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

In the Matter of the Second Amended Accusation Against: **OPTIMAL PHARMACIES INC. dba KOMOTO CUSTOM CARE PHARMACY (formerly Optimal Compounding Pharmacy); BRIAN K. KOMOTO, President; MARY KOMOTO, Secretary; PATRICK NELSON LEROY, PHARMACIST-IN-CHARGE (from July 5, 2007 to November 10, 2014), KIRK FORREST SAKAMOTO, PHARMACIST-IN-CHARGE(from November 10, 2014 to Present)** **2110 Truxtun Avenue, Suite #300** **Bakersfield, CA 93301** **Original Pharmacy Permit No. PHY 46042** **Licensed Sterile Compounding License No. LSC 99071** **BRIAN K. KOMOTO** **1017 Ellington Street** **Delano, CA 93215** **Original Pharmacist License No. RPH 36353** **PATRICK NELSON LEROY** **2110 Truxtun Avenue, Suite #300** **Bakersfield, CA 93301** **Original Pharmacist License No. RPH 58396** **and**	Case No. 4642 **SECOND AMENDED ACCUSATION**

KIRK FORREST SAKAMOTO
1017 Ellington Street
Delano, CA 93215
Original Pharmacist License No. RPH 35651

Respondents.

Complainant alleges:

PARTIES

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

Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy

Original Pharmacy Permit

2. On or about September 12, 2002, the Board of Pharmacy issued Pharmacy Permit Number PHY 46042 to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy (Respondent Pharmacy) with Brian K. Komoto as President, Mary Komoto as Secretary and Patrick Nelson Leroy as Pharmacist-in-Charge. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2017, unless renewed.

Licensed Sterile Compounding License

3. On or about July 1, 2003, the Board of Pharmacy issued Licensed Sterile Compounding License Number 99071 to Respondent Pharmacy with Brian K. Komoto as President, Mary Komoto as Secretary and Patrick Nelson Leroy as Pharmacist-in-Charge. The Licensed Sterile Compounding License expired on September 1, 2016, and has not been renewed.

Brian K. Komoto

Original Pharmacist License

4. On or about August 13, 1981, the Board of Pharmacy issued Original Pharmacist License Number RPH 36353 to Brian K. Komoto (Respondent Komoto). The Original Pharmacist License was in full force and effect at all times relevant herein and will expire on July 31, 2017, unless renewed.

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Patrick Nelson Leroy

Original Pharmacist License

5. On or about July 26, 2006, the Board of Pharmacy issued Original Pharmacist License Number RPH 58396 to Patrick Nelson Leroy (Respondent Leroy). The Original Pharmacist License was in full force and effect at all times relevant herein and will expire on June 30, 2018, unless renewed.

Kirk Forrest Sakamoto

Original Pharmacist License

6. On or about June 8, 2004, the Board of Pharmacy issued Original Pharmacist License Number RPH 35651 to Kirk Forrest Sakamoto (Respondent Sakamoto). The Original Pharmacist License was in full force and effect at all times relevant herein and will expire on June 30, 2018, unless renewed.

JURISDICTION

7. This Second Amended 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), of the Code provides that the suspension/expiration/surrender/cancellation of a license shall not deprive the Board/Registrar/Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

9. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

10. Section 4300(a) of the Code states that every license issued by the Board may be suspended or revoked.

11. 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 PROVISIONS

12. Section 4033, subdivision (a)(1) of the Code states:

"Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."

13. Section 4043, subdivision (a) of the Code states:

"Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board."

14. Section 4301 of the Code states:

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

. . . .

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

"(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

. . . .

"(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 4307, subdivision (a) of the Code states:

"Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follow:

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

"(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated."

16. Section 11170 of Article 1 of the California Health and Safety Code states:

"No person shall prescribe, administer, or furnish a controlled substance for himself."

REGULATORY PROVISIONS

17. California Code of Regulations, title 16, section 1712 states:

"(a) Any requirement in this division for a pharmacist to initial or sign a prescription record or prescription label can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means. The computer used to record the reviewing pharmacist's identity shall not permit such a record to be altered after it is made.

"(b) The record of the reviewing pharmacist's identity made in a computer system pursuant to subdivision (a) of this section shall be immediately retrievable in the pharmacy."

18. California Code of Regulations, title 16, section 1717, subdivision (c) states, in pertinent part:

"Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in section 4019 of the Business and Professions Code are not subject to the provisions of this subsection."

19. California Code of Regulations, title 16, section 1735, states:

"(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

"(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

"(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

"(d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.)."

20. California Code of Regulations, title 16, section 1735.2 states, in pertinent part:

"(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved

use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

"...

"(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. California Code of Regulations, title 16, section 1735.5, states:

"(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

"(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

"(c) The policy and procedure manual shall include the following

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

"(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

"(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

"(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

"(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products."

22. California Code of Regulations, title 16, section 1751.2, subdivision (b) states, in pertinent part:

"Name and concentrations of ingredients contained in the sterile injectable product."

23. California Code of Regulations, title 16, section 1751.7, states:

"(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(1) Cleaning and sanitization of the parenteral medication preparation area.

(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

(3) Actions to be taken in the event of a drug recall.

(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

"(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples

must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented."

"(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens."

"...."

24. California Code of Regulations, title 16, section 1751.6, subdivision (e) states, in pertinent part:

"...

"(e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:

"(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

"(A) Aseptic technique.

"(B) Pharmaceutical calculations and terminology.

"(C) Sterile product compounding documentation.

"(D) Quality assurance procedures.

"(E) Aseptic preparation procedures.

"(F) Proper gowning and gloving technique.

"(G) General conduct in he controlled area.

"(H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.

"(I) Sterilization techniques.

"(J) Container, equipment, and closure system selection.

"(2) Each person assigned to the controlled area must successfully complete practical skills training in aspetic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aspetic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years."

"...."

COST RECOVERY

25. 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.

FIRST CAUSE FOR DISCIPLINE

(Acting as a Manufacturer Without a Permit)

As to Respondent Pharmacy and Leroy

26. Respondent Pharmacy and Leroy are subject to disciplinary action under section Code section 4301, subdivisions (j) and (o) for violating Code section 4033, subdivision (a)(1) in that Respondent Pharmacy and Leroy were acting as a manufacturer without a permit. The circumstances are as follows:

27. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed a large quantities of compounded medications prepared for non-patient specific orders that were being stocked for sale

to veterinarians, veterinarian clinics and doctors' offices. Respondent Pharmacy and Leroy do not hold a manufacturing permit.

28. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondents produced sterile compounded products for resale by "Systems North" identified as Integrated Care Systems. These compounded sterile injectable products were not sold to the ultimate consumer. Respondent Pharmacy and Leroy do not hold a manufacturing permit. Below are examples of the products compounded for resale from on or about September 4, 2013 to October 29, 2013:

Date	Rx number	Medication	Quantity	Dispensed to
9/4/2013	00661294	Calcium gluconate solution	22500	Systems North
9/4/2013	00660842	Sodium phosphates 3mmol/4meq	4500	Systems North
9/9/2013	N0686347	Morphine sulfate 50mg/ml	1000	Systems North
9/16/2013	00687130	Calcium gluconate solution	30000	Systems North
9/16/2013	00665533	Potassium phosphates 4.4meq	500	Systems North
9/16/2013	00664210	Magnesium Sulfate 500mg/ml	4500	Systems North
9/16/2013	00660642	Sodium phosphates 3mmol/4meqml	4500	Systems North
9/30/2013	N00688800	Morphine sulfate 50mg/ml	1500	Systems North
10/2/2013	00660842	Sodium phosphates 3mmol/4meqml	4500	Systems North
10/2/2013	00660842	Magnesium sulfate 500mg/ml	4500	Systems North
10/2/2013	00661294	Calcium gluconate solution	22500	Systems North
10/21/2013	00661294	Calcium gluconate solution	15000	Systems North
10/29/2013	00661294	Calcium gluconate solution	37500	Systems North
10/29/2013	00660642	Sodium phosphates 3mmol/4meq/ml	4500	Systems North
10/29/2013	00664210	Magnesium sulfate 500mg/ml	1000	Systems North

SECOND CAUSE FOR DISCIPLINE

(Acting as a Wholesaler Without a Permit)

29. Respondent Pharmacy and Leroy are subject to disciplinary action under Code section 4301, subdivisions (j) and (o) for violating Code section 4043, subdivision (a) in that Respondent Pharmacy and Leroy were acting as a wholesaler without a permit. The circumstances are as follows:

30. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed during the time period of July 5, 2010 and July 9, 2010, 375 prescriptions were processed by Respondent Pharmacy and Leroy of which 110 were provided to veterinarians, veterinarian clinics and a pharmacy to use for non-specific patients. Respondent's Pharmacy and Leroy do not hold a wholesaler permit.

31. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondents had dispensing records from on or about September 1, 2013 through September 12, 2014 which showed only 7% of prescriptions were compounded and dispensed for individual patients. Ninety-three percent of prescriptions compounded and dispensed were provided to other pharmacies, prescriber offices, clinics, hospitals, animal parks, and farms. Respondents conducted business as a wholesaler and did not have a wholesaler permit.

THIRD CAUSE FOR DISCIPLINE

(Pharmacy Practice-Orally transmitted Prescriptions)

32. Respondent Pharmacy and Leroy are subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1717, subdivision (c) in that Respondents failed to reduce an orally transmitted prescription to writing. The circumstances are as follows:

33. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that between July 9, 2010 and July 12, 2010, prescriptions numbers 582720, 582721 and 582760 were transcribed by someone other than a pharmacist.

FOURTH CAUSE FOR DISCIPLINE

(Labeling Requirements for Injectable Products)

34. Respondent Pharmacy and Leroy are subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1751.2, subdivision (b) in that Respondents failed to include the ingredients used in the sterile injectable product on the labels. The circumstances are as follows:

35. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondent Pharmacy and Leroy failed to have all of the ingredients used in lots numbers 03192010@7, 04302010@5, 06102010@22 and 06182010@8 included on the labels.

