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

11 In the Matter of the Accusation Against:

Case No. 5704

12 **ALGUNAS INC. DBA WOODLAND**
13 **HILLS PHARMACY, STEVEN A. LEVIN**
14 **PRESIDENT**

20631 Ventura Blvd., Ste. 305
Woodland Hills, CA 91364
STEVEN A. LEVIN, Pharmacist-in-Charge

15 **Original Permit No. PHY 50815**

16 **STEVEN A. LEVIN**
22349 Alguas Road
Woodland Hills, CA 91364

17 **Original Pharmacist License No. RPH 46443**

18 Respondents.

A C C U S A T I O N

19
20 Complainant alleges:

21 **PARTIES**

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

24 2. On or about February 1, 2012, the Board of Pharmacy issued Original Permit Number
25 PHY 50815 to Alguas Inc., doing business as Woodland Hills Pharmacy, with Steven A. Levin
26 as the President, Pharmacist-in-Charge, and 100% shareholder ("Respondent Pharmacy"). The
27 Original Permit was in full force and effect at all times relevant to the charges brought herein and
28 will expire on February 1, 2018, unless renewed.

1 3. On or about August 13, 1993, the Board of Pharmacy issued Original Pharmacist
2 License Number RPH 46443 to Steven A. Levin ("Respondent Levin"). The Original Pharmacist
3 License was in full force and effect at all times relevant to the charges brought herein and will
4 expire on December 31, 2018, unless renewed.

5 **JURISDICTION**

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

9 5. Section 4300 provides, in pertinent part, that every license issued by the Board is
10 subject to discipline, including suspension or revocation.

11 6. Section 4300.1 states:

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

17 **STATUTORY PROVISIONS**

18 7. Section 4022 states:

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

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

23 "(b) Any device that bears the statement: "Caution: federal law restricts this device to sale
24 by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled
25 in with the designation of the practitioner licensed to use or order use of the device.

26 8. Section 4036.5 states: "Pharmacist-in-charge" means a pharmacist proposed by a
27 pharmacy and approved by the board as the supervisor or manager responsible for ensuring the
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1 pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of
2 pharmacy.”

3 9. Section 4169 states, in pertinent part:

4 “(a) A person or entity shall not do any of the following:

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6 (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably
7 should have known were adulterated, as set forth in Article 2 (commencing with Section 111250)
8 of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.”

9 10. Section 4301 states, in pertinent part:

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

13

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

16

17 “(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the
18 violation of or conspiring to violate any provision or term of this chapter or of the applicable
19 federal and state laws and regulations governing pharmacy, including regulations established by
20 the board or by any other state or federal regulatory agency.”

21 11. Section 4307 states, in pertinent part:

22 “(a) Any person who has been denied a license or whose license has been revoked or is
23 under suspension, or who has failed to renew his or her license while it was under suspension, or
24 who has been a manager, administrator, owner, member, officer, director, associate, or partner of
25 any partnership, corporation, firm, or association whose application for a license has been denied
26 or revoked, is under suspension or has been placed on probation, and while acting as the manager,
27 administrator, owner, member, officer, director, associate, or partner had knowledge of or
28 knowingly participated in any conduct for which the license was denied, revoked, suspended, or

1 placed on probation, shall be prohibited from serving as a manager, administrator, owner,
2 member, officer, director, associate, or partner of a licensee as follows:

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

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

7 12. Section 4342 states:

8 “(a) The board may institute any action or actions as may be provided by law and that, in its
9 discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not
10 conform to the standard and tests as to quality and strength, provided in the latest edition of the
11 United States Pharmacopoeia or the National Formulary, or that violate any provision of the
12 Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division
13 104 of the Health and Safety Code).

14 “(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006
15 shall be subject to punishment in the same manner as is provided in Sections 4321 and 4336.”

16 13. Health and Safety Code section 111285 states: “Any drug or device is adulterated if
17 its strength differs from, or its purity or quality is below, that which it is represented to possess.”

18 **REGULATORY PROVISIONS**

19 14. California Code of Regulations, title 16, section 1735.2, subdivision (j), states: “The
20 pharmacist performing or supervising compounding is responsible for the proper preparation,
21 labeling, storage, and delivery of the compounded drug preparation.”

22 **COST RECOVERY**

23 15. Section 125.3 states, in pertinent part, that the Board may request the administrative
24 law judge to direct a licentiate found to have committed a violation or violations of the licensing
25 act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the
26 case.

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1 **DANGEROUS DRUGS**

2 16. Amphotericin, brand names AmBisome, Fungizone, and Amphocin, is a dangerous
3 drug pursuant to Business and Professions Code section 4022.

