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

In the Matter of the Accusation Against: **GOLDEN GATE PHARMACY** **LIU, YOW WEN** **1844 Noriega Street** **San Francisco, CA 94122** **Pharmacist License No. RPH 43206** **Pharmacy Permit No. PHY 38113** Respondents.	Case No. 5502 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about August 21, 1992, the Board of Pharmacy issued Pharmacy Permit Number PHY 38113 to Yow Wen Liu, doing business as Golden Gate Pharmacy ("Respondent Golden Gate Pharmacy"). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on August 1, 2016, unless renewed.

3. On or about March 8, 1992, the Board of Pharmacy issued Pharmacist License Number RPH 43206 to Yow Wen Liu ("Respondent Liu"). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on

July 31, 2017, 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, subdivision (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 AND REGULATORY PROVISIONS

8. Section 4301 of the Code states:

"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, or 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 any other state or federal regulatory agency."

9. Code section 4113, subdivision (c), states, "[t]he 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."

10. Code section 4169, subdivision (a)(3) states that a person or entity should not purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 11135 of the Health and Safety Code.

11. Code section 4081, subdivision (a) states, in pertinent part that all records of acquisition of dangerous drugs shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making.

12. Section 4306.5 of the Code states, in pertinent part:

"Unprofessional conduct for a pharmacist may include any of the following:

. . . .

"(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

"(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function."

13. California Code of Regulations, title 16, section 1714, states, in pertinent part:

. . .

"(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

"(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly

lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes."

14. California Code of Regulations, title 16, section 1735.7, Subdivision (b) states:

"(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."

15. California Code of Regulations, title 16, section 1735.2, subdivision (d), states:

"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."

16. California Code of Regulations, title 16, section 1735.3, subdivision (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 numbers for the compounded drug product.

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

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

10. California Code of Regulations, title 16, section 1735.4, subdivision (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).

DRUGS

17 Code section 4021 states:

"'Controlled substance' means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code."

18. Code section 4022 provides:

"'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 . . .

"(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."

19. Liquid Coal Tar Solustion (LCD) is a thick brown or black liquid of extremely hish viscosity. It is used to treat eczema, psoriasis, dermatitis, and other skin disorders. It is a dangerous drug under Code section 4022.

20. Triamcinolone 0.1% is a topical corticosteroid that is used to treat swelling, inflammation, and itching of skin conditions such as eczema, dermatitis, rashes, insect bites, poison ivy, allergies, and other irritations. It is a dangerous drug under Code section 4022.

COST RECOVERY

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

FACTUAL ALLEGATIONS

22. From August 21, 1992, to the present, Respondent Liu has been the Pharmacist-in-Charge ("PIC") of Respondent Golden Gate Pharmacy.

23. On or about March 12, 2015, Board of Pharmacy inspectors went to Respondent Golden Gate Pharmacy and conducted a routine inspection. Respondent Liu was present and assisted with the inspection. During the inspection, the Board inspectors obtained and reviewed compounding records, prescription vial labels, and other documents.

24. During the March 12, 2015 inspection, the Board inspectors observed the following: (1) two unlabeled, 60 gram, prescription vials filled with unlabeled Triamcinolone 0.1% ointment, used in compounding, and (2) several prescription vials filled with different tablets without proper labeling. Board inspectors determined that Respondents had misbranded and sold at least 9 prescriptions for Liquid Coal Tar solution 5% compounded with Triamcinolone 0.1% ointment. The compounding was performed without a master formula. Respondent Liu was unable to provide a compounding record or documentation of compounding staff training. Additionally, Respondent offered at least 9 vials of misbranded tablets for sale.

25. On or about April 7, 2015, Board inspectors went to Respondent Golden Gate Pharmacy and conducted a follow-up inspection. Respondent Liu was present and assisted with the inspection. The Board inspectors observed a Safeway bag containing drug samples and physician's office patient charts. Respondent Liu informed the Board inspectors that the physician who previously had an office in the same building, had left the drug samples (including Nesina, Oseni, Tradjenta, Kazano, and Oseni), and patient charts so that the patients could pick them up from the pharmacy. Drug dispensing reports, compounding topical medication reports, faxed prescriptions, and a compounding self-assessment were obtained and reviewed during and after the

inspection.

26. During the April 7, 2015 inspection, the Board inspectors observed a large hole with visible dirt and debris in the ceiling over the automated drug dispensing machine. There was a cart containing open prescription vials for use with the automated drug dispensing machine directly underneath the hole. Respondent Liu failed to provide a monthly cleaning log. Respondent Liu had not contacted the landlord to repair the hole.