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FIFTH CAUSE FOR DISCIPLINE

(Compounding for Future Use-Beyond Use Dates)

36. Respondent Pharmacy and Leroy are subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1735.2, subdivision (h) in that Respondents failed to give an expiration date representing the date beyond that it should not be used. The circumstances are as follows:

37. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondents allowed compounded products lot numbers 03192010@7, 04302010@5, 06092010@24, 06102010@22, 06182010@8, 07012010@15, 07082010@29, 07092010@24, 07092010@25, 07122010@27, 07122010@31, 07122010@33, 07132010@1, 07132010@2, 07132010@6, 07132010@8, 07132010@9, 07132010@11, 07132010@13, 07132010@15, 07132010@21, 07132010@22, 07132010@23, 07132010@24, 07132010@25, 07132010@26, 07132010@27, and 07132010@32, to be assigned beyond use dates exceeding the expiration date of one or more ingredients.

Lot number	Ingredient	Expiration date of raw ingredient	Assigned beyond use date of completed compound	Beyond use date on master formula if available	Pharmacist
03192010@7	nandrolone decanoate pwdr	09/26/2009	09/15/2010	06/17/2010	Patrick Leroy
	sesame oil	06/12/2010	09/15/2010	06/17/2010	Patrick Leroy
04302010@5	benzyl benzoate USP	09/30/2010	10/27/2010	07/29/2010	Mike Adam Urmston
	sesame oil	06/12/2010	10/27/2010	07/29/2010	Mike Adam Urmston
06092010@24	povidone USP	10/02/2010	12/06/2010		Patrick Leroy
	methylparaben NF	07/06/2010	12/06/2010		Patrick Leroy
	propylparaben NF	07/31/2010	12/06/2010		Patrick Leroy
06102010@22	benzalkonium chloride 5% liquid	12/16/2008	12/07/2010	09/08/2010	Patrick Leroy
	sodium phosphate dried	04/30/2010	12/07/2010	09/08/2010	Patrick

	dibasic pwdr USP				Leroy
06182010@8	Yohimbine hydrochloride	06/30/2010	12/15/2010		Patrick Leroy
07012010@15	pluronic F127 20% gel	06/24/2010	12/28/2010	09/29/2010	Patrick Leroy
07082010@29	vet paste	06/28/2010	01/04/2011		Patrick Leroy
07092010@24	lactic acid 88% USP	01/30/2010	01/05/2011		Brian Komoto
	orange preserved water	04/29/2009	01/05/2011		Brian Komoto
	sorbitol soln USP 70%	07/30/2010	01/05/2011		Brian Komoto
07092010@25	Hyocyamine 0.125mg/0.1ml drops	12/27/2010	01/05/2011		Brian Komoto
07122010@27	testosterone / lactose trituration 10% pow	None provided (lot number indicates this product was made on 09/04/2009 by the pharmacy)	01/08/2011		Patrick Leroy
	base, PCCA emollient cream	11/30//2010	01/09/2011		Patrick Leroy
07122010@31	testosterone cypionate USP	11/21/2010	01/08/2011		Patrick Leroy
	benzyl benzonate USP	09/30/2010	01/08/2011		Patrick Leroy
	sesame oil NF	06/12/2010	01/08/2012		Partick Leroy
07122010@33	sulfadiazine excipients stock solution	08/23/2009	01/08/2011		Patrick Leroy
07132010@1	stevia liquid extract	09/30/2010	11/20/2010		Brian Komoto
07132010@2	lactose NF monohydrate	08/15/2010	01/09/2011		Patrick Leroy
07132010@6	stevia liquid extract	09/30/2010	11/20/2010		Patrick Leroy
07132010@8	methylcellulose USP	06/30/2009	01/09/2011		Patrick Leroy
07132010@9	syrup, simple flavored syrup	12/13/2008	01/09/2011		Patrick Leroy
	carboxymethylcellulose (preserved) 1% sol	08/07/2010	01/09/2011		Patrick Leroy
07132010@11	ABHR 1/12.5/2/10 gel	09/24/2008	10/11/2010		Patrick Leroy
	Haloperidiol 4mg/ml soln.	11/03/2008	10/11/2010		Patrick Leroy
	Hyoscyamine	11/26/2008	10/11/2010		Patrick

	0.125mg/0.1ml drop				Leroy
	Lorazepam anhydrous 1mg/0.1mg drop	09/07/2010	10/11/2010		Patrick Leroy
	morphine sulfate 5mg/0.1ml	11/12/2008	10/11/2010		Patrick Leroy
07132010@13	Syrup, simple flavored syrup	12/31/2008	9/11/2010		Patrick Leroy
07132010@15	benzyl benzoate USP	09/30/2010	01/9/2011		Patrick Leroy
07132010@21	butylatedhydroxy-toluene NF	05/30/2010	09/11/2010		Patrick Leroy
	emollient cream base	11/30/2008	09/11/2010		Patrick Leroy
07132010@22	lactose NF monohydrate	08/15/2010	01/09/2011		Patrick Leroy
07132010@23	pluronic F127 20% gel	08/24/2010	01/09/2011		Patrick Leroy
07132010@24	ethoxy diglycol agent	08/20/2010	01/09/2011		Patrick Leroy
07132010@25	Powdered sugar powder	03/31/2010	01/09/2011		Patrick Leroy
	Levothyroxine trituration 1:1000 powder	12/29/2010	01/09/2011		Patrick Leroy
07132010@26	Powdered sugar powder	03/31/2010	01/09/2011		Patrick Leroy
	Levothyroxine trituration 1:1000 powder	12/29/2010	01/09/2011		Patrick Leroy
07132010@27	aminophylline USP anhydrous	11/30/2010	01/09/2011		Patrick Leroy
	base, PCCA emollient cream	11/30//2010	01/09/2011		Patrick Leroy
07132010@32	lactose NF monohydrate	08/15/2010	01/09/2011		Patrick Leroy

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

38. Respondent Pharmacy and Leroy are subject to disciplinary action under section 4301, subdivisions (j) in that Respondents violated laws of other states. The circumstances are as follows:

39. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that between July 5, 2010 and July 7, 2010, Respondents provided 17 Legend products to customers in Arizona, New

Mexico, Nevada, Texas, Oregon, Washington, New York and South Dakota without obtaining the proper pharmacy licenses from these states.

SEVENTH CAUSE FOR DISCIPLINE

(Compounding for Future Use-Beyond Use Dates)

40. Respondent Komoto is subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1735.2, subdivision (h) in that Respondent Komoto failed to give an expiration date representing the date beyond that it should not be used. The circumstances are as follows:

41. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondent Komoto allowed compounded products lot numbers 07092010@24, 07092010@25 and 07132010@1 to be assigned beyond dates use dates exceeding the expiration date of one of more ingredients.

Lot number	Ingredient	Expiration date of raw ingredient	Assigned beyond use date of completed compound	Beyond use date on master formula if available	Pharmacist
07092010@24	lactic acid 88% USP	01/30/2010	01/05/2011		Brian Komoto
	orange preserved water	04/29/2009	01/05/2011		Brian Komoto
	sorbitol soln USP 70%	07/30/2010	01/05/2011		Brian Komoto
07092010@25	Hyocyamine 0.125mg/0.1ml drops	12/27/2010	01/05/2011		Brian Komoto
07132010@1	stevia liquid extract	09/30/2010	11/20/2010		Brian Komoto

EIGHTH CAUSE FOR DISCIPLINE

(Compounding for Future Use-Beyond Use Dates)

42. Respondent Leroy is subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1735.2, subdivision (h) in that Respondent Leroy failed to give an expiration date representing the date beyond that it should not be used. The circumstances are as follows:

43. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondent Leroy

allowed compounded products lot numbers 04302010@5 to be assigned beyond dates use dates exceeding the expiration date of one of more ingredients.

Lot number	Ingredient	Expiration date of raw ingredient	Assigned beyond use date of completed compound	Beyond use date on master formula if available	Pharmacist
04302010@5	benzyl benzoate USP	09/30/2010	10/27/2010	07/29/2010	Mike Adam Urmston
	sesame oil	06/12/2010	10/27/2010	07/29/2010	Mike Adam Urmston

NINTH CAUSE FOR DISCIPLINE

(Failure to Quarantine Batch Produced Compound Until End Product Testing Confirmed)

44. Respondent Pharmacy and Leroy are subject to disciplinary action under California Code of Regulations, title 16, section 1751.7, subdivision (c) in that Respondent Pharmacy and Respondent Leroy failed to quarantine batch produced compound until after they documented end product testing for sterility and pyrogens. The circumstances are as follows:

45. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondent Pharmacy's sterile compounding permit. This inspection revealed that Respondent Pharmacy and Respondent Leroy did not quarantine batch-produced compounded sterile injectable products such as sodium chloride 23.4% solution, lot number 05012014@53; copper glycinate 20%, lot number 02182014@26, and triamcinolone acetonide 6mg/ml, lot number 06302014@13 until after the end product testing confirmed sterility and acceptable levels of pyrogens.

TENTH CAUSE FOR DISCIPLINE

(Failure to Establish and Follow a Written Program of Training and Performance for Sterile Compounding)

46. Respondent Pharmacy and Leroy are subject to disciplinary action under California Code of Regulations, title 16, section 1751.6, subdivision (e)(1) in that Respondents failed to establish and follow a written program of training and performance evaluation designed to ensure

that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. Namely, California Code of Regulations, title 16, section 1751.6, subdivision (e)(1). The required written program of training and performance evaluation must address the following: (A) Aseptic technique; (B) Pharmaceutical calculations and terminology; (C) Sterile product compounding documentation; (D) Quality assurance procedures; (E) Aseptic preparation procedures; (F) Proper gowning and gloving technique; (G) General conduct in the controlled area; (H) Cleaning, sanitizing and maintaining equipment used in the controlled area; (I) Sterilization techniques; and (J) Container, equipment, and closure selection. The circumstances are as follows:

47. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy and Respondent Leroy did not have a written program of training and performance evaluation for sterile compounding staff.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Train a Sterile Injectable Compounding Staff)

48. Respondent Pharmacy and Leroy are subject to disciplinary action under California Code of Regulations, title 16, section 1751.6, subdivision (e)(2) in that Respondents failed to ensure that any person assigned to the controlled area successfully completed practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures and that their proficiency and continuing training must be reassessed every 12 months. The results of which must be documented and retained in the pharmacy for three years. The circumstances were such that:

49. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy and Respondent Leroy did not have completed training records for sterile compounding staff and the records of training and documentation were incomplete as follows:

