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

In the Matter of the Accusation Against: **ANABELLA SAI-YAN FOO** **931 Amarillo Avenue** **Palo Alto, CA 94303** **Pharmacist License No. RPH 35288,** Respondents.	Case No. 5667 OAH No. 2016100169 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL AS TO ANABELLA SAI-YAN FOO**

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval 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 April 20, 2017.

It is so ORDERED on March 21, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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

In the Matter of the Accusation Against: **SILICON VALLEY PHARMACY** **14107 S. Winchester Boulevard** **Los Gatos, CA 95032** **Pharmacy Permit No. PHY 44228;** **VIVIAN CHOI MATSUO** **14107 S. Winchester Boulevard** **Los Gatos, CA 95032** **Pharmacist License No. RPH 36646;** **DAVID S. MATSUO** **14107 S. Winchester Boulevard** **Los Gatos, CA 95032** **Pharmacist License No. RPH 36383;** **ANABELLA SAI-YAN FOO** **931 Amarillo Avenue** **Palo Alto, CA 94303** **Pharmacist License No. RPH 35288; and** **JENNIFER HWA-YOUNG LEE** **761 N. 11th Street** **San Jose, CA 95112** **Pharmacist License No. RPH 39041** Respondents.	Case No. 5667 OAH No. 2016100169 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL AS TO ANABELLA SAI-YAN FOO** **[Bus. & Prof. Code § 495]**

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 ("Board"). She brought this action solely in her official capacity and is represented in this matter by Kathleen A. Kenealy, Acting Attorney General of the State of California, by Carter Ott, Deputy Attorney General.

2. Respondent Anabella Sai-Yan Foo ("Respondent") is represented in this proceeding by Ivan Petrzelka, California Pharmacy Lawyers, 2855 Michelle Drive, Suite 180, Irvine, CA 92606-1027.

JURISDICTION

3. On or about February 21, 1980, the Board issued Pharmacist License Number RPH 35288 to Respondent. The Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 5667 and will expire on March 31, 2018, unless renewed.

4. Accusation No. 5667 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 June 27, 2016. Respondent timely filed her Notice of Defense contesting the Accusation. A copy of Accusation No. 5667 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5667. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent is fully aware of her legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at her own expense; the right to confront and cross-examine the witnesses against her; the right to present evidence and to testify on her 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.

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

CULPABILITY

8. Respondent understands and agrees that the charges and allegations in Accusation No. 5667, if proven at a hearing, constitute cause for imposing discipline upon her Pharmacist License

9. 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 her right to contest those charges.

10. Respondent agrees that her Pharmacist License is subject to discipline and she agrees to be bound by the Disciplinary Order below.

CONTINGENCY

11. 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 her counsel. By signing the stipulation, Respondent understands and agrees that she may not withdraw her 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 for Public Reproval 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.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including

Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order for Public Reproval 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 for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. 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 Number RPH 35288 issued to Respondent Anabella Sai-Yan Foo shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 5667, attached as Exhibit A.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Ivan Petrzelka. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 1/27/17

ANABELLA SAI-YAN FOO
Respondent

I have read and fully discussed with Respondent Anabella Sai-Yan Foo the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 1/13/2017

IVAN PETRZELKA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated:

Respectfully submitted,

KATHLEEN A. KENEALY
Acting Attorney General of California
DIANN SOKOLOFF
Supervising Deputy Attorney General

