XAVIER BECERRA
Attorney General of California
ANTOINETTE CINCOTTA
Supervising Deputy Attorney General
MARICHELLE S. TAHIMIC
Deputy Attorney General
State Bar No. 147392
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 645-3154
Facsimile: (619) 645-2061
Attorneys for Complainant

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

In the Matter of the Accusation Against: **CHJ PHARMACARE INC. DBA CHJ PHARMACARE** **12841 Western Avenue, Ste. D** **Garden Grove, CA 92841** **Pharmacy Permit No. PHY 45334** **Sterile Compounding License No. LSC 99789** **and** **MATTHEW CHO** **23 Periwinkle** **Irvine, CA 92618** **Pharmacist License RPH 50771** Respondents.	Case No. 5531 **FIRST AMENDED** **ACCUSATION**

Complainant alleges:

PARTIES

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

///

2. On or about January 7, 2003, the Board of Pharmacy issued Pharmacy Permit Number PHY 45334 to CHJ Pharmacare Inc. dba CHJ Pharmacare (Respondent). The Pharmacy Permit expired on October 22, 2014, and was cancelled on January 2, 2015.

3. On or about October 23, 2013, the Board of Pharmacy issued Sterile Compounding License Number LSC 99789 to CHJ Pharmacare Inc. dba CHJ Pharmacare (Respondent). The Sterile Compounding License expired on October 22, 2014, and was cancelled on January 2, 2015.

4. On or about March 31, 1999, the Board of Pharmacy issued Pharmacist License Number RPH 50771 to Matthew Cho (Respondent Cho). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and expired on March 31, 2015, and has not been renewed. Respondent Cho was the Pharmacist-In-Charge ("PIC") of CHJ Pharmacare from July 6, 2013 to October 22, 2014.

JURISDICTION

5. 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.

6. Section 4300 of the Code states:

(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."

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 4022 of the Code states

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

(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."

9. Section 4076 of the Code states:

"(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

...

(8) The quantity of the drug or drugs dispensed.

...

10. Section 4077 of the Code states, in pertinent part, that except as provided in subdivisions (b) and (c) of this section, no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

11. Section 4081 of the Code states:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices 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. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate."

12. Section 4113, subdivision (c) of the Code states, "The 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."

13. 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 issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

...

(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.

...

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction

occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

...

(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.

...

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board. ...

14. Section 4332 of the Code states:

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

15. Health and Safety Code section 111295 states, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

16. Health and Safety Code section 111440 states, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

17. Title 16, California Code of Regulations ("CCR"), section 1709.1 states in part:

(a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.

(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.

...

///

18. Title 16, CCR, section 1718 states in part:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

...

19. Title 16, CCR, section 1735 states in part:

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

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a drug product from chemicals or bulk drug substances.

...

20. Title 16, CCR, section 1735.2 states in part:

...

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

...

21. Title 16, CCR, section 1735.3 states in part:

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

...

(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.

...

22. Title 16, CCR, section 1735.6, subdivision (b) states, "Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications."

23. Title 16, CCR, section 1751.4, subdivision (c) states, "All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected."

COST RECOVERY

24. 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

October 25, 2013 Inspection

25. On or about August 13, 2013, the Board received an anonymous complaint that alleged, among other things, that Respondents were getting medication from an unlicensed wholesaler in Mexico or Puerto Rico and reusing medication that came back to the pharmacy from boarding homes.

26. Board inspectors conducted an inspection of Respondent pharmacy on October 25, 2013. During the inspection, medication bottles on the pharmacy's shelves were found to contain more than the labeled quantity:

Medication	Labeled Quantity	Total counted
Seroquel 25 mg #1	100	383.5
Comptan 200 mg #1	100	185
Comptan 200 mg #2	100	123
Enablex ER 15 mg	30	95
Exelon 3 mg	60	99
Gabatril 4 mg	30	83.5

Exelon 6 mg	60	85
Prandin 2 mg	100	236

27. The Board inspectors asked to see invoices from the drug wholesalers used by Respondents. The inspectors were given access to Respondent's records, including a file containing invoices from Allied Medical Wholesaler ("Allied"). In the file folder were documents that purported to be packing lists from Allied for HIV drugs. Packing lists are typically computer generated and contain an invoice number and all the information contained on an invoice except for the purchase prices. The "packing lists" discovered by the Board inspector did not refer to an invoice number and had a handwritten date. Likewise, the inspector found a document identified as Invoice #721 from Allied dated July 8, 2013 for HIV drugs. The invoice did not resemble any of the other Allied invoices in the file. A representative of Allied confirmed that the packing lists were not from Allied and Invoice #721 was not generated by Allied. Moreover, none of the invoices from Allied matched the packing slips which were purportedly from Allied.

28. On or about October 9, 2014, Board inspectors requested all records of acquisition and disposition, including "Drug Utilization Reports" from January 1, 2013 to October 9, 2014 for the following HIV drugs:

a. Complera 200mg/25mg/300mg

b. Epzicom 600m/300mg

c. Truvada

d. Norvir 100mg

e. Atripla 600/200/300mg

f. Kaletra 200mg/50mg

g. Isentress 400mg

h. Prezista

i. Ziagen

29. On or about October 22, 2014, Respondent Cho provided his audit of the drugs identified in paragraph 29. Respondent Cho's audit showed that Respondents dispensed more of

the HIV drugs than Respondents had purchased. According to Respondent Cho's audit, Respondents could not account for:

a. 90 Complera

b. 60 Epzicom

c. 429 Truvada

d. 269 Norvir

e. 330 Atripla

f. 120 Isentress

g. 120 Prezista 600mg

h. 60 Prezista 800mg

i. 60 Ziagen

30. The Board inspector performed a selected drug audit, starting the audit at "zero" for initial inventory and "zero" for the "Stock on Hand" for the selected drugs and included the drugs on Invoice #721. The inspector's audit showed Respondents could not account for:

a. 90 Complera

b. 60 Epzicom

c. 369 Truvada

d. 209 Norvir

e. 300 Atripla

f. 120 Isentress

g. 30 Prezista 800mg

FIRST CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE AND MATTHEW CHO

(Unlawful Selling. Holding or Offering Misbranded Drugs for Sale)

31. Respondents are subject to disciplinary action under Code section 4301(o) for violating Health and Safety Code section 111440 in that Respondents sold, delivered, held or offered for sale medication in misbranded containers, as more fully set forth in paragraphs 26 – 27 above and incorporated by this reference as though set forth in full herein.

