served  
11 on Respondent on July 22, 2016. Respondent timely filed its Notice of Defense contesting the  
12 Accusation. A copy of Accusation No. 5438 is attached as Exhibit A and incorporated by  
13 reference.

14                                       ADVISEMENT AND WAIVERS

15           5.     Respondent has carefully read, fully discussed with counsel, and understands the  
16 charges and allegations in Accusation No. 5438. Respondent also has carefully read, fully  
17 discussed with counsel, and understands the effects of this Stipulated Surrender of License and  
18 Order.

19           6.     Respondent is fully aware of its legal rights in this matter, including the right to a  
20 hearing on the charges and allegations in the Accusation; the right to confront and cross-examine  
21 the witnesses against them; the right to present evidence and to testify on its own behalf; the right  
22 to the issuance of subpoenas to compel the attendance of witnesses and the production of  
23 documents; the right to reconsideration and court review of an adverse decision; and all other  
24 rights accorded by the California Administrative Procedure Act and other applicable laws.

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

1 CULPABILITY

2 8. Respondent understands that the charges and allegations in Accusation No. 5438, if  
3 proven at a hearing, constitute cause for imposing discipline upon its Pharmacy Permit.

4 9. For the purpose of resolving the Accusation without the expense and uncertainty of  
5 further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual  
6 basis for the charges in the Accusation and that those charges constitute cause for discipline.  
7 Respondent hereby gives up their right to contest that cause for discipline exists based on those  
8 charges.

9 10. Respondent understands that by signing this stipulation, it enables the Board to issue  
10 an order accepting the surrender of its Pharmacy Permit without further process.

11 CONTINGENCY

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

21 12. The parties understand and agree that Portable Document Format (PDF) and facsimile  
22 copies of this Stipulated Surrender of License and Order, including Portable Document Format  
23 (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

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

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

5 **ORDER**

6 IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 40712, issued to Respondent  
7 Friendly Hills Medical Center, doing business as Friendly Hills United Drugs, is surrendered and  
8 accepted by the Board of Pharmacy.

9 1. The surrender of Respondent's Pharmacy Permit and the acceptance of the  
10 surrendered license by the Board shall constitute the imposition of discipline against Respondent.  
11 This stipulation constitutes a record of the discipline and shall become a part of Respondent's  
12 license history with the Board of Pharmacy.

13 2. Respondent surrenders Pharmacy Permit No. PHY 40712 as of the effective date of  
14 this Decision. Respondent shall relinquish the premises wall license and renewal license to the  
15 Board within ten (10) days of the effective date of this Decision.

16 3. If it ever applies for licensure or petitions for reinstatement in the State of California,  
17 the Board shall treat it as a new application for licensure. Respondent must comply with all the  
18 laws, regulations and procedures for licensure in effect at the time the application or petition is  
19 filed, and all of the charges and allegations contained in Accusation No. 5438 shall be deemed to  
20 be true, correct and admitted by Respondent when the Board determines whether to grant or deny  
21 the application or petition.

22 4. Respondent shall pay the agency its costs of investigation and enforcement in the  
23 amount of \$6,552.64 within sixty (60) days of the effective date of this Order.


24 5. If Respondent should ever apply or reapply for a new license or certification, or  
25 petition for reinstatement of a license, by any other health care licensing agency in the State of  
26 California, all of the charges and allegations contained in Accusation, No. 5438 shall be deemed  
27 to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any  
28 other proceeding seeking to deny or restrict licensure.

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6. Respondent shall not apply for licensure or petition for reinstatement for three (3) years from the effective date of the Board's Decision and Order.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it will have on the Pharmacy Permit. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 3/22/2017   
MICHAEL J. RUDOLPH, authorized agent by and  
behalf of FRIENDLY HILLS MEDICAL  
CENTER, DBA FRIENDLY HILLS UNITED  
DRUGS  
*Respondent*

I have read and fully discussed with Respondent Friendly Hills Medical Center, dba Friendly Hills United Drugs the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: 3/22/2017   
HERBERT L. WEINBERG  
*Attorney for Respondent*

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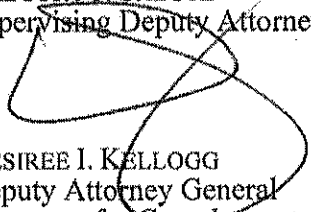
ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 3/27/17