CARTER OTT
Deputy Attorney General
Attorneys for Complainant

SF2015900835

Exhibit A

Accusation No. 5667

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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
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In the Matter of the Accusation Against: **SILICON VALLEY PHARMACY** **14107 S. Winchester Boulevard** **Los Gatos, CA 95032** **Pharmacy Permit No. PHY 44228;** **VIVIAN CHOI MATSUO** **14107 S. Winchester Boulevard** **Los Gatos, CA 95032** **Pharmacist License No. RPH 36646;** **DAVID S. MATSUO** **14107 S. Winchester Boulevard** **Los Gatos, CA 95032** **Pharmacist License No. RPH 36383;** **ANABELLA SAI-YAN FOO** **931 Amarillo Avenue** **Palo Alto, CA 94303** **Pharmacist License No. RPH 35288; and** **JENNIFER HWA-YOUNG LEE** **761 N. 11th Street** **San Jose, CA 95112** **Pharmacist License No. RPH 39041** Respondents.	Case No. 5667 **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 June 8, 1999, the Board of Pharmacy issued Pharmacy Permit Number PHY 44228 to Silicon Valley Pharmacy ("Respondent SV 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 June 1, 2016, unless renewed.

3. On or about August 13, 1981, the Board of Pharmacy issued Pharmacist License Number RPH 36383 to David S. Matsuo ("Respondent David Matsuo"). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on January 31, 2017, unless renewed. Respondent David Matsuo has been the President and a 50% shareholder of Respondent SV Pharmacy since June 8, 1999. At all times relevant to the charges brought in this Accusation against him, Respondent David Matsuo functioned as a compounding pharmacist at Respondent SV Pharmacy.

4. On or about August 20, 1981, the Board of Pharmacy issued Pharmacist License Number RPH 36646 to Vivian Choi Matsuo ("Respondent Vivian Matsuo"). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on September 30, 2017, unless renewed. Respondent Vivian Matsuo has been the Treasurer/Chief Financial Officer and a 50% shareholder of Respondent SV Pharmacy since June 8, 1999. At all times relevant to the charges brought in this Accusation against her, Respondent Vivian Matsuo served as Respondent SV Pharmacy's Pharmacist-in-Charge ("PIC").

5. On or about February 21, 1980, the Board of Pharmacy issued Pharmacist License Number RPH 35288 to Anabella Sai-Yan Foo ("Respondent Foo"). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on March 31, 2016, unless renewed. At all times relevant to the charges brought in this Accusation against her, Respondent Foo was employed as a pharmacist at Respondent SV Pharmacy.

6. On or about October 4, 1984, the Board of Pharmacy issued Pharmacist License Number RPH 39041 to Jennifer Hwa-Young Lee ("Respondent Lee"). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on March 31, 2016, unless renewed. At all times relevant to the charges brought in this Accusation against her, Respondent Lee was employed as a pharmacist at Respondent SV Pharmacy.

JURISDICTION

7. 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.

8. Section 118, subdivision (b) states:

"(b) The suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground."

9. Section 4300 of states, in part:

"(a) Every license issued may be suspended or revoked.

"(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

. . .

"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

RELEVANT STATUTES AND REGULATIONS

10. Health and Safety Code section 111335 states:

"Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

11. Health and Safety Code section 111375 states, in part:

"Any drug or device is misbranded unless its labeling bears all of the following information:

. . .

"(c) Adequate warning against unsafe dosage or methods or duration of administration or application.

"Warnings shall be in a manner and form as are necessary for the protection of users.

"If the department determines that any requirement of subdivision (a), as applied to any drug or device, is not necessary for the protection of the public health, the department may adopt regulations exempting the drug or device from these requirements.

Any drug or device exempted under Section 502(f) of the federal act (21 U.S.C. Sec. 352(f)) is exempt from the requirement of this section. The department, however, may adopt any regulation including a drug or device within, or excluding a drug or device from the requirements of this section, whether or not the inclusion or exclusion of the drug or device is in accord with the federal act."

/////

12. Health and Safety Code section 111400 states:

"Any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling."

13. Section 4169 states, in part:

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

. . .

"(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

. . . ."

14. Section 4301 states, in part:

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

. . .

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

. . . ."

15. Section 4306.5 states, in 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.

. . . ."

16. California Code of Regulations, title 16, section 1707.5 states, in part:

"(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

"(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

"(A) Name of the patient

"(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

"(C) The directions for the use of the drug.

"(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

. . . ."