SECOND CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE AND MATTHEW CHO

(Failure to Maintain Records and Current Inventory)

32. Respondents are subject to disciplinary action under Code section 4301(j) for violating Code section 4081(a) in that Respondents failed to maintain records of sale, acquisition or disposition of dangerous drugs and failed to maintain a current inventory as defined in title 16, CCR, section 1718 as follows:

a. Respondents failed to maintain valid records of acquisition as demonstrated by the "Packing List" dated July 11, 2013 for the HIV drugs Atripla 600/200/30mg, Kaletra 200/50mg, and Isentress 400mg, as more fully set forth in paragraphs 26 – 31 above and incorporated by this reference as though set forth in full herein.

b. Respondents failed to maintain valid records of acquisition as demonstrated by the "Packing List" dated July 11, 2013 for the HIV drugs Complera 200/25/300mg, Epzicom 600/300mg, Truvada, and Norvir, as more fully set forth in paragraphs 26 – 31 above and incorporated by this reference as though set forth in full herein.

c. Respondents failed to maintain valid records of acquisition as demonstrated by Invoice #721, purportedly from Allied, dated July 8, 2013 for the HIV drugs Truvada, Norvir, Prezista 800mg, Prezista 600mg and Ziagen. Invoice #721 did not look like the other invoices from Allied and was refuted as being an invoice of Allied, as more fully set forth in paragraphs 26 – 31 above and incorporated by this reference as though set forth in full herein.

d. Respondents failed to have complete accountability for all dangerous drugs handled by them in that Respondents were not able to account for 90 Complera, 60 Epzicom, 429 Truvada, 269 Norvir, 330 Atripla, 120 Isentress, 120 Prezista 600mg, 60 Prezista 800mg, and 60 Ziagen, as more fully set forth in paragraph 29 above and incorporated by this reference as though set forth in full herein.

///

///

///

THIRD CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE AND MATTHEW CHO

(Violation of Law - Willful Production of False Records)

33. Respondents are subject to disciplinary action under Code section 4301(j) for violating Code section 4332 in that Respondents failed, neglected, or refused to maintain the records required by Section 4081 and who, when called upon by an authorized officer or a member of the board, willfully produced or furnished records that are false, as more fully set forth in paragraph 26 – 31 above and incorporated by this reference as though set forth in full herein.

FOURTH CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE AND MATTHEW CHO

(Unprofessional Conduct – Knowingly Making or Signing Any Document That Falsely Represents a State of Facts)

34. Respondents are subject to disciplinary action under Code section 4301(g) for unprofessional conduct in that Respondents knowingly made or signed a certificate or other document that falsely represents the existence or nonexistence of a state of facts in that Respondents made, furnished, or signed false records of acquisition from Allied Med Wholesale, as more fully set forth in paragraph 26 – 31 above and incorporated by this reference as though set forth in full herein.

FIFTH CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE AND MATTHEW CHO

(Unprofessional Conduct – Commission of Act Involving Dishonesty)

35. Respondents are subject to disciplinary action under Code section 4301(f) for unprofessional conduct in that Respondents committed acts involving dishonesty, fraud or deceit in that Respondent maintained and furnished to Board inspectors false acquisition records of dangerous drugs, as more fully set forth in paragraph 26 – 31 above and incorporated by this reference as though set forth in full herein.

///

///

SIXTH CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE AND MATTHEW CHO

(Unlawful Selling, Holding, or Offering for Sale Any Adulterated Drug)

36. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o), in conjunction with Health and Safety Code section 111295, for selling, delivering, holding or offering for sale any drug that is adulterated in that Respondents produced to the Board fraudulent records of acquisition of dangerous drugs, thereby putting into question the quality and purity of those drugs, as more fully set forth in paragraph 26 – 31 above and incorporated by this reference as though set forth in full herein.

July 17, 2014 Inspection

37. On March 30, 2014, the Board received another anonymous complaint regarding Respondents. The complaint alleged that compounded drugs were being dispensed without a pharmacist verification. The complaint also alleged that the unlicensed owner was entering the pharmacy without a pharmacist present, was placing dangerous drugs from unknown sources on the dispensing shelves, was mixing different batches of dangerous drugs to extend the expiration dates, among other things.

38. On July 17, 2014, Board inspectors conducted an inspection of Respondent Pharmacy. The inspection focused on Respondents' compounding areas and practices.

39. During the inspection, Board inspectors found documents bearing the names of other businesses such as CHJ Pharmacare Compouning, Triad Compounding Pharmacy, RxScript Compounding, Coastal Medical and Cosmetic Dermatology and Wish Western Institute for Sexual Health. The pharmacy's owner, Robert Weber, denied that Respondent pharmacy was compounding drugs for the private label of doctors' offices.

40. Inspection of the sterile compounding area, or "cleanroom" showed that:

a. the hood was not turned on;

b. there were non-sterile compounding components in the cleanroom;

c. the hood was certified as ISO Class 5 on June 23 2014 at rest;

d. the hood was in dis-repair;

e. there was no pressure differential between the cleanroom and the anteroom;

f. there was a gap between the door and door frame of the door between the cleanroom and anteroom;

g. there were items in the cleanroom that were not made of material that could be easily cleaned and disinfected such as a wooden stool;

h. the stir plate in the cleanroom was not clean;

i. there was a convection oven in the cleanroom that was for "Household Use Only" that was filled with glassware;

j. there was a caulking gun in the cleanroom;

k. there were opened, used vials;

l. there was a spiked and undated 1,000 ml bag of sterile water for injection hanging in the hood;

m. the ceiling tiles in the cleanroom were poorly sealed with caulking; and,

n. spackle, a porous and non-cleanable surface, was visible by the window between the cleanroom and anteroom.