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**



1 KAMALA D. HARRIS  
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2 GREGORY J. SALUTE  
Supervising Deputy Attorney General  
3 DESIREE I. KELLOGG  
Deputy Attorney General  
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7 Facsimile: (619) 645-2061  
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14 **15141 East Whittier Boulevard, Suite 115**  
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**A C C U S A T I O N**

15 **Pharmacy Permit No. PHY 40712**

16 **DENNIS AKIRA AMANO**  
17 **5076 Avenida De Los Reyes**  
**Yorba Linda, CA 92886**

18 **Pharmacist License No. RPH 41015**

19 Respondents.

20  
21  
22 Complainant alleges:

23 **PARTIES**

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

26 2. On or about March 5, 2005, the Board of Pharmacy issued Pharmacy Permit Number  
27 PHY 40712 to Friendly Hills Medical Center, doing business as Friendly Hills United Drugs with  
28 Dennis Akira Amano designated as the Pharmacist-in-Charge (Respondent Friendly Hills United

1 Drugs). The Pharmacy Permit expired on October 25, 2014 and was cancelled on January 23,  
2 2015.

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

### 7 JURISDICTION

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

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

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

16 7. Section 4300.1 of the Code states:

17 The expiration, cancellation, forfeiture, or suspension of a board-issued license  
18 by operation of law or by order or decision of the board or a court of law, the  
19 placement of a license on a retired status, or the voluntary surrender of a license by a  
20 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.

### 21 STATUTORY PROVISIONS

22 8. Section 4022 of the Code states:

23 "Dangerous drug" or "dangerous device" means any drug or device unsafe for  
24 self-use in humans or animals, and includes the following:

25 (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing  
without prescription," "Rx only," or words of similar import.

26 (b) Any device that bears the statement: "Caution: federal law restricts this  
27 device to sale by or on the order of a \_\_\_\_\_," "Rx only," or words of similar import,  
28

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

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

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

9 10. Section 4113, subdivision (c) of the Code states:

10 The pharmacist-in-charge shall be responsible for a pharmacy's compliance  
11 with all state and federal laws and regulations pertaining to the practice of  
12 pharmacy.

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

14 The board shall take action against any holder of a license who is guilty of  
15 unprofessional conduct or whose license has been procured by fraud or  
16 misrepresentation or issued by mistake. Unprofessional conduct shall include, but is  
17 not limited to, any of the following:

18 . . . .

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

21 . . . .

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

27 . . . .

28 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.

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

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

7 **REGULATORY PROVISIONS**

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

9 "Compounding" means any of the following activities occurring in a licensed  
10 pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a  
prescription:

- 11 (1) Altering the dosage form or delivery system of a drug  
12 (2) Altering the strength of a drug  
13 (3) Combining components or active ingredients  
14 (4) Preparing a drug product from chemicals or bulk drug substances

15 .....

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

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

- 19 (1) Active ingredients to be used.  
20 (2) Equipment to be used.  
21 (3) Expiration dating requirements.  
22 (4) Inactive ingredients to be used.  
23 (5) Process and/or procedure used to prepare the drug.  
24 (6) Quality reviews required at each step in preparation of the drug.  
25 (7) Post-compounding process or procedures required, if any.

26 .....

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

1 developed by the board. (Incorporated by reference is "Community Pharmacy &  
2 Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev.  
3 (02/12.) That form contains a first section applicable to all compounding, and a  
4 second section applicable to sterile injectable compounding. The first section must  
5 be completed by the pharmacist-in-charge before any compounding is performed in  
6 the pharmacy. The second section must be completed by the pharmacist-in-charge  
7 before any sterile injectable compounding is performed in the pharmacy. The  
8 applicable sections of the self-assessment shall subsequently be completed before  
9 July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-  
10 in-charge, and within 30 days of the issuance of a new pharmacy license. The  
11 primary purpose of the self-assessment is to promote compliance through self-  
12 examination and education.

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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).