17. California Code of Regulations, title 16, section 1714, subdivision (c) states:

"(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."

18. California Code of Regulations, title 16, section 1717.3, subdivision (b) states:

"(b) A person may dispense a dangerous drug, that is not a controlled substance, pursuant to a preprinted multiple checkoff prescription blank and may dispense more than one dangerous drug, that is not a controlled substance, pursuant to such a blank if the prescriber has indicated on the blank the number of dangerous drugs he or she has prescribed."

19. California Code of Regulations, title 16, section 1735.3 states, in part:

"(a) For each compounded drug product, the pharmacy records shall include:

. . .

"(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.

. . .

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

. . .

"(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

. . . ."

20. California Code of Regulations, title 16, section 1735.6, subdivision (b) states:

"(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications."

21. California Code of Regulations, title 16, section 1761 states, in part:

"(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

. . . ."

COST RECOVERY

22. Section 125.3 provides, in 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.

RELEVANT DRUG INFORMATION

23. "Domperidone," also known as motilium, is an anti-dopaminergic drug which acts as an antiemetic and a prokinetic agent. It is used in many countries for the treatment of gastroparesis, a condition in which the stomach cannot empty itself of food in a normal fashion.

Compounding with domperidone is not allowed in the United States with the exception of investigational new drug application filing. Only Dougherty's Pharmacy, located in Dallas, Texas, is approved to compound domperidone at this time. Distribution of any domperidone-containing products is illegal. The Federal Drug Administration ("FDA") has instructed its field personnel to detain shipments of domperidone and refuse its admission into the United States.

24. Domperidone is believed to promote lactation. But the drug is not approved in any country, including the United States, for promoting lactation. In fact, the FDA warns against using domperidone for promoting lactation. In particular, on June 7, 2004, the FDA published a talk paper titled "FDA Warns Against Women Using Unapproved Drug, Domperidone, to Increase Milk Production,"[1] in which it warns about the public risks associated with use of the drug:

> The [FDA] is concerned with the potential public health risks associated with domperidone. There have been several published reports and case studies of cardiac arrhythmias, cardiac arrest, and sudden death in patients receiving an intravenous form of domperidone . . . . In several countries where the oral form of domperidone continues to be marketed, labels for the product contain specific warnings against use of domperidone by breastfeeding women and note that the drug is excreted in breast milk that could expose a breastfeeding infant to unknown risks. Because of the possibility of serious adverse effects, FDA recommends that breastfeeding women not use domperidone to increase milk production.
>
> . . .
>
> The letters issued by FDA today stated that all drug products containing domperidone (whether compounded or not) violate the Federal Food, Drug, and Cosmetic Act (the Act) because they are unapproved new drugs and misbranded. In addition, distribution within the U.S., or importation of domperidone-containing products, violates the law. FDA informed the warning letter recipients that further violations of the Act may result in enforcement actions including seizure and injunction.

[1] http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm173886.htm

FIRST CAUSE FOR DISCIPLINE
(Sale of Misbranded Drug)
(Bus. & Prof. Code § 4169, subd. (a)(3); and Health and Safety Code §§ 111335; 111375, subd. (c); and 111400)

25. Respondents SV Pharmacy, David Matsuo, Vivian Matsuo, Foo, and Lee have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for their trade, sale, or transfer of a dangerous drug that they knew or reasonably should have known was misbranded, as defined in Health and Safety Code section 111335. (Bus. & Prof. Code § 4169, subd. (a)(3); and Health and Safety Code §§ 111335; 111375, subd. (c); and 111400). In particular:

a. From January 3, 2014 to April 8, 2015, Respondent SV Pharmacy compounded domperidone 10 mg, 20 mg, 30 mg, and 40 mg capsules and dispensed to patients approximately 393 domperidone prescriptions (42,060 capsules) which were compounded from domperidone.