41. Inspection of the general compounding area showed:

a. the ointment mill was greasy;

b. two ants were walking on the compounding counters;

c. there was a used ointment jar containing a small amount of white powder that was labeled progesterone mixer without a lot number or expiration date in the powder hood;

d. the wall behind the compounding counter was in disrepair and drywall spackle, a porous and non-cleanable surface, was visible.

42. In addition, the general compounding area had not been cleaned the night before the Board's inspection although the cleaning log indicated the compounding area had been cleaned.

43. A review of Respondents' compounding logs showed missing lot numbers and "beyond use dates" ("BUD") as follows:

///

///

Compound	Date Compounded	Lot Number	Item(s) missing Lot/BUD	Notes
HCG 1,000 units/ml Soln	7/2/14	7//2/14/5	HCG Buffered diluent solution	Missing lot and BUD
Cyclosporine 0.2% eye drop	7/3/14	7/3/14/13	Cyclosporine Opthalmic Emulsion Vehicle solution	Missing lot and BUD
Cyclosporine 1% eye drop	7/3/14	7/3/14/8	Cyclosporine 5% oil stock solution	Missing lot and BUD
Cyclosporine 1% eye drop	7/3/14	7/3/14/8	Cyclosporine Opthalmic Emulsion Vehicle solution	Missing lot and BUD
Cyclosporine 5% oil stock solution	7/3/14	7/3/14/14	Caprylic/Capric trg solution	Missing BUD
Cyclosporine 5% oil stock solution	7/3/14	7/3/14/14	Cyclosporine Pwd	Missing lot and BUD
Cyclosporine 5% oil stock solution	7/3/14	7/3/14/9	Caprylic/Capric trg solution	Missing BUD
Cyclosporine 5% oil stock solution	7/3/14	7/3/14/9	Cyclosporine Pwd	Missing lot and BUD
Cyclosporine 0.2% eye drop	7/9/14	7/9/14/6	Cyclosporine 5% oil stock solution	Missing lot and BUD
Cyclosporine 0.2% eye drop	7/9/14	7/9/14/6	Cyclosporine Opthalmic Emulsion Vehicle solution	Missing lot and BUD
Cyclosporine 5% oil stock solution	7/9/14	7/9/14/8	Caprylic/Capric trg solution	Missing lot and BUD
Cyclosporine 0.2% eye drop	7/14/14	7/14/14/14	Cyclosporine 5% oil stock solution	Missing lot and BUD
Cyclosporine 0.2% eye drop	7/14/14	7/14/14/14	Cyclosporine Opthalmic Emulsion Vehicle solution	Missing lot and BUD
Cyclosporine 1% eye drop	7/14/14	7/14/14/10	Cyclosporine Opthalmic Emulsion Vehicle solution	Missing lot and BUD
Cyclosporine 1% eye drop	7/14/14	7/14/14/10	Cyclosporine 5% oil stock solution	Missing lot and BUD
Cyclosporine 5% oil stock solution	7/14/14	7/14/14/15	Caprylic/Capric trg solution	Missing BUD
Cyclosporine 5% oil stock solution	7/14/14	7/14/14/12	Caprylic/Capric trg solution	Missing BUD
Cyclosporine 5% oil stock solution	7/14/14	7/14/14/12	Cyclosporine Pwd	Missing lot and BUD
HCG 1,000 units/ml Soln	7/14/14	7/14/14/17	HCG Buffered diluent solution	Missing lot and BUD
Cyclosporine 5% oil stock solution	7/16/14	7/16/14/4	Cyclosporine Pwd	Missing lot and BUD
Cyclosporine 5% oil stock solution	7/16/14	7/16/14/4	Caprylic/Capric trg solution	Missing BUD

44. Respondents extended the "beyond use date" of the following compounded drug products by exceeding 180 days from preparation of the compounded drugs or exceeding the shortest expiration date of any component in the compounded drug product as follows:

Compound	Date Compounded	Lot Number	First to Expire	Assigned BUD of Final Product
HQ/HC/Kojic acid/Retinoic Acid	11/12/13	11/12/13:3	BHT Lot: 80903/B Exp: 4/1/14	5/11/14
BLT topical	12/23/13	12/23/13:3	BHT Lot: 80903/B Exp: 4/1/14	6/21/14
BLT topical	12/23/13	12/23/13:3	Liposome Cream Lot: K1321F Exp: 4/1/14	6/21/14
HQ/HC/Kojic acid/Retinoic Acid	1/9/14	1/9/14;2	Vitamin E Lot: 81547/C Exp: 5/30/14	7/8/14
HQ/HC/Kojic acid/Retinoic Acid	1/9/14	1/9/14:2	BHT Lot: 80903/B Exp: 4/1/14	7/8/14
HQ/HC/Kojic acid/Retinoic Acid	1/9/14	1/9/14:2	Ascorbic acid Lot: 12190115 Exp: 5/28/14	7/8/14
HQ/HC/Kojic acid/Retinoic Acid	1/9/14	1/9/14:2	Versapro Gel Lot: 85517/C Exp: 4/14	7/8/14
HQ/HC/Kojic acid/Retinoic Acid	3/6/14	3/6/14/2	Vitamin E Lot: 81547/C Exp: 5/30/14	9/2/14
HQ/HC/Kojic acid/Retinoic Acid	3/6/14	3/6/14/2	BHT Lot: 80903/B Exp: 4/1/14	9/2/14
HQ/HC/Kojic acid/Retinoic Acid	3/6/14	3/6/14/2	Ascorbic acid Lot: 12190115 Exp: 5/28/14	9/2/14
HQ/HC/Kojic acid/Retinoic Acid	3/26/14	3/26/14/8	Vitamin E Lot: 81547/C Exp: 5/30/14	9/22/14
HQ/HC/Kojic acid/Retinoic Acid	3/26/14	3/26/14/8	Ascorbic acid Lot: 12190115 Exp: 5/28/14	9/22/14
HQ/HC/Kojic acid/Retinoic Acid	5/13/14	5/13/14/3	Vitamin E Lot: 81547/C Exp: 5/30/14	11/9/14
HQ/HC/Kojic acid/Retinoic Acid	5/13/14	5/13/14/3	Ascorbic acid Lot: 12190115 Exp: 5/28/14	11/9/14
HQ/HC/Kojic acid/Retinoic Acid	5/13/14	5/13/14/3	Sodium Metabisulfate Lot: 12100218 Exp: 10/12/14	11/9/14
Tri-mix 30/1/10	7/2/14	7/2/14/11	Alprostadil 500mcg/ml Lot: 1/24/14/3 BUD: 7/23/14	8/16/14
Nandrolone Deconoate 100mg/ml	7/8/14	7/8/14/7	Benzyl Benzoate Lot: 1303220089 Exp: 10/9/14	4/5/15
Nandrolone Deconoate 100mg/ml	7/8/14	7/8/14/7	Sesame oil Lot: 106624/A Exp: 10/14	4/5/15
HCG Buffered diluent solution	7/14/14	7/14/14/19	Benzyl Benzoate Lot: 1303220089 Exp: 10/9/14	10/12/14
Tri-mix 30/1/10	7/14/14	7/14/14/3	Alprostadil 500mcg/ml Lot: 1/24/14/3 BUD 7/23/14	8/28/14
Tri-mix 30/1/10	7/14/14	7/14/14/13	Alprostadil 500mcg/ml Lot: 1/24/14/3 BUD 7/23/14	8/28/14
Testosterone Cyp 250mg/ml	7/16/14	7/16/14/2	Benzyl Benzoate Lot: 1303220089 Exp: 10/9/14	10/14/14