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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) of 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

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

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

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

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

### 16 COST RECOVERY

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

### 21 FACTUAL ALLEGATIONS

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

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

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

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

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

9                           **FIRST CAUSE FOR DISCIPLINE**

10                                       **(Held Misbranded Drugs)**

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

16                           **SECOND CAUSE FOR DISCIPLINE**

17                                       **(Received Misbranded Drugs)**

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

23                           **THIRD CAUSE FOR DISCIPLINE**

24                                       **(Inadequate Record-Keeping)**

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



- 1 a. California Code of Regulations, title 16, section 1735.7(a): Failure to  
2 maintain training records for compounding staff.
- 3 b. California Code of Regulations, title 16, section 1735.5(a): Failure to  
4 maintain current written policies and procedures for compounding.
- 5 c. California Code of Regulations, title 16, section 1735.5(b): Failure to  
6 review policy and procedures manual on an annual basis and update it.
- 7 d. California Code of Regulations, title 16, section 1735.6(a): Failure to  
8 maintain written documentation of facilities and equipment for compounding.
- 9 e. California Code of Regulations, title 16, section 1735.5(c)(3): Failure to  
10 maintain policies and procedures regarding facilities and equipment cleaning, maintenance, and  
11 operation and facilities and equipment necessary for safe and accurate compounded drug  
12 products.
- 13 f. California Code of Regulations, title 16, section 1735.5(c)(4): Failure to  
14 produce and maintain documentation of the methodology used to test integrity, potency, quality,  
15 and labeled strength of compounded drug products.
- 16 g. California Code of Regulations, title 16, section 1735.5(c)(5): Failure to  
17 produce and maintain documentation of the methodology used to determine appropriate  
18 expiration dates for compounded drug products.
- 19 h. California Code of Regulations, title 16, section 1735.3: Failure to produce  
20 and maintain complete records or any records of compounded drugs, including failing to record  
21 the lot number, the expiration date of all components, the pharmacist who verified the  
22 compounded drugs and the identity of the pharmacy staff who compounded the drug product.
- 23 i. California Code of Regulations, title 16, section 1735.7(b): Failure to  
24 produce and maintain written documentation sufficient to demonstrate pharmacy personnel have  
25 the skills and training necessary to complete compounding, an on-going competency evaluation  
26 process and the training completed by pharmacy personnel.
- 27 j. California Code of Regulations, title 16, section 1735.8(a)-(c): Failure to  
28 produce and maintain a written quality assurance plan to monitor and ensure the integrity,

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

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

8 **FOURTH CAUSE FOR DISCIPLINE**

9 **(Failure to Label Drug With All Active Ingredients)**

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

14 **FIFTH CAUSE FOR DISCIPLINE**

15 **(Failure to Complete Compounding Self-Assessment Form)**

16 35. Respondents are subject to disciplinary action under section 4301, subdivision (o) for  
17 violating California Code of Regulations, title 16, section 1735.2(j), in that Respondents did not  
18 complete a self-assessment form prior to compounding drug products, as set forth in paragraphs  
19 26 through 30, which are incorporated herein by reference.

20 **SIXTH CAUSE FOR DISCIPLINE**

21 **(Failure to Maintain Master Formulas)**

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

1 SEVENTH CAUSE FOR DISCIPLINE

2 (Unprofessional Conduct)

3 37. Respondents are subject to disciplinary action under Code section 4301 for  
4 unprofessional conduct in that they engaged in the activities described in paragraphs 26 through  
5 30 above, which are incorporated herein by reference.

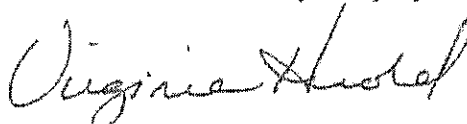
6 **PRAYER**

7 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,  
8 and that following the hearing, the Board of Pharmacy issue a decision:

- 9 1. Revoking or suspending Pharmacy Permit Number PHY 40712 issued to Friendly  
10 Hills Medical Center, doing business as Friendly Hills United Drugs;
- 11 2. Revoking or suspending Pharmacist License Number RPH 41015 issued to Dennis  
12 Akira Amano;
- 13 3. Ordering Friendly Hills Medical Center, doing business as Friendly Hills United  
14 Drugs and Dennis Akira Amano to pay the Board of Pharmacy the reasonable costs of the  
15 investigation and enforcement of this case, pursuant to Business and Professions Code section  
16 125.3; and
- 17 4. Taking such other and further action as deemed necessary and proper.

18  
19 DATED: \_\_\_\_\_

7/19/16



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

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