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

In the Matter of the Accusation Against: **GOLDEN GATE PHARMACY** **1844 Noriega Street** **San Francisco, CA 94122** **Pharmacy Permit No. PHY 38113** **YOW WEN LIU** **1844 Noriega Street** **San Francisco, CA 94122** **Pharmacist License No. RPH 43206** Respondents.	Case No. 5502 OAH No. 2016010535

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary 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 September 9, 2016.

It is so ORDERED on August 10, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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BEFORE THE
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In the Matter of the Accusation Against: **GOLDEN GATE PHARMACY** **1844 Noriega Street** **San Francisco, CA 94122** **Pharmacy Permit No. PHY 38113** **YOW WEN LIU** **1844 Noriega Street** **San Francisco, CA 94122** **Pharmacist License No. RPH 43206** Respondent.	Case No. 5502 OAH Case No. 2016010535 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

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 Herold (Complainant) is the Executive Officer of the Board of Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Kim M. Settles, Deputy Attorney General.

2. Respondent Golden Gate Pharmacy; Yow Wen Liu ("Respondent") is represented in this proceeding by attorney Ivan Petrzeka, whose address is: Ivan Petrzeka, Pharm D., J.D., M.B.A., California Pharmacy Lawyers - Law Office of Tony J. Park, Inc., 2855 Michelle Drive,

Suite 180, Irvine, CA 92606-1027, telephone number (530) 366-8485.

3. On or about March 8, 1990, the Board of Pharmacy issued Pharmacist License No. RPH 43206 to Yow Wen Liu (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 5502, and will expire on July 31, 2017, unless renewed.

4. 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.

JURISDICTION

5. Accusation No. 5502 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on December 1, 2015. Respondent timely filed his Notice of Defense contesting the Accusation.

6. A copy of Accusation No. 5502 is attached as exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5502. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

8. 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 him; 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.

9. Respondent voluntarily, knowingly, and intelligently waives and gives up each and

every right set forth above.

CULPABILITY

10. Respondent understands and agrees that the charges and allegations in Accusation No. 5502, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacist License and Pharmacy Permit.

11. 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 his right to contest those charges.

12. Respondent agrees that his Pharmacist License and Pharmacy permit are subject to discipline and he agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

13. 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.

14. 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.

15. 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.

16. 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 43206, issued to Respondent Yow Wen Liu and Pharmacy Permit PHY 38113 issued to Respondent Golden Gate Pharmacy; Yow Wen Liu are revoked. However, the revocations are stayed and Respondents are placed on probation for two and one-half (2.5) years on the following terms and conditions.

1. **Obey All Laws**

Respondents shall obey all state and federal laws and regulations.

Respondents 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 pharmacy permit and/or 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.

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2. **Report to the Board**

Respondents 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, respondents 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, respondents 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**

Respondents 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 his probation. Failure to cooperate shall be considered a violation of probation.

5. **Continuing Education**

Respondent, Yow Wen Liu 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, Yow Wen Liu shall notify all present and prospective employers of the decision in case number 5502 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 his 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 5502, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his 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 his 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 5502 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 his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number 5502 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his 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, Yow Wen Liu 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, respondents shall be jointly and severally liable to pay to the board its costs of investigation and prosecution in the amount of $5,615.50. Respondents shall make said payments as follows: $234.00 per month for 24 months.

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 respondents shall not relieve respondents of his responsibility to reimburse the board its costs of investigation and prosecution.

9. **Probation Monitoring Costs**

Respondents 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**

Respondents shall, at all times while on probation, maintain an active, current license and/or permit with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license and/or permit shall be considered a violation of probation.

If respondents' license and/or permit 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 respondents' license and/or permit shall be subject to all terms and conditions of this probation not previously satisfied.

11. **License Surrender While on Probation**

Following the effective date of this decision, should respondent, Yow Wen Liu cease

practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his 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 his 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. **License Surrender While on Probation**

Following the effective date of this decision, should respondent, Golden Gate Pharmacy discontinue business, respondent, Golden Gate Pharmacy may tender the premises 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 shall no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent, Golden Gate Pharmacy shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent, Golden Gate Pharmacy shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer. Respondent shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the

patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, respondent shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

13. **Notification of a Change in Name, Residence Address, Mailing Address or Employment**

Respondent, Yow Wen Liu 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.

14. **Tolling of Probation**

Except during periods of suspension, respondent, Yow Wen Liu shall, at all times while on probation, be employed as a pharmacist in California for a minimum of forty 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 forty 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 forty 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 forty hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

15. **Violation of Probation**

If a respondents have not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondents, 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 respondents violate probation in any respect, the board, after giving respondents 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 and charges and allegations in Accusation No. 5502 shall be deemed true and correct.

16. **Completion of Probation**

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

17. **Remedial Education**

Within sixty days of the effective date of this decision, respondent, Yow Wen Liu shall submit to the board or its designee, for prior approval, an appropriate program of remedial

education related to the grounds for discipline. The program of remedial education shall consist of at least ten units of continuing education in compounding and pharmacy law , which shall be completed within two years and three months 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 his 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.

18. **Notice to Employees**

Respondent, Golden Gate Pharmacy shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent, Golden Gate Pharmacy shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent, Golden Gate Pharmacy shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

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"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

19. **Owners and Officers: Knowledge of the Law**

Respondent, Golden Gate Pharmacy shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any other officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

20. **Posted Notice of Probation**

Respondent, Golden Gate Pharmacy shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent, Golden Gate Pharmacy shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such a notice shall be considered a violation of probation.

21. **Consultant for Owner or Pharmacist-In-Charge**

During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge. However, if during the period of probation respondent serves as a pharmacist-in-charge, respondent shall retain an independent consultant at his own expense who shall be responsible for reviewing pharmacy operations on a quarterly basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist

licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Respondent shall not be the pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Ivan Petrzelka. I understand the stipulation and the effect it will have on my Pharmacist License and Pharmacy Permit. 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: 04/24/2016 Golden Gate Pharmacy; Yow Wen Liu

GOLDEN GATE PHARMACY; YOW WEN LIU
Respondent

I have read and fully discussed with Respondent Golden Gate Pharmacy; Yow Wen Liu the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: April 25, 2016

IVAN PETRZELKA
Attorney for Respondent

ENDORSEMENT

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

Dated: April 25, 2016

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
DIANN SOKOLOFF
Supervising Deputy Attorney General

Kim M. Settles

KIM M. SETTLES
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 5502

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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 **ACCUSATION**

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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