Bi-testosterone 200mg/50mg	7/16/14	7/16/14/8	Benzyl Benzoate Lot: 1303220089 Exp: 10/9/14	10/14/14

SEVENTH CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE (PHY 45334 and LSC 99789)

AND MATTHEW CHO

(Unlawful Extension of a Beyond Use Date)

45. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with title 16, CCR, section 1735.2(h), for unlawfully extending the "beyond use date" of its compounded products from November 12, 2013 to July 16, 2014, as more fully set forth in paragraph 45 above and incorporated by this reference as though set forth in full herein.

EIGHTH CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE (PHY 45334 and LSC 99789)

AND MATTHEW CHO

(Failure to Keep Records of Compounded Products)

46. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with title 16, CCR, section 1735.3(a), for failing to record the manufacturer and/or lot number of components of its compounded drug products from November 12, 2013 to July 16, 2014, as more fully set forth in paragraph 44 above and incorporated by this reference as though set forth in full herein.

NINTH CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE (PHY 45334 and LSC 99789)

AND MATTHEW CHO

(Failure to Use Equipment According to Manufacturer's Specification)

47. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with title 16, CCR, section 1735..6(b), in that on July 17, 2014 during the Board's inspection, Respondents were using a convection oven specified by the manufacturer for

"household use" to sterilize glassware in the cleanroom, as more fully set forth in paragraphs 39 – 41 above and incorporated by this reference as though set forth in full herein.

TENTH CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE (PHY 45334 and LSC 99789)

AND MATTHEW CHO

(Failure to Have an Appropriate Cleanroom)

48. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with title 16, CCR, section 1751.4(c), in that on July 17, 2014 all equipment used in the cleanroom were not made of material that can be easily cleaned and disinfected. On July 17, 2014, there was a wooden chair in Respondents' cleanroom and there were porous areas on the walls of the cleanroom, as more fully set forth in paragraphs 39 – 43 above and incorporated by this reference as though set forth in full herein.

ELEVENTH CAUSE FOR DISCIPLINE

AS TO MATTHEW CHO ONLY

(October 5, 2015 Conviction of Conspiracy to Distribute Controlled Substances)

49. Respondent Cho is subject to disciplinary action under Code section 4301, subdivision (l), for conviction of a crime substantially related to the qualifications, functions, and duties of a pharmacist in that on October 5, 2015, in *United States of America v. Mike Mikaelian, et al.*, Unitied States District Court, Central District, Case No. CR 11-922-(a)-DDP, Respondent was convicted on his guilty plea, of conspiracy to distribute controlled substances, to wit, Oxycontin, in violation of title 21, U.S.C. section 846 and title 21, U.S.C., section 841(b)(1)(C), a felony.

50. As a result of the conviction, Respondent was sentenced to three years of supervised release, ordered to eight months home detention, pay a fine of $5,000.00, pay a special assessment of $100.00, and was ordered not to be employed in any position that requires licensing and/or certification by any local, state, or federal agency, without the prior written approval of the Probation Officer, among other terms.

///

DISCIPLINE CONSIDERATIONS

50. To determine the degree of discipline, if any, to be imposed on Respondent CHJ Pharmacare Inc. dba CHJ Pharmacare, Complainant alleges that on or about October 29, 2013, in a prior action, the Board of Pharmacy issued Citation Number CI 2012 54957 and ordered Respondent to pay a civil penalty in the amount of $4,500.00. That Citation is now final and is incorporated by reference as if fully set forth.

51. To determine the degree of discipline, if any, to be imposed on Respondent Cho, Complainant alleges that on or about September 7, 2010, in a prior action, the Board of Pharmacy issued Citation Number CI 2010 45616 and ordered Respondent Cho to pay a civil penalty in the amount of $375.00. That Citation is now final and is incorporated by reference as if fully set forth.