4 **FACTUAL BACKGROUND**

5 17. On or about November 28, 2014, the Board received a complaint from S.C. regarding
6 her prescription for amphotericin filled at Respondent Pharmacy. In her complaint, S.C. alleged
7 that after she moved to Hawaii, it took five days for her amphotericin prescription to arrive from
8 Respondent Pharmacy and the amphotericin was shipped without ice. Within three days of taking
9 the amphotericin, S.C. alleged that she had trouble breathing. S.C. notified Respondent Levin but
10 continued to have problems properly receiving the medication. S.C. alleged that a shipment of
11 amphotericin she received in June was again shipped without ice and did not work, and another
12 shipment of amphotericin she received in November was shipped with no ice and did not work,
13 causing her to have difficulty breathing. S.C. then submitted her complaint to the Board.

14 18. On or about May 11, 2015, a Board inspector performed a complaint investigation at
15 Respondent Pharmacy. Respondent Levin was present during the investigation and told the
16 Board inspector the amphotericin solution was compounded at the pharmacy, that it was not
17 shipped with ice, but included instructions to be refrigerated upon arrival.

18 19. During the investigation at Respondent Pharmacy, the Board inspector inspected the
19 pharmacy's refrigerator and found a compounded preparation of amphotericin that was packaged
20 in a plastic opaque bottle and not protected from light. The master formula for amphotericin
21 requires that the compounded medication be refrigerated and protected from light. At the
22 conclusion of the investigation, the board inspector requested that Respondent Levin provide a
23 copy of laboratory testing results for the compounded amphotericin within fourteen days.

24 20. On or about May 18, 2015, the Board inspector spoke with Respondent Levin who
25 stated that he received laboratory test results for the compounded amphotericin, but that the
26 compounded amphotericin had only a sixty (60) percent potency. Potency range must be within
27 plus or minus ten (10) percent of the expected potency to be acceptable. Respondent Levin stated
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1 that he would revise his policies and procedures for preparing amphotericin and obtain additional
2 laboratory results.

3 21. On or about May 28, 2015, Respondent Levin faxed the Board inspector a written
4 statement, wherein Respondent Levin admitted that after reviewing the master formula, he
5 realized he made an error in obtaining solubility by heating the amphotericin solution instead of
6 using a cold preparation process. Over the next month, Respondent Levin compounded
7 additional amphotericin, with solution potency ranging from 83.3% to 125%. Respondent Levin
8 was instructed to continue testing his samples to assure his master formula was reliable and to
9 determine appropriate beyond use dating prior to dispensing the compound.

10 **FIRST CAUSE FOR DISCIPLINE**

11 **(Sale of Adulterated Dangerous Drugs)**

12 22. Respondent Pharmacy and Respondent Levin (collectively, Respondents") are subject
13 to disciplinary action under section 4301, subdivisions (j), and (o), in conjunction with section
14 4169, subdivision (a)(2), and Health and Safety Code section 111285 in that Respondents sold
15 adulterated dangerous drugs that did not conform to standards and tests as to quality and strength.
16 The potency of the dangerous drugs sold by Respondents also deviated well outside of the
17 acceptable range for the medication.

18 23. The circumstances of the violation include that between January 15, 2014, and May 8,
19 2015, Respondents dispensed at least 249 prescriptions of amphotericin that were found to be
20 adulterated and lacking in potency. During the Board's inspection of Respondent Pharmacy on
21 May 11, 2015, it was revealed that Respondents compounded amphotericin using incorrect
22 procedures, including using a hot plate instead of a cold plate and that the final amphotericin
23 preparation was packaged in a plastic polypropylene container which resulted in polymer
24 degradation and caused the amphotericin to fail to meet its stated quality and strength.

25 Complainant refers to, and by this reference incorporates, the allegations contained in paragraphs
26 17 through 21, as though set forth fully.

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1 **SECOND CAUSE FOR DISCIPLINE**

2 **(Failure to Properly Store and Deliver Compounded Medication)**

3 24. Respondents are subject to disciplinary action under section 4301, subdivision (o), in
4 conjunction with California Code of Regulations, title 16, section 1735.2, subdivision (j), in that
5 Respondents failed to properly store and deliver compounded amphotericin.

6 25. The circumstances of the violation include that between January 15, 2014, and May 8,
7 2015, Respondents dispensed at least 249 prescriptions of amphotericin that had not been
8 properly stored and delivered. Respondent Pharmacy's master formula for the amphotericin
9 solution required that the compounded medication be refrigerated and protected from light.
10 However, the compounded medication was not packaged in a light sensitive container and was
11 shipped without proper refrigeration. Complainant refers to, and by this reference incorporates,
12 the allegations contained in paragraphs 17 through 21, as though set forth fully.