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Staff	License #	2013 training	2014 training	Fingertip testing	Assessment Record (checklist)	Process validation
Patrick Leroy	RPH 58396	7/16/13-WAT 7/16/13-P/C	2/28/14 P/C	6/14/14	2/1/13-OAT 8/29/13-OAT	2/15/13-PATT 8/29/13-PATT 3/14/14- PATT (all incomplete documentation)
Cynric Cho	RPH67772	7/1/13-P/C 7/1/13-WAT	1/17/14 P/C 1/17/14 ATE 2/18/14 BBP	6/19/13 (*test results said possible retake but no follow-up found)* 5/30/14	6/19/13-OAT (*incomplete*)	6/19/13-PATT
Jeannie Smith	TCH51822	7/16/13 P/C 7/16/13 WAT	2/24/14-PC	2/10/14	6/19/13-OAT	6/19/13-PATT 2/10/14-PATT (Incomplete documentation)
Amanda Bishop	TCH117509	7/1/13-WAT	2/14/14-P/C	None	None	None
Karen Olsen	TCH13694	7/1/13-WAT	2/24/14-P/C	5/1/14	6/19/13-OAT	6/19/13-PATT 4/1/14-PATT
Rovilyn Estanislao	TCH131775		04/07/14-ATE	6/23/14	06/10/14-OAT	04/07/14-PATT (incomplete documentation)
Amada Clark	TCH89452	7/16/13-WAT	2/24/14-P/C	4/23/14	1/31/13-OAT 6/11/14-OAT	1/30/13 PATT 4/1/14-PATT (both incomplete documentation)
Olivia Ornelas	TCH97629	7/16/13-P/C 7/16/13-WAT	2/24/14-P/C 2/18/14-BBP	2/27/14	8/27/13-OAT	8/27/13-PATT 2/27/14-PATT (both incomplete documentation)

PATT= Personal Aseptic Technique (Media fill)
ATE= Aseptic Technique Exam
OAT=Observed aseptic technique
WAT= Aseptic Technique Article
P/C= Pharmacy Calculations exam
BBP= Blood Borne Pathogens

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Complete a Validation Process Before Preparing Sterile Products)

50. Respondent Pharmacy and Leroy are subject to disciplinary action under California Code of Regulations, title 16, section 1751.7, subdivision (b) in that Respondents failed to ensure that each individual involved in the preparation of sterile injectable products first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. Respondent Pharmacy and Respondent Leroy further failed to ensure that this personal competency be revalidated at least every twelve months. The circumstances are such that:

51. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy

and Respondent Leroy allowed Amanda Bishop to prepare sterile injectable products without completing a validation process on aseptic technique. In addition, Respondent Pharmacy and Respondent Leroy did not ensure that Pharmacist Cynric Cho complete a revalidation on aseptic technique within the required twelve months.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Document Appropriate Beyond Use Date for Compounded Products)

52. Respondent Pharmacy and Leroy are subject to disciplinary action under California Code of Regulations, title 16, sections 1735.5, subdivision (a) and (c)(5) and 1751.7 subdivision (a)(4) in that Respondent Pharmacy and Respondent Leroy failed to maintain a master formula record with the expiration date of the final compounded drug product, as well as maintain a written quality assurance plan which includes a justification for the expiration dates chosen. The circumstances are such that:

53. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy and Respondent Leroy compounded 42 "prescriptions" for bevacizumab syringes. Komoto Custom Care Pharmacy compounded the 42 prescriptions of bevacizumab .05ml syringes from single dose vials of bevacizumab and failed to document the methodology used to establish a beyond use date that exceeded the manufacturer's and USP 797 guidelines. Respondent Pharmacy and Respondent Leroy also failed to document the methodology used to establish the 90 day beyond use date given to compounded acetazolamide 100mg/ml injectable which exceeded the beyond use date of 14 days, or 28 days refrigerated established on the product's master formula.

FOURTEENTH CAUSE FOR DISCIPLINE

(Compounding Commercially Available Products without Documented Medical Need)

54. Respondent Pharmacy and Leroy are subject to disciplinary action under California Code of Regulations, title 16, sections 1735 subdivision (c) and 1735.2 subdivision (a) in that Respondents compounded a drug product that is commercially available in the marketplace or

that is essentially a copy of a drug product that is commercially available in the marketplace and did so without a valid prescription. The circumstances are such that:

55. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy and Respondent Leroy compounded FDA approved commercially available products for human use:

Generic Name	Brand name of FDA approved product	Number of prescriptions
hyaluronidase injection	Vitrase, Hylenex	34
hydroxyprogesterone	Makena	49
methocarbamal injection	Robaxin Injection	17
mitomycin	Mitosol	79
phenobarbital Inj. 60mg/ml	phenobarbital injection 65mg/ml (West-Ward)	7

56. The August 12, 2014 inspection further revealed that Respondent Pharmacy and Respondent Leroy compounded FDA approved the following commercially available products for resale for veterinary use:

Generic Name	Brand name of FDA approved product	Number of prescriptions
xylazine 100mg/ml	Xylamed	4
triamcinolone acetonide 6mg/ml	Vetalog	55
praziquantel 5.68% injection	Droncit 5.68% injection	9

Respondent Pharmacy and Respondent Leroy failed to provide documentation as to why FDA commercial products were compounded.

FIFTEENTH CAUSE FOR DISCIPLINE

(Compounding Commercially Available Products without Documented Medical Need)

57. Respondent Pharmacy, Komoto and Sakamoto are subject to disciplinary action under California Code of Regulations, title 16, section 1735 subdivision (c) in that Respondents compounded a drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace and did so without a valid prescription. The circumstances are such that:

58. On or about July 28, 2015, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy Respondent Komoto and Respondent Sakamoto compounded and dispensed the following

commercially available products and were unable to offer proof they were unavailable from the manufacturer in the marketplace at the time of compounding:

a. Acety-d-glucosamine for veterinary use: June 1, 2015, June 4, 2015, June 9, 2015, June 15, 2015, June 16, 2015 and June 29, 2015.

b. Mitomycin 0.02% ophthalmic drops: June 1, 2015, June 11, 2015, June 15, 2015, June 18, 2015 and June 23, 2015.

c. Magnesium sulfate 4meq/ml: June 18, 2015.

d. Calcium gluconate 10%: June 18, 2015.

SIXTEENTH CAUSE FOR DISCIPLINE

(Compounding a Drug Product Prior to Receipt by a Pharmacy of a Valid Prescription)

59. Respondent Pharmacy, Komoto and Sakamoto are subject to disciplinary action under California Code of Regulations, title 16, section 1735.2 subdivision (a) in that Respondents compounded a drug products without a valid prescription. The circumstances are such that:

60. On or about July 28, 2015, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy Respondent Komoto and Respondent Sakamoto sold the following drug products to Integrated Care Systems without valid prescriptions:

Calcium Gluconate 10% Injectable	
Date	**Volume**
June 18, 2015	35000ml
July 6, 2015	37000ml
July 28, 2015	40000ml
Magnesium Solfate 4meg/ml	
Date	**Volume**
June 18, 2015	4000ml
July 6, 2015	4000ml
July 28, 2015	4000ml

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SEVENTEETH CAUSE FOR DISCIPLINE

(Dispensing Controlled Substance Prescription Written for Self)

61. Respondent Pharmacy and Respondent Leroy are subject to disciplinary action under California Health and Safety Code section 11170 which prohibits one from prescribing, administering and/or furnishing a controlled substance for him or herself. The circumstances are such that:

62. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy and Respondent Leroy provided dispensing records for the time period from on or about September 1, 2013 through August 12, 2014. Respondent Pharmacy and Respondent Leroy's dispensing records showed 38 controlled substance prescriptions were furnished to prescribers who self-prescribed the controlled substance medication as follows:

Date	Rx Number	Patient	Controlled substance	Prescriber	Quantity
9/3/2013	C00685808	S.S.	stanozolol	S.S. DVM	150
9/3/2013	C00685810	S.S.	stanozolol	S.S. DVM	20
9/10/2013	C00686695	P.D.	stanozolol	P.D. DVM	30
9/25/2013	C00688458	K.J.	buprenorphine	K.J. DVM	30
10/2/2013	C00689123	G.L.	buprenorphine	G.L.VMD	400
10/21/2013	C00690906	N.Z.	buprenorphine	N.Z. DVM	15
10/24/2013	C00691407	J.C.	stanozolol	J.C. DVM	30
10/30/2013	C00691899	T.F.	stanozolol	T.F. DVM	50
10/31/2013	C00692051	P.A.	stanozolol	P.A. DVM	90
11/4/2013	C00692350	G.D.	stanozolol	G.D. DVM	50
11/13/2013	C00693399	K.J.	stanozolol	K.J. DVM	120
11/13/2013	C00693446	G.D.	stanozolol	G.D. DVM	30
11/14/2013	C00693479	B.O.	testosterone	Bouldoukian, K. MD	225
11/18/2013	C00693865	G.L.	buprenorphine	G.L.VMD	400
11/19/2013	C00683957	L.	stanozolol	L.	30
11/20/2013	C00694066	J.R.	testosterone	J.R. DVM	100
11/20/2013	C00694135	N.Z.	buprenorphine	N.Z. DVM	30
11/25/2013	C00693957	L.	stanozolol	L.	30
12/18/2013	C00696961	K.J.	buprenorphine	K.J. DVM	30
12/20/2013	C00697149	K.S.	stanozolol	K.S. DVM	30
01/16/2014	C00699721	K.J.	buprenorphine	K.J. DVM	60
01/31/2104	C00701454	B.O.	testosterone cypionate	Bouldoukian, K. MD	225
02/05/2014	C00702113	K.J.	buprenorphine	K.J. DVM	30
02/15/2014	C00703059	S.S.	stanozolol	S.S. DVM	90
02/14/2014	C00702061	S.S.	stanozolol	S.S. DVM	30
02/20/2014	C00703683	J.C.	stanozolol	J.C. DVM	30