b. From January 3, 2014 to April 8, 2015, Respondent David Matsuo, while working at Respondent SV Pharmacy, compounded domperidone 10 mg, 20 mg, 30 mg, and 40 mg capsultes and dispensed to patients approximately 28,913 capsules which were compounded from domperidone.

c. From January 3, 2014 to April 8, 2015, Respondent Vivian Matsuo, while working at Respondent SV Pharmacy, compounded domperidone 10 mg, 20 mg, 30 mg, and 40 mg capsules and dispensed to patients 7,877 capsules which were compounded from domperidone.

d. From January 3, 2014 to April 8, 2015, Respondent Foo, while working at Respondent SV Pharmacy, compounded domperidone 10 mg, 20 mg, 30 mg, and 40 mg capsules and dispensed to patients approximately 4,120 capsules which were compounded from domperidone.

e. From January 3, 2014 to April 8, 2015, Respondent Lee, while working at Respondent SV Pharmacy, compounded domperidone 10 mg, 20 mg, 30 mg, and 40 mg capsules and dispensed to patients approximately 1,150 capsules which were compounded from domperidone.

f. In each of these instances, the domperidone was misbranded because Respondents SV Pharmacy, David Matsuo, Vivian Matsuo, Foo, and Lee branded, labeled, or otherwise represented to patients that the drug was appropriate for consumption by humans when they knew or reasonably should that it is not appropriate for consumption by humans.

SECOND CAUSE FOR DISCIPLINE
(Failure to Exercise Professional Judgment)
(Bus. & Prof. Code § 4306.5, subd. (b))

26. Respondents David Matsuo and Vivian Matsuo have subjected their Pharmacist Licenses to disciplinary action for failing to exercise or implement their 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. (Bus. & Prof. Code § 4306.5, subd. (b)). In particular,

a. From January 3, 2014 to April 8, 2015, Respondent David Matsuo, while working at Respondent SV Pharmacy, compounded domperidone 10 mg, 20 mg, 30 mg, and 40 mg capsultes and dispensed to patients approximately 28,913 capsules which were compounded from domperidone.

b. From January 3, 2014 to April 8, 2015, Respondent Vivian Matsuo, while working at Respondent SV Pharmacy, compounded domperidone 10 mg, 20 mg, 30 mg, and 40 mg capsules and dispensed to patients 7,877 capsules which were compounded from domperidone.

c. In both instances, the bulk container of domperidone stated "Not for human use, not for use in food producing animals."

THIRD CAUSE FOR DISCIPLINE
(Failure to Maintain Compounding Equipment)
(Cal. Code Regs., title 16, § 1735.6, subd. (b))

27. Respondents SV Pharmacy, David Matsuo, Vivian Matsuo, and Foo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to store, use, and maintain equipment used to compound drug products in accordance with manufacturers' specifications. In particular, since 2010, SV Pharmacy, David Matsuo, Vivian Matsuo, and Foo used and maintained a powder hood to compound domperidone, and that

powder hood had not been certified according to manufacturer's guidelines or certified annually, as required by the manufacturer.

FOURTH CAUSE FOR DISCIPLINE
(Failure to Maintain Operational Standards)
(Cal. Code Regs., title 16, § 1714, subd. (c))

28. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to maintain the pharmacy and equipment in a clean and orderly condition. (Cal. Code Regs., title 16, § 1714, subd. (c)). In particular, during an inspection of Respondent SV Pharmacy on April 8, 2015, two balances located in the powder hood were discovered with a visible amount of powder residue and had not been cleaned. Respondent Vivian Matsuo, as the PIC, and Respondent David Matsuo, as a compounding pharmacist, should have made sure daily cleaning of the equipment was performed.