13 **DISCIPLINARY CONSIDERATIONS**

14 26. To determine the degree of discipline, if any, to be imposed on Respondent Levin,
15 Complainant alleges the following:

16 a. On or about January 4, 2012, the Board of Pharmacy issued Respondent Levin
17 Citation Number CI 2011 50850, with a \$4,000.00 fine. Respondent Levin complied with the
18 citation and it is final. The citation alleged the following violations:

19 b. Respondent Levin, during a pharmacy Board inspection, failed to provide a written
20 copy of the pharmacy's pharmacy technician job description and policies and procedures in
21 violation of California Code of Regulations, title 16, section 1793.7, subdivision (d).

22 c. Respondent Levin, during a pharmacy Board inspection, failed to provide a written
23 copy of the pharmacy's theft and impairment policies and procedures in violation of section 4104,
24 subdivisions (a) and (b).

25 d. Respondent Levin allowed a clerk to transcribe new telephone prescriptions in
26 violation of California Code of Regulations, title 16, section 1793.1, subdivision (a).

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1 e. Respondent Levin failed to complete a compounding self assessment prior to
2 allowing any drug product to be compounded in violation of California Code of Regulations, title
3 16, section 1735.2, subdivision (j).

4 f. Respondent Levin failed to keep records of compounded drug products in violation of
5 California Code of Regulations, title 16, section 1735.3, subdivision (a).

6 g. Respondent Levin, during a pharmacy Board inspection, was found to have assigned
7 an expiration date to a final compounded product that was beyond the expiration date of
8 ingredients used to compound the product in violation of California Code of Regulations, title 16,
9 section 1735.2, subdivision (h).

10 **OTHER MATTERS**

11 27. Pursuant to section 4307, if discipline is imposed on Original Permit Number PHY
12 50815 issued to Alguas Inc., doing business as Woodland Hills Pharmacy, then Alguas Inc.,
13 doing business as Woodland Hills Pharmacy, shall be prohibited from serving as a manager,
14 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
15 Original Permit Number PHY 50815 is placed on probation or until Original Permit Number
16 PHY 50815 is reinstated if the license is revoked.

17 28. Pursuant to section 4307, if discipline is imposed on Original Permit Number PHY
18 50815 issued to Alguas Inc., doing business as Woodland Hills Pharmacy, while Steven A.
19 Levin has been an officer and owner and had knowledge of, or knowingly participated in, any
20 conduct for which Alguas Inc., doing business as Woodland Hills Pharmacy, was disciplined,
21 Steven A. Levin shall be prohibited from serving as a manager, administrator, owner, member,
22 officer, director, associate, or partner of a licensee for five years if Original Permit Number PHY
23 50815 is placed on probation or until Original Permit Number PHY 50815 is reinstated if the
24 license is revoked.

25 **PRAYER**

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

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1 1. Revoking or suspending Original Permit Number PHY 50815, issued to Alguas Inc.,
2 doing business as Woodland Hills Pharmacy, with Steven A. Levin as the President, Pharmacist-
3 in-Charge, and 100% shareholder;

4 2. Prohibiting Alguas Inc., doing business as Woodland Hills Pharmacy, from serving
5 as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee
6 for five years if Original Permit Number PHY 50815 is placed on probation or until Original
7 Permit Number PHY 50815 is reinstated if Original Permit Number PHY 50815 issued to
8 Alguas Inc., doing business as Woodland Hills Pharmacy, is revoked;

9 3. Prohibiting Steven A. Levin from serving as a manager, administrator, owner,
10 member, officer, director, associate, or partner of a licensee for five years if Original Permit
11 Number PHY 50815 is placed on probation or until Original Permit Number PHY 50815 is
12 reinstated if Original Permit Number PHY 50815 issued to Alguas Inc., doing business as
13 Woodland Hills Pharmacy, is revoked;

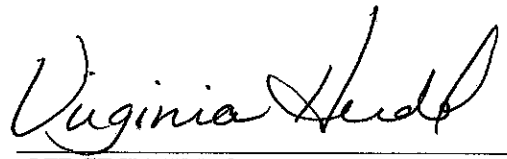
14 4. Revoking or suspending Original Pharmacist License Number RPH 46443 to Steven
15 A. Levin;

16 5. Ordering Alguas Inc., doing business as Woodland Hills Pharmacy, and Steven A.
17 Levin to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of
18 this case, pursuant to Business and Professions Code section 125.3; and,

19 6. Taking such other and further action as deemed necessary and proper.

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DATED: 2/13/17



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

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