02/21/2014	C00703728	N.Z.	buprenorphine	N.Z. DVM	30
02/25/2014	C00704032	K.S.	stanozolol	K.S. DVM	30
03/06/2014	C00705129	K.J.	buprenorphine	K.J. DVM	30
03/12/2014	C00705584	L. DVM	stanozolol	L. DVM	30
03/13/2014	C00705806	B.DVM	stanozolol	B.DVM	60
04/02/2014	C00707860	K.J.	buprenorphine	K.J.	15
04/10/2014	C00708820	L., DVM	stanozolol	L., DVM	30
04/14/2014	C00709207	D.V.	stanozolol	D.V. DVM	50
04/14/2014	C00709269	A. DVM	stanozolol	A.DVM	90
04/24/2014	C00710445	K.B.	testosterone cypionate	Bouldoukian, K	250
04/25/2014	C00710655	K.S.	stanozolol	K.S. DVM	30
04/25/2014	C00710660	J.C.	stanozolol	J.C. DVM	30
04/25/2014	C00710768	S.S.	stanozolol	S.S. DVM	90
04/25/2014	C00710769	S.S.	stanozolol	S.S. DVM	30
05/06/2014	C00719900	T.F.	stanozolol	T.F. DVM	50
05/20/2014	C00713420	K.J.	buprenorphine	K.J. DVM	15
05/30/2014	C00714673	A. DVM	stanozolol	A. DVM	90
06/02/2014	C00715019	N.Z.	buprenorphine	N.Z. DVM	60
06/18/2014	C00717149	K.J.	buprenorphine	K.J. DVM	15
06/25/2014	C00717913	L.M.	stanozolol	Martin, Larry DVM	30
07/21/2014	C90000147	G.D.	stanzolol	G.D. DVM	50

EIGHTEETH CAUSE FOR DISCIPLINE

(Out of State Discipline)

63. Respondent Pharmacy is subject to disciplinary action under California section 4301 subdivision (n), in that on or about October 16, 2013, Respondent Pharmacy's Colorado Registration OSP 6054 was relinquished and cancelled by the Colorado State Board of Pharmacy in the administrative matter entitled: *In the Matter of disciplinary Proceedings Regarding the Non Resident Prescription Drug Outlet Registration in the State of Colorado of Optimal Pharmacies, Inc. dba Komoto Custom Care Pharmacy, Registration No. OSP 6054, Case No. 2013-587.* The Stipulation and Final Agency Order, Case No. 2013-587, is final and incorporated herein in full.

64. The Conclusions of Law found violations of Colorado Revised Statues (CRS) section 12-42.5-123 for Unprofessional Conduct and section 12-42.5-303 for violations of Wholesaler License Requirements, as follows: Between March 1, 2011 and March 1, 2013, Respondent Pharmacy distributed 51 prescription drugs and controlled substances to licensed prescribers in Colorado in response to requests from those prescribers, but without prescription orders.

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OTHER MATTERS

65. Pursuant to Code section 4307, if discipline is imposed on Original Pharmacy Permit Number PHY 46042 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy with Brian K. Komoto as President, Mary Komoto as Secretary, Patrick Nelson Leroy as Pharmacist-in-Charge and Kirk Forrest Sakamoto as Pharmacist-in-Charge, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 46042 is placed on probation or until Original Pharmacy Permit Number PHY 46042 is reinstated if it is revoked.

66. Pursuant to Code section 4307, if discipline is imposed on Original Pharmacy Permit Number PHY 46042 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy while Brian K. Komoto and/or Patrick Nelson Leroy and/or Kirk Forrest Sakamoto have been an officer and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Brian K. Komoto, Patrick Nelson Leroy and Kirk Forrest Sakamoto shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 46042 is placed on probation or until Original Pharmacy Permit Number PHY 46042 is reinstated if it is revoked.

67. Pursuant to Code section 4307, if discipline is imposed on Licensed Sterile Compounding License Number 99071 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy with Brian K. Komoto as President, Mary Komoto as Secretary, Patrick Nelson Leroy as Pharmacist-in-Charge and Kirk Forrest Sakamoto as Pharmacist-in-Charge, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Licensed Sterile Compounding License Number 99071 is placed on probation or until Licensed Sterile Compounding License Number 99071 is reinstated if it is revoked.

68. Pursuant to Code section 4307, if discipline is imposed on Licensed Sterile Compounding License Number 99071 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy while Brian K. Komoto and/or Patrick Nelson Leroy and/or Kirk Forrest Sakamoto have been an officer and had knowledge of or knowingly participated in any conduct

for which the licensee was disciplined, Brian K. Komoto, Patrick Nelson Leroy and Kirk Forrest Sakamoto shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Licensed Sterile Compounding License Number 99071 is placed on probation or until Licensed Sterile Compounding License Number 99071 is reinstated if it is revoked.

DISCIPLINE CONSIDERATIONS

69. To determine the degree of discipline, if any, to be imposed on Respondent Brian K. Komoto, Complainant alleges that on or about March 19, 2008, in a prior action, the Board of Pharmacy issued Citation Number CI 2007 35296 and ordered Respondent Komoto to pay a citation fine of $1,200.00. That Citation is now final and is incorporated by reference as if fully set forth.

70. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant alleges that on or about August 29, 2013, in a prior action, the Board of Pharmacy issued Citation Number CI 2012 53582 and ordered Respondent Pharmacy to pay a citation fine of $500.00. That Citation is now final and is incorporated by reference as if fully set forth.

71. To determine the degree of discipline, if any, to be imposed on Respondent Leroy, Complainant alleges that on or about August 29, 2013, in a prior action, the Board of Pharmacy issued Citation Number CI 2012 58065 and ordered Respondent Leroy to pay a citation fine 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 Original Pharmacy Permit Number PHY 46042, issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy;

2. Revoking or suspending Licensed Sterile Compounding License Number 99071, issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy;

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3. Revoking or suspending Original Pharmacist License Number RPH 36353, issued to Brian K. Komoto;

4. Revoking or suspending Original Pharmacist License Number RPH 58396, issued to Patrick Nelson Leroy;

5. Revoking or suspending Original Pharmacist License Number RPH 35651, issued to Kirk Forrest Sakamoto;

6. Prohibiting Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy with Brian K. Komoto as President, Mary Komoto as Secretary, Patrick Nelson Leroy as Pharmacist-in-Charge and Kirk Forrest Sakamoto as Pharmacist-in-Charge from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 46042 is placed on probation or until Original Pharmacy Permit Number PHY 46042 is reinstated if Original Pharmacy Permit Number PHY 46042 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy is revoked;

7. Prohibiting Brian K. Komoto from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 46042 is placed on probation or until Original Pharmacy Permit Number PHY 46042 is reinstated if Original Pharmacy Permit Number PHY 46042 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy is revoked;

8. Prohibiting Patrick Nelson Leroy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 46042 is placed on probation or until Original Pharmacy Permit Number PHY 46042 is reinstated if Original Pharmacy Permit Number PHY 46042 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy is revoked;

9. Prohibiting Kirk Forrest Sakamoto from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 46042 is placed on probation or until Original Pharmacy Permit Number PHY 46042 is reinstated if Original Pharmacy Permit Number PHY 46042 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy is revoked;

10. Prohibiting Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy with Brian K. Komoto as President, Mary Komoto as Secretary, Patrick Nelson Leroy as Pharmacist-in-Charge and Kirk Forrest Sakamoto as Pharmacist-in-Charge from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Licensed Sterile Compounding License Number 99071 is placed on probation or until Licensed Sterile Compounding License Number 99071 is reinstated if Licensed Sterile Compounding License Number 99071 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy is revoked;

11. Prohibiting Brian K. Komoto from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Licensed Sterile Compounding License Number 99071 is placed on probation or until Licensed Sterile Compounding License Number 99071 is reinstated if Licensed Sterile Compounding License Number 99071 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy is revoked;

12. Prohibiting Patrick Nelson Leroy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Licensed Sterile Compounding License Number 99071 is placed on probation or until Licensed Sterile Compounding License Number 99071 is reinstated if Licensed Sterile Compounding License Number 99071 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy is revoked;

13. Prohibiting Kirk Forrest Sakamoto from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Licensed Sterile Compounding License Number 99071 is placed on probation or until Licensed Sterile Compounding License Number 99071 is reinstated if Licensed Sterile Compounding License Number 99071 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy is revoked;

14. Ordering Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy, Brian K. Komoto, Patrick Nelson Leroy and Kirk Forrest Sakamoto 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

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

DATED: 9/14/16

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

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

In the Matter of the Accusation Against: **OPTIMAL PHARMACIES INC. dba KOMOTO CUSTOM CARE PHARMACY (formerly Optimal Compounding Pharmacy); BRIAN K. KOMOTO, President; MARY KOMOTO, Secretary; PATRICK NELSON LEROY, PHARMACIST-IN- CHARGE** **2110 Truxtun Avenue, Suite #300** **Bakersfield, CA 93301** **Original Pharmacy Permit No. PHY 46042** **Licensed Sterile Compounding License No. LSC 99071** **BRIAN K. KOMOTO** **1017 Ellington Street** **Delano, CA 93215** **Original Pharmacist License No. RPH 36353** **and** **PATRICK NELSON LEROY** **2110 Truxtun Avenue, Suite #300** **Bakersfield, CA 93301** **Original Pharmacist License No. RPH 58396** Respondents.	Case No. 4642 **FIRST AMENDED ACCUSATION**

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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.

Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy

Original Pharmacy Permit

2. On or about September 12, 2002, the Board of Pharmacy issued Pharmacy Permit Number PHY 46042 to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy (Respondent Pharmacy) with Brian K. Komoto as President, Mary Komoto as Secretary and Patrick Nelson Leroy as Pharmacist-in-Charge. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2016, unless renewed.

Licensed Sterile Compounding License

3. On or about July 1, 2003, the Board of Pharmacy issued Licensed Sterile Compounding License Number 99071 to Respondent Pharmacy with Brian K. Komoto as President, Mary Komoto as Secretary and Patrick Nelson Leroy as Pharmacist-in-Charge. The Licensed Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2016, unless renewed.

Brian K. Komoto

Original Pharmacist License

4. On or about August 13, 1981, the Board of Pharmacy issued Original Pharmacist License Number RPH 36353 to Brian K. Komoto (Respondent Komoto). The Original Pharmacist License was in full force and effect at all times relevant herein and will expire on July 31, 2017, unless renewed.

Patrick Nelson Leroy

Original Pharmacist License

5. On or about July 26, 2006, the Board of Pharmacy issued Original Pharmacist License Number RPH 58396 to Patrick Nelson Leroy (Respondent Leroy). The Original

Pharmacist License was in full force and effect at all times relevant herein and will expire on June 30, 2016, unless renewed.