52. To determine the degree of discipline, if any, to be imposed on Respondent Cho, Complainant alleges that on or about December 28, 2010, in a prior action, the Board of Pharmacy issued Citation Number CI 2010 46839 and ordered Respondent Cho to pay a civil penalty in the amount of $500.00. That Citation is now final and is incorporated by reference as if fully set forth.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 45334, issued to CHJ Pharmacare Inc., dba CHJ Pharmacare;

2. Revoking or suspending Sterile Compunding License Number LSC 99789, issued to CHJ Pharmacare Inc., dba CHJ Pharmacare;

3. Revoking or suspending Pharmacist License Number RPH 50771 issued to Matthew Cho;

4. Ordering CHJ Pharmacare Inc. dba CHJ Pharmacare, jointly and severally, 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;

5. Ordering Matthew Cho, jointly and severally, 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,

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

DATED: 2/13/17

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

SD2015801655/81442878.doc

KAMALA D. HARRIS
Attorney General of California
JAMES M. LEDAKIS
Supervising Deputy Attorney General
MARICHELLE S. TAHIMIC
Deputy Attorney General
State Bar No. 147392
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 645-3154
Facsimile: (619) 645-2061
Attorneys for Complainant

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

In the Matter of the Accusation Against: **CHJ PHARMACARE INC. DBA CHJ PHARMACARE** **12841 Western Avenue, Ste. D** **Garden Grove, CA 92841** **Pharmacy Permit No. PHY 45334** **Sterile Compounding License No. LSC 99789** **and** **MATTHEW CHO** **23 Periwinkle** **Irvine, CA 92618** **Pharmacist License RPH 50771** Respondents.	Case No. 5531 **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 January 7, 2003, the Board of Pharmacy issued Pharmacy Permit Number PHY 45334 to CHJ Pharmacare Inc. dba CHJ Pharmacare (Respondent). The Pharmacy Permit expired on October 22, 2014, and was cancelled on January 2, 2015.

3. On or about October 23, 2013, the Board of Pharmacy issued Sterile Compounding License Number LSC 99789 to CHJ Pharmacare Inc. dba CHJ Pharmacare (Respondent). The Sterile Compounding License expired on October 22, 2014, and was cancelled on January 2, 2015.

4. On or about March 31, 1999, the Board of Pharmacy issued Pharmacist License Number RPH 50771 to Matthew Cho (Respondent Cho). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and expired on March 31, 2015, and has not been renewed. Respondent Cho was the Pharmacist-In-Charge ("PIC") of CHJ Pharmacare from July 6, 2013 to October 22, 2014.

JURISDICTION

5. 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.

6. Section 4300 of the Code states:

(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."

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 4022 of the Code states

> 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, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
>
> (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."

9. Section 4076 of the Code states:

"(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

...

(8) The quantity of the drug or drugs dispensed.

...

10. Section 4077 of the Code states, in pertinent part, that except as provided in subdivisions (b) and (c) of this section, no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

11. Section 4081 of the Code states:

> (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices 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. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer,

physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate."

12. Section 4113, subdivision (c) of the Code states, "The 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."

13. 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:

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

...

(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 by any other state or federal regulatory agency.

...

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board. ...

14. Section 4332 of the Code states:

> Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

15. Health and Safety Code section 111295 states, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

16. Health and Safety Code section 111440 states, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

17. Title 16, California Code of Regulations ("CCR"), section 1709.1 states in part:

> (a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.
>
> (b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.
>
> ...

18. Title 16, CCR, section 1718 states in part:

> "Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.
>
> ...

19. Title 16, CCR, section 1735 states in part:

> (a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
>
> (1) Altering the dosage form or delivery system of a drug
>
> (2) Altering the strength of a drug
>
> (3) Combining components or active ingredients
>
> (4) Preparing a drug product from chemicals or bulk drug substances.
>
> ...

///

///

///

20. Title 16, CCR, section 1735.2 states in part:

...

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

...

21. Title 16, CCR, section 1735.3 states in part:

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

...

(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.

...

22. Title 16, CCR, section 1735.6, subdivision (b) states, "Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications."

23. Title 16, CCR, section 1751.4, subdivision (c) states, "All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected."

COST RECOVERY

24. 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, with failure of the licentiate to comply subjecting the license to not being

renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

October 25, 2013 Inspection

25. On or about August 13, 2013, the Board received an anonymous complaint that alleged, among other things, that Respondents were getting medication from an unlicensed wholesaler in Mexico or Puerto Rico and reusing medication that came back to the pharmacy from boarding homes.

26. Board inspectors conducted an inspection of Respondent pharmacy on October 25, 2013. During the inspection, medication bottles on the pharmacy's shelves were found to contain more than the labeled quantity:

Medication	Labeled Quantity	Total counted
Seroquel 25 mg #1	100	383.5
Comptan 200 mg #1	100	185
Comptan 200 mg #2	100	123
Enablex ER 15 mg	30	95
Exelon 3 mg	60	99
Gabatril 4 mg	30	83.5
Exelon 6 mg	60	85
Prandin 2 mg	100	236

27. The Board inspectors asked to see invoices from the drug wholesalers used by Respondents. The inspectors were given access to Respondent's records, including a file containing invoices from Allied Medical Wholesaler ("Allied"). In the file folder were documents that purported to be packing lists from Allied for HIV drugs. Packing lists are typically computer generated and contain an invoice number and all the information contained on an invoice except for the purchase prices. The "packing lists" discovered by the Board inspector did not refer to an invoice number and had a handwritten date. Likewise, the inspector found a document identified as Invoice #721 from Allied dated July 8, 2013 for HIV drugs. The invoice did not resemble any of the other Allied invoices in the file. A representative of Allied confirmed that the packing lists were not from Allied and Invoice #721 was not generated by Allied. Moreover, none of the invoices from Allied matched the packing slips which were purportedly from Allied.