FIRST CAUSE FOR DISCIPLINE
(Misbranding of Dangerous Drugs)

27. Respondent Golden Gate Pharmacy and Respondent Liu have subjected their licenses to disciplinary action pursuant to Code sections 4301, subdivisions (j) and (o) and 4169, subdivision (a)(3), as defined in Health and Safety Code sections 111330, 111440, and 111335, in that Respondents misbranded and sold at least 9 prescriptions for Liquid Coal Tar solution 5% compounded with triamcinolone 0.1% ointment., and offered at least 9 vials of misbranded tablets for sale, in violation of Health and Safety Code section 11130 and Code section 4169, subdivision (a)(3). The circumstances are set forth in paragraphs 22 through 24, above.

SECOND CAUSE FOR DISCIPLINE
(Failure to Maintain Clean and Sanitary Conditions)

28. Respondent Golden Gate Pharmacy and Respondent Liu have subjected their licenses to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), as defined in Health and Safety Code section 1261.6 and California Code of Regulations, title 16, section 1714, subdivision (b), in that they failed to maintain Golden Gate Pharmacy's facility, space, fixtures, and equipment so that drugs could be safely and properly prepared, maintained, secured and distributed. The circumstances are set forth in paragraphs 22, 25, and 26, above.

THIRD CAUSE FOR DISCIPLINE
(Failure to Have Master Formula Prior to Compounding)

29. Respondent Golden Gate Pharmacy and Respondent Liu have subjected their licenses to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), as defined in California Code of Regulations, title 16, section 1735.2, subdivision (b), in that they compounded

at least 9 prescriptions for Liquid Coal Tar solution 5% with Triamcinolone 0.1% ointment, without a master formula. The circumstances are set forth in paragraphs 22 and 24, above.

FOURTH CAUSE FOR DISCIPLINE
(Failure to Have a Compounding Record for Compounded Medications)

30. Respondent Golden Gate Pharmacy and Respondent Liu have subjected their licenses to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), as defined in California Code of Regulations, title 16, section 1735.3, subdivision (a)(1-10) in that they failed to maintain a compounding record for at least 9 prescriptions for Liquid Coal Tar solution 5% with Triamcinolone 0.1% ointment. The circumstances are set forth in paragraphs 22 through 24, above.

FIFTH CAUSE FOR DISCIPLINE
(Failure to Maintain Training Records for Staff that Compound Medications)

31. Respondent Golden Gate Pharmacy and Respondent Liu have subjected their licenses to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), as defined in California Code of Regulations, title 16, section 1735.7, subdivision (b), in that they failed to maintain documentation of compounding staff training. The circumstances are set forth in paragraphs 22 through 24, above.

SIXTH CAUSE FOR DISCIPLINE
(Failure To Verify Authenticity of Controlled Prescriptions)

32. Respondent Golden Gate Pharmacy and Respondent Liu have subjected their licenses to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), as defined in Health and Safety Code section 1164, subdivision (a)(1) in that they failed to verify the authenticity of controlled prescriptions and filled two faxed prescriptions for controlled substances that did not have the prescribers wet signature and date.

SEVENTH CAUSE FOR DISCIPLINE
(Failure to Provide Records of Acquisition for Drug Samples)

33. Respondent Golden Gate Pharmacy and Respondent Liu have subjected their licenses to disciplinary action pursuant to Business and Professions Code sections 4301, subdivisions (j) and (o) and 4081, subdivision (a) in that Respondents failed to provide records of acquisition for

drug samples that were found in the facility. Specifically, on April 7, 2015, during a follow-up inspection, Board inspectors observed drug samples for Nesina (42 tablets), Oseni (70 tablets), Tradjenta (14 tablets), Kazano (28 tablets), Oseni (70 tablets). The circumstances are set forth in paragraphs 22 and 25, above.

EIGHTH CAUSE FOR DISCIPLINE
(Incorrectly Labeled Compound Drugs)

34. Respondents Golden Gate Pharmacy and Respondent Liu have subjected their licenses to disciplinary action pursuant to Business and Professions Code section 4301, subdivisions (j) and (o), as defined in California Code of Regulations, title 16, section 1735.4, subdivision (a), in that Respondents dispensed Liquid Coal Tar Solution 5% and Triamcinolone 0.1% ointment that was labeled only as "LCD 5%/TAC 0.1% ont."

NINTH CAUSE FOR DISCIPLINE
(Unlawful Trade and Distribution of Drug Samples)

35. Respondents Golden Gate Pharmacy and Respondent Liu have subjected their licenses to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), as defined in Title 21, United States Code, section 353, subdivision (c)(1), in that Respondent's accepted drug samples as described in paragraph 33, above, with the intent to distribute them. The circumstances are set forth in paragraphs 22 and 25, above.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this Accusation, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy Permit Number PHY 38113, issued to Golden Gate Pharmacy;

2. Revoking or suspending Pharmacist License Number RPH 43206, issued to Yow Wen Liu;

3. Ordering Respondents 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;

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

DATED: 9/11/15

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

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