JURISDICTION

6. 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.

7. Section 118, subdivision (b), of the Code provides that the suspension/expiration/surrender/cancellation of a license shall not deprive the Board/Registrar/Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

8. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

9. Section 4300(a) of the Code states that every license issued by the Board may be suspended or revoked.

10. 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 PROVISIONS

11. Section 4033, subdivision (a)(1) of the Code states:

"Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."

12. Section 4043, subdivision (a) of the Code states:

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"Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board."

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:

. . . .

"(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.

"(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

. . . .

"(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."

14. Section 4307, subdivision (a) of the Code states:

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

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

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

"(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated."

15. Section 11170 of Article 1 of the California Health and Safety Code states:

"No person shall prescribe, administer, or furnish a controlled substance for himself."

REGULATORY PROVISIONS

16. California Code of Regulations, title 16, section 1712 states:

"(a) Any requirement in this division for a pharmacist to initial or sign a prescription record or prescription label can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means. The computer used to record the reviewing pharmacist's identity shall not permit such a record to be altered after it is made.

"(b) The record of the reviewing pharmacist's identity made in a computer system pursuant to subdivision (a) of this section shall be immediately retrievable in the pharmacy."

17. California Code of Regulations, title 16, section 1717, subdivision (c) states, in pertinent part:

"Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in section 4019 of the Business and Professions Code are not subject to the provisions of this subsection."

18. California Code of Regulations, title 16, section 1735, states:

"(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

"(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

"(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

"(d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.)."

19. California Code of Regulations, title 16, section 1735.2 states, in pertinent part:

"(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

"...

"(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."

20. California Code of Regulations, title 16, section 1735.5, states:

"(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

"(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

"(c) The policy and procedure manual shall include the following

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

"(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

"(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

"(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

"(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products."

21. California Code of Regulations, title 16, section 1751.2, subdivision (b) states, in pertinent part:

"Name and concentrations of ingredients contained in the sterile injectable product."

22. California Code of Regulations, title 16, section 1751.7, states:

"(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be

examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(1) Cleaning and sanitization of the parenteral medication preparation area.

(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

(3) Actions to be taken in the event of a drug recall.

(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

"(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented."

"(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens."

"...."

23. California Code of Regulations, title 16, section 1751.6, subdivision (e) states, in pertinent part:

"...

"(e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:

"(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

"(A) Aseptic technique.

"(B) Pharmaceutical calculations and terminology.

"(C) Sterile product compounding documentation.

"(D) Quality assurance procedures.

"(E) Aseptic preparation procedures.

"(F) Proper gowning and gloving technique.

"(G) General conduct in he controlled area.

"(H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.

"(I) Sterilization techniques.

"(J) Container, equipment, and closure system selection.

"(2) Each person assigned to the controlled area must successfully complete practical skills training in aspetic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aspetic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years."

"...."

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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.

FIRST CAUSE FOR DISCIPLINE

(Acting as a Manufacturer Without a Permit)

As to Respondent Pharmacy and Leroy

25. Respondent Pharmacy and Leroy are subject to disciplinary action under section Code section 4301, subdivisions (j) and (o) for violating Code section 4033, subdivision (a)(1) in that Respondent Pharmacy and Leroy were acting as a manufacturer without a permit. The circumstances are as follows:

26. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed a large quantities of compounded medications prepared for non-patient specific orders that were being stocked for sale to veterinarians, veterinarian clinics and doctors' offices. Respondent Pharmacy and Leroy do not hold a manufacturing permit.

27. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondents produced sterile compounded products for resale by "Systems North" identified as Integrated Care Systems. These compounded sterile injectable products were not sold to the ultimate consumer. Respondent Pharmacy and Leroy do not hold a manufacturing permit. Below are examples of the products compounded for resale from on or about September 4, 2013 to October 29, 2013:

Date	Rx number	Medication	Quantity	Dispensed to
9/4/2013	00661294	Calcium gluconate solution	22500	Systems North
9/4/2013	00660842	Sodium phosphates 3mmol/4meq	4500	Systems North
9/9/2013	N0686347	Morphine sulfate 50mg/ml	1000	Systems North
9/16/2013	00687130	Calcium gluconate solution	30000	Systems North

9/16/2013	00665533	Potassium phosphates 4.4meq	500	Systems North
9/16/2013	00664210	Magnesium Sulfate 500mg/ml	4500	Systems North
9/16/2013	00660642	Sodium phosphates 3mmol/4meqml	4500	Systems North
9/30/2013	N00688800	Morphine sulfate 50mg/ml	1500	Systems North
10/2/2013	00660842	Sodium phosphates 3mmol/4meqml	4500	Systems North
10/2/2013	00660842	Magnesium sulfate 500mg/ml	4500	Systems North
10/2/2013	00661294	Calcium gluconate solution	22500	Systems North
10/21/2013	00661294	Calcium gluconate solution	15000	Systems North
10/29/2013	00661294	Calcium gluconate solution	37500	Systems North
10/29/2013	00660642	Sodium phosphates 3mmol/4meq/ml	4500	Systems North
10/29/2013	00664210	Magnesium sulfate 500mg/ml	1000	Systems North

SECOND CAUSE FOR DISCIPLINE

(Acting as a Wholesaler Without a Permit)

28. Respondent Pharmacy and Leroy are subject to disciplinary action under Code section 4301, subdivisions (j) and (o) for violating Code section 4043, subdivision (a) in that Respondent Pharmacy and Leroy were acting as a wholesaler without a permit. The circumstances are as follows:

29. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed during the time period of July 5, 2010 and July 9, 2010, 375 prescriptions were processed by Respondent Pharmacy and Leroy of which 110 were provided to veterinarians, veterinarian clinics and a pharmacy to use for non-specific patients. Respondent's Pharmacy and Leroy do not hold a wholesaler permit.

30. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondents had dispensing records from on or about September 1, 2013 through September 12, 2014 which showed only 7% of prescriptions were compounded and dispensed for individual patients. Ninety-three percent of prescriptions compounded and dispensed were provided to other pharmacies, prescriber offices, clinics, hospitals, animal parks, and farms. Respondents conducted business as a wholesaler and did not have a wholesaler permit.

THIRD CAUSE FOR DISCIPLINE

(Pharmacy Practice-Orally transmitted Prescriptions)

31. Respondent Pharmacy and Leroy are subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1717,

subdivision (c) in that Respondents failed to reduce an orally transmitted prescription to writing. The circumstances are as follows:

32. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that between July 9, 2010 and July 12, 2010, prescriptions numbers 582720, 582721 and 582760 were transcribed by someone other than a pharmacist.

FOURTH CAUSE FOR DISCIPLINE

(Labeling Requirements for Injectable Products)

33. Respondent Pharmacy and Leroy are subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1751.2, subdivision (b) in that Respondents failed to include the ingredients used in the sterile injectable product on the labels. The circumstances are as follows:

34. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondent Pharmacy and Leroy failed to have all of the ingredients used in lots numbers 03192010@7, 04302010@5, 06102010@22 and 06182010@8 included on the labels.

FIFTH CAUSE FOR DISCIPLINE

(Compounding for Future Use-Beyond Use Dates)

35. Respondent Pharmacy and Leroy are subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1735.2, subdivision (h) in that Respondents failed to give an expiration date representing the date beyond that it should not be used. The circumstances are as follows:

36. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondents allowed compounded products lot numbers 03192010@7, 04302010@5, 06092010@24, 06102010@22, 06182010@8, 07012010@15, 07082010@29, 07092010@24, 07092010@25, 07122010@27, 07122010@31, 07122010@33, 07132010@1, 07132010@2, 07132010@6, 07132010@8, 07132010@9, 07132010@11, 07132010@13, 07132010@15, 07132010@21, 07132010@22,

07132010@23, 07132010@24, 07132010@25, 07132010@26, 07132010@27, and 07132010@32, to be assigned beyond use dates exceeding the expiration date of one or more ingredients.

Lot number	Ingredient	Expiration date of raw ingredient	Assigned beyond use date of completed compound	Beyond use date on master formula if available	Pharmacist
03192010@7	nandrolone decanoate pwdr	09/26/2009	09/15/2010	06/17/2010	Patrick Leroy
	sesame oil	06/12/2010	09/15/2010	06/17/2010	Patrick Leroy
04302010@5	benzyl benzoate USP	09/30/2010	10/27/2010	07/29/2010	Mike Adam Urmston
	sesame oil	06/12/2010	10/27/2010	07/29/2010	Mike Adam Urmston
06092010@24	povidone USP	10/02/2010	12/06/2010		Patrick Leroy
	methylparaben NF	07/06/2010	12/06/2010		Patrick Leroy
	propylparaben NF	07/31/2010	12/06/2010		Patrick Leroy
06102010@22	benzalkonium chloride 5% liquid	12/16/2008	12/07/2010	09/08/2010	Patrick Leroy
	sodium phosphate dried dibasic pwdr USP	04/30/2010	12/07/2010	09/08/2010	Patrick Leroy
06182010@8	Yohimbine hydrochloride	06/30/2010	12/15/2010		Patrick Leroy
07012010@15	pluronic F127 20% gel	06/24/2010	12/28/2010	09/29/2010	Patrick Leroy
07082010@29	vet paste	06/28/2010	01/04/2011		Patrick Leroy
07092010@24	lactic acid 88% USP	01/30/2010	01/05/2011		Brian Komoto
	orange preserved water	04/29/2009	01/05/2011		Brian Komoto
	sorbitol soln USP 70%	07/30/2010	01/05/2011		Brian Komoto
07092010@25	Hyocyamine 0.125mg/0.1ml drops	12/27/2010	01/05/2011		Brian Komoto
07122010@27	testosterone / lactose trituration 10% pow	None provided (lot number indicates this product was made on	01/08/2011		Patrick Leroy