28. On or about October 9, 2014, Board inspectors requested all records of acquisition and disposition, including "Drug Utilization Reports" from January 1, 2013 to October 9, 2014 for the following HIV drugs:

a. Complera 200mg/25mg/300mg

b. Epzicom 600m/300mg

c. Truvada

d. Norvir 100mg

e. Atripla 600/200/300mg

f. Kaletra 200mg/50mg

g. Isentress 400mg

h. Prezista

i. Ziagen

29. On or about October 22, 2014, Respondent Cho provided his audit of the drugs identified in paragraph 29. Respondent Cho's audit showed that Respondents dispensed more of the HIV drugs than Respondents had purchased. According to Respondent Cho's audit, Respondents could not account for:

a. 90 Complera

b. 60 Epzicom

c. 429 Truvada

d. 269 Norvir

e. 330 Atripla

f. 120 Isentress

g. 120 Prezista 600mg

h. 60 Prezista 800mg

i. 60 Ziagen

30. The Board inspector performed a selected drug audit, starting the audit at "zero" for initial inventory and "zero" for the "Stock on Hand" for the selected drugs and included the drugs on Invoice #721. The inspector's audit showed Respondents could not account for:

a. 90 Complera

b. 60 Epzicom

c. 369 Truvada

d. 209 Norvir

e. 300 Atripla

f. 120 Isentress

g. 30 Prezista 800mg

FIRST CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE AND MATTHEW CHO

(Unlawful Selling, Holding or Offering Misbranded Drugs for Sale)

31. Respondents are subject to disciplinary action under Code section 4301(o) for violating Health and Safety Code section 111440 in that Respondents sold, delivered, held or offered for sale medication in misbranded containers, as more fully set forth in paragraphs 25 – 26 above and incorporated by this reference as though set forth in full herein.

SECOND CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE AND MATTHEW CHO

(Failure to Maintain Records and Current Inventory)

32. Respondents are subject to disciplinary action under Code section 4301(j) for violating Code section 4081(a) in that Respondents failed to maintain records of sale, acquisition or disposition of dangerous drugs and failed to maintain a current inventory as defined in title 16, CCR, section 1718 as follows:

a. Respondents failed to maintain valid records of acquisition as demonstrated by the "Packing List" dated July 11, 2013 for the HIV drugs Atripla 600/200/30mg, Kaletra 200/50mg, and Isentress 400mg, as more fully set forth in paragraphs 25 – 30 above and incorporated by this reference as though set forth in full herein.

b. Respondents failed to maintain valid records of acquisition as demonstrated by the "Packing List" dated July 11, 2013 for the HIV drugs Complera 200/25/300mg, Epzicom

600/300mg, Truvada, and Norvir, as more fully set forth in paragraphs 25 – 30 above and incorporated by this reference as though set forth in full herein.

c. Respondents failed to maintain valid records of acquisition as demonstrated by Invoice #721, purportedly from Allied, dated July 8, 2013 for the HIV drugs Truvada, Norvir, Prezista 800mg, Prezista 600mg and Ziagen. Invoice #721 did not look like the other invoices from Allied and was refuted as being an invoice of Allied, as more fully set forth in paragraphs 25 – 30 above and incorporated by this reference as though set forth in full herein.

d. Respondents failed to have complete accountability for all dangerous drugs handled by them in that Respondents were not able to account for 90 Complera, 60 Epzicom, 429 Truvada, 269 Norvir, 330 Atripla, 120 Isentress, 120 Prezista 600mg, 60 Prezista 800mg, and 60 Ziagen, as more fully set forth in paragraph 28 above and incorporated by this reference as though set forth in full herein.

THIRD CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE AND MATTHEW CHO

(Violation of Law - Willful Production of False Records)

33. Respondents are subject to disciplinary action under Code section 4301(j) for violating Code section 4332 in that Respondents failed, neglected, or refused to maintain the records required by Section 4081 and who, when called upon by an authorized officer or a member of the board, willfully produced or furnished records that are false, as more fully set forth in paragraph 25 – 30 above and incorporated by this reference as though set forth in full herein.

FOURTH CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE AND MATTHEW CHO

(Unprofessional Conduct – Knowingly Making or Signing Any Document That Falsely Represents a State of Facts)

34. Respondents are subject to disciplinary action under Code section 4301(g) for unprofessional conduct in that Respondents knowingly made or signed a certificate or other document that falsely represents the existence or nonexistence of a state of facts in that Respondents made, furnished, or signed false records of acquisition from Allied Med Wholesale,

as more fully set forth in paragraph 25 – 30 above and incorporated by this reference as though set forth in full herein.

FIFTH CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE AND MATTHEW CHO

(Unprofessional Conduct – Commission of Act Involving Dishonesty)

35. Respondents are subject to disciplinary action under Code section 4301(f) for unprofessional conduct in that Respondents committed acts involving dishonesty, fraud or deceit in that Respondent maintained and furnished to Board inspectors false acquisition records of dangerous drugs, as more fully set forth in paragraph 25 – 30 above and incorporated by this reference as though set forth in full herein.

SIXTH CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE AND MATTHEW CHO

(Unlawful Selling, Holding, or Offering for Sale Any Adulterated Drug)

36. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o), in conjunction with Health and Safety Code section 111295, for selling, delivering, holding or offering for sale any drug that is adulterated in that Respondents produced to the Board fraudulent records of acquisition of dangerous drugs, thereby putting into question the quality and purity of those drugs, as more fully set forth in paragraph 25 – 30 above and incorporated by this reference as though set forth in full herein.

July 17, 2014 Inspection

37. On March 30, 2014, the Board received another anonymous complaint regarding Respondents. The complaint alleged that compounded drugs were being dispensed without a pharmacist verification. The complaint also alleged that the unlicensed owner was entering the pharmacy without a pharmacist present, was placing dangerous drugs from unknown sources on the dispensing shelves, was mixing different batches of dangerous drugs to extend the expiration dates, among other things.

38. On July 17, 2014, Board inspectors conducted an inspection of Respondent Pharmacy. The inspection focused on Respondents' compounding areas and practices.

39. During the inspection, Board inspectors found documents bearing the names of other businesses such as CHJ Pharmacare Compouning, Triad Compounding Pharmacy, RxScript Compounding, Coastal Medical and Cosmetic Dermatology and Wish Western Institute for Sexual Health. The pharmacy's owner, Robert Weber, denied that Respondent pharmacy was compounding drugs for the private label of doctors' offices.