FIFTH CAUSE FOR DISCIPLINE
(Failure to Obtain Drugs from Reliable Suppliers, Acquire and Retain Certificates of Purity or Analysis)
(Cal. Code Regs., title 16, § 1735.3, subd. (c))

29. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to obtain chemicals, bulk drug substances, drug products, or compounds used to compound drug products from a reliable supplier and/or acquire and retain certificates of purity or analysis. (Cal. Code Regs., title 16, § 1735.3, subd. (c)). In particular, during an inspection of Respondent SV Pharmacy on April 8, 2015, a Board investigator found many bulk chemicals that had no certificate of analysis. Respondent Vivian Matsuo, as the PIC, and Respondent David Matsuo, as a compounding pharmacist, should have overseen the process and ensured each bulk chemical used in the process of compounding complied with the law.

SIXTH CAUSE FOR DISCIPLINE
(Failure to Dispense Using Compliant Patient-Centered Labels)
(Cal. Code Regs., title 16, § 1707.5, subd. (a)(1))

30. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for using non-compliant labels for drug containers dispensed to patients. (Cal. Code Regs., title 16, § 1707.5, subd. (a)(1)). In particular, during an inspection of Respondent SV Pharmacy on April 8, 2015, a Board investigator found the pharmacy's prescription labels were printed in approximately 10 point sans serif typeface, rather than 12 point as required by law. Respondent Vivian Matsuo, as the PIC, and Respondent David Matsuo, as a pharmacist, were responsible for making sure the prescription labels were compliant with the law.

SEVENTH CAUSE FOR DISCIPLINE
(Failure to Maintain Records of Compounded Drug Products – Identity of Pharmacist Reviewing Final Drug Product)
(Cal. Code Regs., title 16, § 1735.3, subd. (a)(4))

31. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to record the identity of the pharmacist reviewing final drug products. (Cal. Code Regs., title 16, § 1735.3, subd. (a)(4)). In particular, in the course of a Board investigation, it was discovered that the records for the following compounded drug products did not state the verifying final check by a pharmacist:

a. Domperidone 10 mg on July 31, 2012; June 25, 2013; and July 5, 2013.

b. Domperidone 20 mg on June 5, 2012; March 10, 2014; September 17, 2014; December 18, 2014; and April 2, 2015.

32. Respondent Vivian Matsuo, as the PIC, and Respondent David Matsuo, as a pharmacist, were responsible for ensuring this documentation was complete.

EIGHTH CAUSE FOR DISCIPLINE
(Failure to Maintain Records of Compounded Drug Products – Identity Personnel who Compounded Drug product)
(Cal. Code Regs., title 16, § 1735.3, subd. (a)(3))

33. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to record the identity of the pharmacy personnel who compounded drug products. (Cal. Code Regs., title 16, § 1735.3, subd. (a)(3)). In particular, in the course of a Board investigation, it was discovered that the records for the following compounded drug products did not state the identity of the personnel who compounded the drug product:

a. Domperidone 10 mg on March 20, 2015; December 18, 2013; November 29, 2013; June 30, 2010; August 10, 2011; December 22, 2011; November 9, 2011; December 20, 2010; and October 18, 2010.

b. Domperidone 20 mg on August 9, 2014; April 2, 2015; December 26, 2012; February 19, 2013; May 20, 2013; June 27, 2014; November 28, 2011; March 7, 2012; December 3, 2012; November 25, 2012; September 4, 2012; March 16, 2010; June 8, 2010; August 4, 2010; October 12, 2010; January 13, 2011; July 8, 2011; and October 5, 2011.

c. Domperidone 30 mg on April 2, 2015.

34. Respondent Vivian Matsuo, as the PIC, and Respondent David Matsuo, as a pharmacist, were responsible for ensuring this documentation was complete.

NINTH CAUSE FOR DISCIPLINE
(Failure to Maintain Records of Compounded Drug Products – Date Drug Product Compounded)
(Cal. Code Regs., title 16, § 1735.3, subd. (a)(2))

35. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to record the date a drug product was compounded. (Cal. Code Regs., title 16, § 1735.3, subd. (a)(2)). In particular, in reviewing the domperidone compounding records from January 5, 2010 to April 2, 2015, the following errors were discovered: February 6, 2014 was actually February 6, 2015; November 29, 2013 was actually November 29, 2012; and December 26, 2014 was

actually December 26, 2012. Respondent Vivian Matsuo, as the PIC, and Respondent David Matsuo, as a pharmacist, were responsible for ensuring this documentation was correct.