		09/04/2009 by the pharmacy)			
	base, PCCA emollient cream	11/30//2010	01/09/2011		Patrick Leroy
07122010@31	testosterone cypionate USP	11/21/2010	01/08/2011		Patrick Leroy
	benzyl benzonate USP	09/30/2010	01/08/2011		Patrick Leroy
	sesame oil NF	06/12/2010	01/08/2012		Partick Leroy
07122010@33	sulfadiazine excipients stock solution	08/23/2009	01/08/2011		Patrick Leroy
07132010@1	stevia liquid extract	09/30/2010	11/20/2010		Brian Komoto
07132010@2	lactose NF monohydrate	08/15/2010	01/09/2011		Patrick Leroy
07132010@6	stevia liquid extract	09/30/2010	11/20/2010		Patrick Leroy
07132010@8	methylcellulose USP	06/30/2009	01/09/2011		Patrick Leroy
07132010@9	syrup, simple flavored syrup	12/13/2008	01/09/2011		Patrick Leroy
	carboxymethylcellulose (preserved) 1% sol	08/07/2010	01/09/2011		Patrick Leroy
07132010@11	ABHR 1/12.5/2/10 gel	09/24/2008	10/11/2010		Patrick Leroy
	Haloperidiol 4mg/ml soln.	11/03/2008	10/11/2010		Patrick Leroy
	Hyoscyamine 0.125mg/0.1ml drop	11/26/2008	10/11/2010		Patrick Leroy
	Lorazepam anhydrous 1mg/0.1mg drop	09/07/2010	10/11/2010		Patrick Leroy
	morphine sulfate 5mg/0.1ml	11/12/2008	10/11/2010		Patrick Leroy
07132010@13	Syrup, simple flavored syrup	12/31/2008	9/11/2010		Patrick Leroy
07132010@15	benzyl benzoate USP	09/30/2010	01/9/2011		Patrick Leroy
07132010@21	butylatedhydroxy-toluene NF	05/30/2010	09/11/2010		Patrick Leroy
	emollient cream base	11/30/2008	09/11/2010		Patrick Leroy
07132010@22	lactose NF monohydrate	08/15/2010	01/09/2011		Patrick Leroy
07132010@23	pluronic F127 20% gel	08/24/2010	01/09/2011		Patrick Leroy
07132010@24	ethoxy diglycol agent	08/20/2010	01/09/2011		Patrick Leroy
07132010@25	Powdered sugar powder	03/31/2010	01/09/2011		Patrick Leroy
	Levothyroxine trituration 1:1000	12/29/2010	01/09/2011		Patrick Leroy

	powder				
07132010@26	Powdered sugar powder	03/31/2010	01/09/2011		Patrick Leroy
	Levothyroxine trituration 1:1000 powder	12/29/2010	01/09/2011		Patrick Leroy
07132010@27	aminophylline USP anhydrous	11/30/2010	01/09/2011		Patrick Leroy
	base, PCCA emollient cream	11/30//2010	01/09/2011		Patrick Leroy
07132010@32	lactose NF monohydrate	08/15/2010	01/09/2011		Patrick Leroy

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

37. Respondent Pharmacy and Leroy are subject to disciplinary action under section 4301, subdivisions (j) in that Respondents violated laws of other states. The circumstances are as follows:

38. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that between July 5, 2010 and July 7, 2010, Respondents provided 17 Legend products to customers in Arizona, New Mexico, Nevada, Texas, Oregon, Washington, New York and South Dakota without obtaining the proper pharmacy licenses from these states.

SEVENTH CAUSE FOR DISCIPLINE

(Compounding for Future Use-Beyond Use Dates)

39. Respondent Komoto is subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1735.2, subdivision (h) in that Respondent Komoto failed to give an expiration date representing the date beyond that it should not be used. The circumstances are as follows:

40. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondent Komoto allowed compounded products lot numbers 07092010@24, 07092010@25 and 07132010@1 to be assigned beyond dates use dates exceeding the expiration date of one of more ingredients.

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Lot number	Ingredient	Expiration date of raw ingredient	Assigned beyond use date of completed compound	Beyond use date on master formula if available	Pharmacist
07092010@24	lactic acid 88% USP	01/30/2010	01/05/2011		Brian Komoto
	orange preserved water	04/29/2009	01/05/2011		Brian Komoto
	sorbitol soln USP 70%	07/30/2010	01/05/2011		Brian Komoto
07092010@25	Hyocyamine 0.125mg/0.1ml drops	12/27/2010	01/05/2011		Brian Komoto
07132010@1	stevia liquid extract	09/30/2010	11/20/2010		Brian Komoto

EIGHTH CAUSE FOR DISCIPLINE

(Compounding for Future Use-Beyond Use Dates)

41. Respondent Leroy is subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1735.2, subdivision (h) in that Respondent Leroy failed to give an expiration date representing the date beyond that it should not be used. The circumstances are as follows:

42. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondent Leroy allowed compounded products lot numbers 04302010@5 to be assigned beyond dates use dates exceeding the expiration date of one of more ingredients.

Lot number	Ingredient	Expiration date of raw ingredient	Assigned beyond use date of completed compound	Beyond use date on master formula if available	Pharmacist
04302010@5	benzyl benzoate USP	09/30/2010	10/27/2010	07/29/2010	Mike Adam Urmston
	sesame oil	06/12/2010	10/27/2010	07/29/2010	Mike Adam Urmston

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NINTH CAUSE FOR DISCIPLINE

(Failure to Quarantine Batch Produced Compound Until End Product Testing Confirmed)

43. Respondent Pharmacy and Leroy are subject to disciplinary action under California Code of Regulations, title 16, section 1751.7, subdivision (c) in that Respondent Pharmacy and Respondent Leroy failed to quarantine batch produced compound until after they documented end product testing for sterility and pyrogens. The circumstances are as follows:

44. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondent Pharmacy's sterile compounding permit. This inspection revealed that Respondent Pharmacy and Respondent Leroy did not quarantine batch-produced compounded sterile injectable products such as sodium chloride 23.4% solution, lot number 05012014@53; copper glycinate 20%, lot number 02182014@26, and triamcinolone acetonide 6mg/ml, lot number 06302014@13 until after the end product testing confirmed sterility and acceptable levels of pyrogens.

TENTH CAUSE FOR DISCIPLINE

(Failure to Establish and Follow a Written Program of Training and Performance for Sterile Compounding)

45. Respondent Pharmacy and Leroy are subject to disciplinary action under California Code of Regulations, title 16, section 1751.6, subdivision (e)(1) in that Respondents failed to establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. Namely, California Code of Regulations, title 16, section 1751.6, subdivision (e)(1). The required written program of training and performance evaluation must address the following: (A) Aseptic technique; (B) Pharmaceutical calculations and terminology; (C) Sterile product compounding documentation; (D) Quality assurance procedures; (E) Aseptic preparation procedures; (F) Proper gowning and gloving technique; (G) General conduct in the controlled area; (H) Cleaning, sanitizing and maintaining equipment used in the controlled area; (I) Sterilization techniques; and (J) Container, equipment, and closure selection. The circumstances are as follows:

46. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy and Respondent Leroy did not have a written program of training and performance evaluation for sterile compounding staff.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Train a Sterile Injectable Compounding Staff)

47. Respondent Pharmacy and Leroy are subject to disciplinary action under California Code of Regulations, title 16, section 1751.6, subdivision (e)(2) in that Respondents failed to ensure that any person assigned to the controlled area successfully completed practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures and that their proficiency and continuing training must be reassessed every 12 months. The results of which must be documented and retained in the pharmacy for three years. The circumstances were such that:

48. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy and Respondent Leroy did not have completed training records for sterile compounding staff and the records of training and documentation were incomplete as follows:

Staff	License #	2013 training	2014 training	Fingertip testing	Assessment Record (checklist)	Process validation
Patrick Leroy	RPH 58396	7/16/13-WAT 7/16/13-P/C	2/28/14 P/C	6/14/14	2/1/13-OAT 8/29/13-OAT	2/15/13-PATT 8/29/13-PATT 3/14/14- PATT (all incomplete documentation)
Cynric Cho	RPH67772	7/1/13-P/C 7/1/13-WAT	1/17/14 P/C 1/17/14 ATE 2/18/14 BBP	6/19/13 *(test results said possible retake but no follow-up found)* 5/30/14	6/19/13-OAT *(incomplete)*	6/19/13-PATT
Jeannie Smith	TCH51822	7/16/13 P/C 7/16/13 WAT	2/24/14-PC	2/10/14	6/19/13-OAT	6/19/13-PATT 2/10/14-PATT (incomplete documentation)
Amanda Bishop	TCH117509	7/1/13-WAT	2/14/14-P/C	None	None	None
Karen	TCH13694	7/1/13-WAT	2/24/14-P/C	5/1/14	6/19/13-OAT	6/19/13-PATT

Olsen						4/1/14-PATT
Rovilyn Estanislao	TCH131775		04/07/14-ATE	6/23/14	06/10/14-OAT	04/07/14-PATT (incomplete documentation)
Amada Clark	TCH89452	7/16/13-WAT	2/24/14-P/C	4/23/14	1/31/13-OAT 6/11/14-OAT	1/30/13 PATT 4/1/14-PATT (both incomplete documentation)
Olivia Ornelas	TCH97629	7/16/13-P/C 7/16/13-WAT	2/24/14-P/C 2/18/14-BBP	2/27/14	8/27/13-OAT	8/27/13-PATT 2/27/14-PATT (both incomplete documentation)

PATT= Personal Aseptic Technique (Media fill)
ATE= Aseptic Technique Exam
OAT=Observed aseptic technique
WAT= Aseptic Technique Article
P/C= Pharmacy Calculations exam
BBP= Blood Borne Pathogens

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Complete a Validation Process Before Preparing Sterile Products)

49. Respondent Pharmacy and Leroy are subject to disciplinary action under California Code of Regulations, title 16, section 1751.7, subdivision (b) in that Respondents failed to ensure that each individual involved in the preparation of sterile injectable products first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. Respondent Pharmacy and Respondent Leroy further failed to ensure that this personal competency be revalidated at least every twelve months. The circumstances are such that:

50. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy and Respondent Leroy allowed Amanda Bishop to prepare sterile injectable products without completing a validation process on aseptic technique. In addition, Respondent Pharmacy and Respondent Leroy did not ensure that Pharmacist Cynric Cho complete a revalidation on aseptic technique within the required twelve months.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Document Appropriate Beyond Use Date for Compounded Products)

51. Respondent Pharmacy and Leroy are subject to disciplinary action under California Code of Regulations, title 16, sections 1735.5, subdivision (a) and (c)(5) and 1751.7 subdivision (a)(4) in that Respondent Pharmacy and Respondent Leroy failed to maintain a master formula record with the expiration date of the final compounded drug product, as well as maintain a

written quality assurance plan which includes a justification for the expiration dates chosen. The circumstances are such that:

52. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy and Respondent Leroy compounded 42 "prescriptions" for bevacizumab syringes. Komoto Custom Care Pharmacy compounded the 42 prescriptions of bevacizumab .05ml syringes from single dose vials of bevacizumab and failed to document the methodology used to establish a beyond use date that exceeded the manufacturer's and USP 797 guidelines. Respondent Pharmacy and Respondent Leroy also failed to document the methodology used to establish the 90 day beyond use date given to compounded acetazolamide 100mg/ml injectable which exceeded the beyond use date of 14 days, or 28 days refrigerated established on the product's master formula.