40. Inspection of the sterile compounding area, or "cleanroom" showed that:

a. the hood was not turned on;

b. there were non-sterile compounding components in the cleanroom;

c. the hood was certified as ISO Class 5 on June 23 2014 at rest;

d. the hood was in dis-repair;

e. there was no pressure differential between the cleanroom and the anteroom;

f. there was a gap between the door and door frame of the door between the cleanroom and anteroom;

g. there were items in the cleanroom that were not made of material that could be easily cleaned and disinfected such as a wooden stool;

h. the stir plate in the cleanroom was not clean;

i. there was a convection oven in the cleanroom that was for "Household Use Only" that was filled with glassware;

j. there was a caulking gun in the cleanroom;

k. there were opened, used vials;

l. there was a spiked and undated 1,000 ml bag of sterile water for injection hanging in the hood;

m. the ceiling tiles in the cleanroom were poorly sealed with caulking; and,

n. spackle, a porous and non-cleanable surface, was visible by the window between the cleanroom and anteroom.

41. Inspection of the general compounding area showed:

a. the ointment mill was greasy;

b. two ants were walking on the compounding counters;

c. there was a used ointment jar containing a small amount of white powder that was labeled progesterone mixer without a lot number or expiration date in the powder hood;

d. the wall behind the compounding counter was in disrepair and drywall spackle, a porous and non-cleanable surface, was visible.

42. In addition, the general compounding area had not been cleaned the night before the Board's inspection although the cleaning log indicated the compounding area had been cleaned.

43. A review of Respondents' compounding logs showed missing lot numbers and "beyond use dates" ("BUD") as follows:

Compound	Date Compounded	Lot Number	Item(s) missing Lot/BUD	Notes
HCG 1,000 units/ml Soln	7/2/14	7//2/14/5	HCG Buffered diluent solution	Missing lot and BUD
Cyclosporine 0.2% eye drop	7/3/14	7/3/14/13	Cyclosporine Opthalmic Emulsion Vehicle solution	Missing lot and BUD
Cyclosporine 1% eye drop	7/3/14	7/3/14/8	Cyclosporine 5% oil stock solution	Missing lot and BUD
Cyclosporine 1% eye drop	7/3/14	7/3/14/8	Cyclosporine Opthalmic Emulsion Vehicle solution	Missing lot and BUD
Cyclosporine 5% oil stock solution	7/3/14	7/3/14/14	Caprylic/Capric trg solution	Missing BUD
Cyclosporine 5% oil stock solution	7/3/14	7/3/14/14	Cyclosporine Pwd	Missing lot and BUD
Cyclosporine 5% oil stock solution	7/3/14	7/3/14/9	Caprylic/Capric trg solution	Missing BUD
Cyclosporine 5% oil stock solution	7/3/14	7/3/14/9	Cyclosporine Pwd	Missing lot and BUD
Cyclosporine 0.2% eye drop	7/9/14	7/9/14/6	Cyclosporine 5% oil stock solution	Missing lot and BUD
Cyclosporine 0.2% eye drop	7/9/14	7/9/14/6	Cyclosporine Opthalmic Emulsion Vehicle solution	Missing lot and BUD
Cyclosporine 5% oil stock solution	7/9/14	7/9/14/8	Caprylic/Capric trg solution	Missing lot and BUD
Cyclosporine 0.2% eye drop	7/14/14	7/14/14/14	Cyclosporine 5% oil stock solution	Missing lot and BUD
Cyclosporine 0.2% eye drop	7/14/14	7/14/14/14	Cyclosporine Opthalmic Emulsion Vehicle solution	Missing lot and BUD
Cyclosporine 1% eye drop	7/14/14	7/14/14/10	Cyclosporine Opthalmic Emulsion Vehicle solution	Missing lot and BUD
Cyclosporine 1% eye drop	7/14/14	7/14/14/10	Cyclosporine 5% oil stock solution	Missing lot and BUD
Cyclosporine 5% oil stock solution	7/14/14	7/14/14/15	Caprylic/Capric trg solution	Missing BUD

Cyclosporine 5% oil stock solution	7/14/14	7/14/14/12	Caprylic/Capric trg solution	Missing BUD
Cyclosporine 5% oil stock solution	7/14/14	7/14/14/12	Cyclosporine Pwd	Missing lot and BUD
HCG 1,000 units/ml Soln	7/14/14	7/14/14/17	HCG Buffered diluent solution	Missing lot and BUD
Cyclosporine 5% oil stock solution	7/16/14	7/16/14/4	Cyclosporine Pwd	Missing lot and BUD
Cyclosporine 5% oil stock solution	7/16/14	7/16/14/4	Caprylic/Capric trg solution	Missing BUD

44. Respondents extended the "beyond use date" of the following compounded drug products by exceeding 180 days from preparation of the compounded drugs or exceeding the shortest expiration date of any component in the compounded drug product as follows:

Compound	Date Compounded	Lot Number	First to Expire	Assigned BUD of Final Product
HQ/HC/Kojic acid/Retinoic Acid	11/12/13	11/12/13:3	BHT Lot: 80903/B Exp: 4/1/14	5/11/14
BLT topical	12/23/13	12/23/13:3	BHT Lot: 80903/B Exp: 4/1/14	6/21/14
BLT topical	12/23/13	12/23/13:3	Liposome Cream Lot: K1321F Exp: 4/1/14	6/21/14
HQ/HC/Kojic acid/Retinoic Acid	1/9/14	1/9/14;2	Vitamin E Lot: 81547/C Exp: 5/30/14	7/8/14
HQ/HC/Kojic acid/Retinoic Acid	1/9/14	1/9/14:2	BHT Lot: 80903/B Exp: 4/1/14	7/8/14
HQ/HC/Kojic acid/Retinoic Acid	1/9/14	1/9/14:2	Ascorbic acid Lot: 12190115 Exp: 5/28/14	7/8/14
HQ/HC/Kojic acid/Retinoic Acid	1/9/14	1/9/14:2	Versapro Gel Lot: 85517/C Exp: 4/14	7/8/14
HQ/HC/Kojic acid/Retinoic Acid	3/6/14	3/6/14/2	Vitamin E Lot: 81547/C Exp: 5/30/14	9/2/14
HQ/HC/Kojic acid/Retinoic Acid	3/6/14	3/6/14/2	BHT Lot: 80903/B Exp: 4/1/14	9/2/14
HQ/HC/Kojic acid/Retinoic Acid	3/6/14	3/6/14/2	Ascorbic acid Lot: 12190115 Exp: 5/28/14	9/2/14
HQ/HC/Kojic acid/Retinoic Acid	3/26/14	3/26/14/8	Vitamin E Lot: 81547/C Exp: 5/30/14	9/22/14
HQ/HC/Kojic acid/Retinoic Acid	3/26/14	3/26/14/8	Ascorbic acid Lot: 12190115 Exp: 5/28/14	9/22/14
HQ/HC/Kojic acid/Retinoic Acid	5/13/14	5/13/14/3	Vitamin E Lot: 81547/C Exp: 5/30/14	11/9/14
HQ/HC/Kojic acid/Retinoic Acid	5/13/14	5/13/14/3	Ascorbic acid Lot: 12190115 Exp: 5/28/14	11/9/14
HQ/HC/Kojic acid/Retinoic Acid	5/13/14	5/13/14/3	Sodium Metabisulfate Lot: 12100218 Exp: 10/12/14	11/9/14