TENTH CAUSE FOR DISCIPLINE
(Failure to Maintain Records of Compounded Drug Products – Expiration Date)
(Cal. Code Regs., title 16, § 1735.3, subd. (a)(8))

36. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to record the expiration date of the final compounded drug product. (Cal. Code Regs., title 16, § 1735.3, subd. (a)(8)). In particular, in reviewing the domperidone compounding records from January 5, 2010 to April 2, 2015, a Board investigator discovered that, on seven of the compounding logs, the expiration date reads "6 months" instead of the actual expiration. In addition, two domperidone compounding logs do not state an expiration date. Respondent Vivian Matsuo, as the PIC, and Respondent David Matsuo, as a pharmacist, were responsible for ensuring this documentation was correct.

ELEVENTH CAUSE FOR DISCIPLINE
(Failure to Indicate Number of Drugs Prescribed)
(Cal. Code Regs., title 16, §§ 1717.3, subd. (b), and 1761, subd. (a))

37. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to indicate on a preprinted multiple check-off prescription blank the number of dangerous drugs he or she prescribed. (Cal. Code Regs., title 16, §§ 1717.3, subd. (b), and 1761, subd. (a)). In particular, during an investigation on April 8, 2015, a Board investigator discovered a preprinted check-off list prescription for a dangerous drug where the prescriber did not indicate on the blank the total number of dangerous drugs he or she has prescribed. This non-compliant prescription was accepted and dispensed by Respondent SV Pharmacy without clarification and correction. Respondent Vivian Matsuo, as the PIC, and Respondent David Matsuo, as a pharmacist, were responsible for ensuring this prescription was clarified and corrected.

TWELFTH CAUSE FOR DISCIPLINE
(Errors in Prescriptions)
(Cal. Code Regs., title 16, § 1761, subd. (a))

38. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for dispensing prescriptions containing a significant error, omission, irregularity, uncertainty, ambiguity or alteration. (Cal. Code Regs., title 16, § 1761, subd. (a)). In particular, a Board investigator discovered the following:

a. Prescription number 5013354 did not state which pharmacist received the refill authorization from the doctor's office.

b. In prescription number 5013424, two strengths of domperidone and three quantities to dispense are written on the face of the prescription and it lacks documentation of clarification by a pharmacist.

c. In prescription number 5013166, two quantities of domperidone to dispense are written on the face of the prescription and it lacks documentation of clarification by a pharmacist.

THIRTEENTH CAUSE FOR DISCIPLINE
(Unprofessional Conduct – Violation of the Law Governing Pharmacy)
(Bus. & Prof. Code § 4301, subd. (o); and Health and Safety Code §§ 111375, sub. (c), and 111400)

39. Respondents SV Pharmacy, David Matsuo, Vivian Matsuo, Foo, and Lee have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for unprofessional conduct by violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate applicable federal and state laws and regulations governing pharmacy. ((Bus. & Prof. Code § 4301, subd. (o); and Health and Safety Code §§ 111375, sub. (c)), and 111400)). The circumstances are set forth in paragraph 23 through paragraph 38.

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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 44228, issued to Respondent Silicon Valley Pharmacy;

2. Revoking or suspending Pharmacist License Number RPH 36383, issued to Respondent David S. Matsuo;

3. Revoking or suspending Pharmacist License Number RPH 36646, issued to Respondent Vivian Choi Matsuo;

4. Revoking or suspending Pharmacist License Number RPH 35288, issued to Respondent Anabella Sai-Yan Foo;

5. Revoking or suspending Pharmacist License Number RPH 39041, issued to Respondent Jennifer Hwa-Young Lee;

6. 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; and

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

DATED: 6/13/16

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

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