FOURTEENTH CAUSE FOR DISCIPLINE

(Compounding Commercially Available Products without Documented Medical Need)

53. Respondent Pharmacy and Leroy are subject to disciplinary action under California Code of Regulations, title 16, sections 1735 subdivision (c) and 1735.2 subdivision (a) in that Respondents compounded a drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace and did so without a valid prescription. The circumstances are such that:

54. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy and Respondent Leroy compounded FDA approved commercially available products for human use:

Generic Name	Brand name of FDA approved product	Number of prescriptions
hyaluronidase injection	Vitrase, Hylenex	34
hydroxyprogesterone	Makena	49
methocarbamal injection	Robaxin Injection	17
mitomycin	Mitosol	79
phenobarbital Inj. 60mg/ml	phenobarbital injection 65mg/ml (West-Ward)	7

55. The August 12, 2014 inspection further revealed that Respondent Pharmacy and Respondent Leroy compounded FDA approved the following commercially available products for resale for veterinary use:

Generic Name	Brand name of FDA approved product	Number of prescriptions
xylazine 100mg/ml	Xylamed	4
triamcinolone acetonide 6mg/ml	Vetalog	55
praziquantel 5.68% injection	Droncit 5.68% injection	9

Respondent Pharmacy and Respondent Leroy failed to provide documentation as to why FDA commercial products were compounded.

FIFTEENTH CAUSE FOR DISCIPLINE

(Dispensing Controlled Substance Prescription Written for Self)

56. Respondent Pharmacy and Respondent Leroy are subject to disciplinary action under California Health and Safety Code section 11170 which prohibits one from prescribing, administering and/or furnishing a controlled substance for him or herself. The circumstances are such that:

57. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy and Respondent Leroy provided dispensing records for the time period from on or about September 1, 2013 through August 12, 2014. Respondent Pharmacy and Respondent Leroy's dispensing records showed 38 controlled substance prescriptions were furnished to prescribers who self-prescribed the controlled substance medication as follows:

Date	Rx Number	Patient	Controlled substance	Prescriber	Quantity
9/3/2013	C00685808	S.S.	stanozolol	S.S. DVM	150
9/3/2013	C00685810	S.S.	stanozolol	S.S. DVM	20
9/10/2013	C00686695	P.D.	stanozolol	P.D. DVM	30
9/25/2013	C00688458	K.J.	buprenorphine	K.J. DVM	30
10/2/2013	C00689123	G.L.	buprenorphine	G.L.VMD	400
10/21/2013	C00690906	N.Z.	buprenorphine	N.Z. DVM	15
10/24/2013	C00691407	J.C.	stanozolol	J.C. DVM	30
10/30/2013	C00691899	T.F.	stanozolol	T.F. DVM	50
10/31/2013	C00692051	P.A.	stanozolol	P.A. DVM	90
11/4/2013	C00692350	G.D.	stanozolol	G.D. DVM	50
11/13/2013	C00693399	K.J.	stanozolol	K.J. DVM	120
11/13/2013	C00693446	G.D.	stanozolol	G.D.	30

				DVM	
11/14/2013	C00693479	B.O.	testosterone	Bouldoukian, K. MD	225
11/18/2013	C00693865	G.L.	buprenorphine	G.L.VMD	400
11/19/2013	C00683957	L.	stanozolol	L.	30
11/20/2013	C00694066	J.R.	testosterone	J.R. DVM	100
11/20/2013	C00694135	N.Z.	buprenorphine	N.Z. DVM	30
11/25/2013	C00693957	L.	stanozolol	L.	30
12/18/2013	C00696961	K.J.	buprenorphine	K.J. DVM	30
12/20/2013	C00697149	K.S.	stanozolol	K.S. DVM	30
01/16/2014	C00699721	K.J.	buprenorphine	K.J. DVM	60
01/31/2104	C00701454	B.O.	testosterone cypionate	Bouldoukian, K. MD	225
02/05/2014	C00702113	K.J.	buprenorphine	K.J. DVM	30
02/15/2014	C00703059	S.S.	stanozolol	S.S. DVM	90
02/14/2014	C00702061	S.S.	stanozolol	S.S. DVM	30
02/20/2014	C00703683	J.C.	stanozolol	J.C. DVM	30
02/21/2014	C00703728	N.Z.	buprenorphine	N.Z. DVM	30
02/25/2014	C00704032	K.S.	stanozolol	K.S. DVM	30
03/06/2014	C00705129	K.J.	buprenorphine	K.J. DVM	30
03/12/2014	C00705584	L. DVM	stanozolol	L. DVM	30
03/13/2014	C00705806	B.DVM	stanozolol	B.DVM	60
04/02/2014	C00707860	K.J.	buprenorphine	K.J.	15
04/10/2014	C00708820	L., DVM	stanozolol	L., DVM	30
04/14/2014	C00709207	D.V.	stanozolol	D.V. DVM	50
04/14/2014	C00709269	A. DVM	stanozolol	A.DVM	90
04/24/2014	C00710445	K.B.	testosterone cypionate	Bouldoukian, K	250
04/25/2014	C00710655	K.S.	stanozolol	K.S. DVM	30
04/25/2014	C00710660	J.C.	stanozolol	J.C. DVM	30
04/25/2014	C00710768	S.S.	stanozolol	S.S. DVM	90
04/25/2014	C00710769	S.S.	stanozolol	S.S. DVM	30
05/06/2014	C00719900	T.F.	stanozolol	T.F. DVM	50
05/20/2014	C00713420	K.J.	buprenorphine	K.J. DVM	15
05/30/2014	C00714673	A. DVM	stanozolol	A. DVM	90
06/02/2014	C00715019	N.Z.	buprenorphine	N.Z. DVM	60
06/18/2014	C00717149	K.J.	buprenorphine	K.J. DVM	15
06/25/2014	C00717913	L.M.	stanozolol	Martin, Larry DVM	30
07/21/2014	C90000147	G.D.	stanzolol	G.D. DVM	50

SIXTEENTH CAUSE FOR DISCIPLINE

(Out of State Discipline)

58. Respondent Pharmacy is subject to disciplinary action under California section 4301 subdivision (n), in that on or about October 16, 2013, Respondent Pharmacy's Colorado Registration OSP 6054 was relinquished and cancelled by the Colorado State Board of Pharmacy in the administrative matter entitled: *In the Matter of disciplinary Proceedings Regarding the Non Resident Prescription Drug Outlet Registration in the State of Colorado of Optimal Pharmacies, Inc. dba Komoto Custom Care Pharmacy, Registration No. OSP 6054,*

Case No. 2013-587. The Stipulation and Final Agency Order, Case No. 2013-587, is final and incorporated herein in full.

59. The Conclusions of Law found violations of Colorado Revised Statues (CRS) section 12-42.5-123 for Unprofessional Conduct and section 12-42.5-303 for violations of Wholesaler License Requirements, as follows: Between March 1, 2011 and March 1, 2013, Respondent Pharmacy distributed 51 prescription drugs and controlled substances to licensed prescribers in Colorado in response to requests from those prescribers, but without prescription orders.

OTHER MATTERS

60. Pursuant to Code section 4307, if discipline is imposed on Original Pharmacy Permit Number PHY 46042 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy with Brian K. Komoto as President, Mary Komoto as Secretary and Patrick Nelson Leroy as Pharmacist-in-Charge, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 46042 is placed on probation or until Original Pharmacy Permit Number PHY 46042 is reinstated if it is revoked.

61. Pursuant to Code section 4307, if discipline is imposed on Original Pharmacy Permit Number PHY 46042 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy while Brian K. Komoto and/or Patrick Nelson Leroy have been an officer and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Brian K. Komoto and Patrick Nelson Leroy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 46042 is placed on probation or until Original Pharmacy Permit Number PHY 46042 is reinstated if it is revoked.

62. Pursuant to Code section 4307, if discipline is imposed on Licensed Sterile Compounding License Number 99071 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy with Brian K. Komoto as President, Mary Komoto as Secretary and Patrick Nelson Leroy as Pharmacist-in-Charge, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if

Licensed Sterile Compounding License Number 99071 is placed on probation or until Licensed Sterile Compounding License Number 99071 is reinstated if it is revoked.

63. Pursuant to Code section 4307, if discipline is imposed on Licensed Sterile Compounding License Number 99071 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy while Brian K. Komoto and/or Patrick Nelson Leroy have been an officer and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Brian K. Komoto and Patrick Nelson Leroy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Licensed Sterile Compounding License Number 99071 is placed on probation or until Licensed Sterile Compounding License Number 99071 is reinstated if it is revoked.

DISCIPLINE CONSIDERATIONS

64. To determine the degree of discipline, if any, to be imposed on Respondent Brian K. Komoto, Complainant alleges that on or about March 19, 2008, in a prior action, the Board of Pharmacy issued Citation Number CI 2007 35296 and ordered Respondent Komoto to pay a citation fine of $1,200.00. That Citation is now final and is incorporated by reference as if fully set forth.

65. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant alleges that on or about August 29, 2013, in a prior action, the Board of Pharmacy issued Citation Number CI 2012 53582 and ordered Respondent Pharmacy to pay a citation fine of $500.00. That Citation is now final and is incorporated by reference as if fully set forth.