Tri-mix 30/1/10	7/2/14	7/2/14/11	Alprostadil 500mcg/ml Lot: 1/24/14/3 BUD: 7/23/14	8/16/14
Nandrolone Deconoate 100mg/ml	7/8/14	7/8/14/7	Benzyl Benzoate Lot: 1303220089 Exp: 10/9/14	4/5/15
Nandrolone Deconoate 100mg/ml	7/8/14	7/8/14/7	Sesame oil Lot: 106624/A Exp: 10/14	4/5/15
HCG Buffered diluent solution	7/14/14	7/14/14/19	Benzyl Benzoate Lot: 1303220089 Exp: 10/9/14	10/12/14
Tri-mix 30/1/10	7/14/14	7/14/14/3	Alprostadil 500mcg/ml Lot: 1/24/14/3 BUD 7/23/14	8/28/14
Tri-mix 30/1/10	7/14/14	7/14/14/13	Alprostadil 500mcg/ml Lot: 1/24/14/3 BUD 7/23/14	8/28/14
Testosterone Cyp 250mg/ml	7/16/14	7/16/14/2	Benzyl Benzoate Lot: 1303220089 Exp: 10/9/14	10/14/14
Bi-testosterone 200mg/50mg	7/16/14	7/16/14/8	Benzyl Benzoate Lot: 1303220089 Exp: 10/9/14	10/14/14

SEVENTH CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE (PHY 45334 and LSC 99789)

AND MATTHEW CHO

(Unlawful Extension of a Beyond Use Date)

45. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with title 16, CCR, section 1735.2(h), for unlawfully extending the "beyond use date" of its compounded products from November 12, 2013 to July 16, 2014, as more fully set forth in paragraph 44 above and incorporated by this reference as though set forth in full herein.

EIGHTH CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE (PHY 45334 and LSC 99789)

AND MATTHEW CHO

(Failure to Keep Records of Compounded Products)

46. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with title 16, CCR, section 1735.3(a), for failing to record the manufacturer and/or lot number of components of its compounded drug products from November 12, 2013 to July 16, 2014, as more fully set forth in paragraph 43 above and incorporated by this reference as though set forth in full herein.

NINTH CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE (PHY 45334 and LSC 99789)

AND MATTHEW CHO

(Failure to Use Equipment According to Manufacturer's Specification)

47. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with title 16, CCR, section 1735..6(b), in that on July 17, 2014 during the Board's inspection, Respondents were using a convection oven specified by the manufacturer for "household use" to sterilize glassware in the cleanroom, as more fully set forth in paragraphs 38 – 40 above and incorporated by this reference as though set forth in full herein.

TENTH CAUSE FOR DISCIPLINE

AS TO CHJ PHARMACARE (PHY 45334 and LSC 99789)

AND MATTHEW CHO

(Failure to Have an Appropriate Cleanroom)

48. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with title 16, CCR, section 1751.4(c), in that on July 17, 2014 all equipment used in the cleanroom were not made of material that can be easily cleaned and disinfected. On July 17, 2014, there was a wooden chair in Respondents' cleanroom and there were porous areas on the walls of the cleanroom, as more fully set forth in paragraphs 38 – 42 above and incorporated by this reference as though set forth in full herein.

DISCIPLINE CONSIDERATIONS

49. To determine the degree of discipline, if any, to be imposed on Respondent CHJ Pharmacare Inc. dba CHJ Pharmacare, Complainant alleges that on or about October 29, 2013, in a prior action, the Board of Pharmacy issued Citation Number CI 2012 54957 and ordered Respondent to pay a civil penalty in the amount of $4,500.00. That Citation is now final and is incorporated by reference as if fully set forth.

50. To determine the degree of discipline, if any, to be imposed on Respondent Cho, Complainant alleges that on or about September 7, 2010, in a prior action, the Board of Pharmacy issued Citation Number CI 2010 45616 and ordered Respondent Cho to pay a civil penalty in the

amount of $375.00. That Citation is now final and is incorporated by reference as if fully set forth.

51. To determine the degree of discipline, if any, to be imposed on Respondent Cho, Complainant alleges that on or about December 28, 2010, in a prior action, the Board of Pharmacy issued Citation Number CI 2010 46839 and ordered Respondent Cho to pay a civil penalty in the amount of $500.00. That Citation is now final and is incorporated by reference as if fully set forth.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 45334, issued to CHJ Pharmacare Inc., dba CHJ Pharmacare.

2. Revoking or suspending Sterile Compunding License Number LSC 99789, issued to CHJ Pharmacare Inc., dba CHJ Pharmacare;

3. Revoking or suspending Pharmacist License Number RPH 50771 issued to Matthew Cho;

4. Ordering CHJ Pharmacare Inc. dba CHJ Pharmacare, jointly and severally, 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;

5. Ordering Matthew Cho, jointly and severally, 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,

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

DATED: 7/19/16

Virginia Herold

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

SD2015801655/81147027.doc