66. To determine the degree of discipline, if any, to be imposed on Respondent Leroy, Complainant alleges that on or about August 29, 2013, in a prior action, the Board of Pharmacy issued Citation Number CI 2012 58065 and ordered Respondent Leroy to pay a citation fine 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 Original Pharmacy Permit Number PHY 46042, issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy;

2. Revoking or suspending Licensed Sterile Compounding License Number 99071, issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy;

3. Revoking or suspending Original Pharmacist License Number RPH 36353, issued to Brian K. Komoto;

4. Revoking or suspending Original Pharmacist License Number RPH 58396, issued to Patrick Nelson Leroy;

5. Prohibiting Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy with Brian K. Komoto as President, Mary Komoto as Secretary and Patrick Nelson Leroy as Pharmacist-in-Charge from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 46042 is placed on probation or until Original Pharmacy Permit Number PHY 46042 is reinstated if Original Pharmacy Permit Number PHY 46042 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy is revoked;

6. Prohibiting Brian K. Komoto from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 46042 is placed on probation or until Original Pharmacy Permit Number PHY 46042 is reinstated if Original Pharmacy Permit Number PHY 46042 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy is revoked;

7. Prohibiting Patrick Nelson Leroy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 46042 is placed on probation or until Original Pharmacy Permit Number PHY 46042 is reinstated if Original Pharmacy Permit Number PHY 46042 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy is revoked;

8. Prohibiting Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy with Brian K. Komoto as President, Mary Komoto as Secretary and Patrick Nelson Leroy as Pharmacist-in-Charge from serving as a manager, administrator, owner, member, officer, director, associate, or

partner of a licensee for five years if Licensed Sterile Compounding License Number 99071 is placed on probation or until Licensed Sterile Compounding License Number 99071 is reinstated if Licensed Sterile Compounding License Number 99071 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy is revoked;

9. Prohibiting Brian K. Komoto from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Licensed Sterile Compounding License Number 99071 is placed on probation or until Licensed Sterile Compounding License Number 99071 is reinstated if Licensed Sterile Compounding License Number 99071 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy is revoked;

10. Prohibiting Patrick Nelson Leroy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Licensed Sterile Compounding License Number 99071 is placed on probation or until Licensed Sterile Compounding License Number 99071 is reinstated if Licensed Sterile Compounding License Number 99071 issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy is revoked;

11. Ordering Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy, Brian K. Komoto and Patrick Nelson Leroy 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

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

DATED: 4/21/16

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

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

In the Matter of the Accusation Against: **OPTIMAL PHARMACIES INC. dba KOMOTO CUSTOM CARE PHARMACY (formerly Optimal Compounding Pharmacy); BRIAN K. KOMOTO, President; MARY KOMOTO, Secretary; PATRICK NELSON LEROY, PHARMACIST-IN- CHARGE** **2110 Truxtun Avenue, Suite #300** **Bakersfield, CA 93301** **Original Pharmacy Permit No. PHY 46042** **Licensed Sterile Compounding License No. LSC 99071** **BRIAN K. KOMOTO** **1017 Ellington Street** **Delano, CA 93215** **Original Pharmacist License No. RPH 36353** **and** **PATRICK NELSON LEROY** **2110 Truxtun Avenue, Suite #300** **Bakersfield, CA 93301** **Original Pharmacist License No. RPH 58396** Respondents.	Case No. 4642 **A C C U S A T I O N**

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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.

Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy

Original Pharmacy Permit

2. On or about September 12, 2002, the Board of Pharmacy issued Pharmacy Permit Number PHY 46042 to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy (Respondent Pharmacy) with Brian K. Komoto as President, Mary Komoto as Secretary and Patrick Nelson Leroy as Pharmacist-in-Charge. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2014, unless renewed.

Licensed Sterile Compounding License

3. On or about July 1, 2003, the Board of Pharmacy issued Licensed Sterile Compounding License Number 99071 to Respondent Pharmacy with Brian K. Komoto as President, Mary Komoto as Secretary and Patrick Nelson Leroy as Pharmacist-in-Charge. The Licensed Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2014, unless renewed.

Brian K. Komoto

Original Pharmacist License

4. On or about August 13, 1981, the Board of Pharmacy issued Original Pharmacist License Number RPH 36353 to Brian K. Komoto (Respondent Komoto). The Original Pharmacist License was in full force and effect at all times relevant herein and will expire on July 31, 2015, unless renewed.

Patrick Nelson Leroy

Original Pharmacist License

5. On or about July 26, 2006, the Board of Pharmacy issued Original Pharmacist License Number RPH 58396 to Patrick Nelson Leroy (Respondent Leroy). The Original Pharmacist

License was in full force and effect at all times relevant herein and will expire on June 30, 2014, unless renewed.

JURISDICTION

6. 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.

7. Section 118, subdivision (b), of the Code provides that the suspension/expiration/surrender/cancellation of a license shall not deprive the Board/Registrar/Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

8. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

9. Section 4300(a) of the Code states that every license issued by the Board may be suspended or revoked.

10. 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 PROVISIONS

11. Section 4033, subdivision (a)(1) of the Code states:

"Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."

12. Section 4043, subdivision (a) of the Code states:

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"Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board."

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:

. . . .

"(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."

REGULATORY PROVISIONS

14. California Code of Regulations, title 16, section 1717, subdivision (c) states, in pertinent part:

"Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in section 4019 of the Business and Professions Code are not subject to the provisions of this subsection."

15. California Code of Regulations, title 16, section 1735.2, subdivision (h) states, in pertinent part:

"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."

16. California Code of Regulations, title 16, section 1751.2, subdivision (b) states, in pertinent part:

"Name and concentrations of ingredients contained in the sterile injectable product."

COST RECOVERY

17. 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.

FIRST CAUSE FOR DISCIPLINE

(Acting as a Manufacturer Without a Permit)

As to Respondent Pharmacy and Leroy

18. Respondent Pharmacy and Leroy are subject to disciplinary action under section Code section 4301, subdivisions (j) and (o) for violating Code section 4033, subdivision (a)(1) in that Respondent Pharmacy and Leroy were acting as a manufacturer without a permit. The circumstances are as follows:

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19. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed a large quantities of compounded medications prepared for non-patient specific orders that were being stocked for sale to veterinarians, veterinarian clinics and doctors' offices. Respondent Pharmacy and Leroy do not hold a manufacturing permit.

SECOND CAUSE FOR DISCIPLINE

(Acting as a Wholesaler Without a Permit)

20. Respondent Pharmacy and Leroy are subject to disciplinary action under Code section 4301, subdivisions (j) and (o) for violating Code section 4043, subdivision (a) in that Respondent Pharmacy and Leroy were acting as a wholesaler without a permit. The circumstances are as follows:

21. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed during the time period of July 5, 2010 and July 9, 2010, 375 prescriptions were processed by Respondent Pharmacy and Leroy of which 110 were provided to veterinarians, veterinarian clinics and a pharmacy to use for non-specific patients. Respondent's Pharmacy and Leroy do not hold a wholesaler permit.

THIRD CAUSE FOR DISCIPLINE

(Pharmacy Practice-Orally transmitted Prescriptions)

22. Respondent Pharmacy and Leroy are subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1717, subdivision (c) in that Respondents failed to reduce an orally transmitted prescription to writing. The circumstances are as follows:

23. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that between July 9, 2010 and July 12, 2010, prescriptions numbers 582720, 582721 and 582760 were transcribed by someone other than a pharmacist.

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FOURTH CAUSE FOR DISCIPLINE

(Labeling Requirements for Injectable Products)

24. Respondent Pharmacy and Leroy are subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1751.2, subdivision (b) in that Respondents failed to include the ingredients used in the sterile injectable product on the labels. The circumstances are as follows:

25. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondent Pharmacy and Leroy failed to have all of the ingredients used in lots numbers 03192010@7, 04302010@5, 06102010@22 and 06182010@8 included on the labels.

FIFTH CAUSE FOR DISCIPLINE

(Compounding for Future Use-Beyond Use Dates)

26. Respondent Pharmacy and Leroy are subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1735.2, subdivision (h) in that Respondents failed to give an expiration date representing the date beyond that it should not be used. The circumstances are as follows:

27. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondents allowed compounded products lot numbers 03192010@7, 04302010@5, 06092010@24, 06102010@22, 06182010@8, 07012010@15, 07082010@29, 07092010@24, 07092010@25, 07122010@27, 07122010@31, 07122010@33, 07132010@1, 07132010@2, 07132010@6, 07132010@8, 07132010@9, 07132010@11, 07132010@13, 07132010@15, 07132010@21, 07132010@22, 07132010@23, 07132010@24, 07132010@25, 07132010@26, 07132010@27, and 07132010@32, to be assigned beyond use dates exceeding the expiration date of one or more ingredients.

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Lot number	Ingredient	Expiration date of raw ingredient	Assigned beyond use date of completed compound	Beyond use date on master formula if available	Pharmacist
03192010@7	nandrolone decanoate pwdr	09/26/2009	09/15/2010	06/17/2010	Patrick Leroy
	sesame oil	06/12/2010	09/15/2010	06/17/2010	Patrick Leroy
04302010@5	benzyl benzoate USP	09/30/2010	10/27/2010	07/29/2010	Mike Adam Urmston
	sesame oil	06/12/2010	10/27/2010	07/29/2010	Mike Adam Urmston
06092010@24	povidone USP	10/02/2010	12/06/2010		Patrick Leroy
	methylparaben NF	07/06/2010	12/06/2010		Patrick Leroy
	propylparaben NF	07/31/2010	12/06/2010		Patrick Leroy
06102010@22	benzalkonium chloride 5% liquid	12/16/2008	12/07/2010	09/08/2010	Patrick Leroy
	sodium phosphate dried dibasic pwdr USP	04/30/2010	12/07/2010	09/08/2010	Patrick Leroy
06182010@8	Yohimbine hydrochloride	06/30/2010	12/15/2010		Patrick Leroy
07012010@15	pluronic F127 20% gel	06/24/2010	12/28/2010	09/29/2010	Patrick Leroy
07082010@29	vet paste	06/28/2010	01/04/2011		Patrick Leroy
07092010@24	lactic acid 88% USP	01/30/2010	01/05/2011		Brian Komoto
	orange preserved water	04/29/2009	01/05/2011		Brian Komoto
	sorbitol soln USP 70%	07/30/2010	01/05/2011		Brian Komoto
07092010@25	Hyocyamine 0.125mg/0.1ml drops	12/27/2010	01/05/2011		Brian Komoto
07122010@27	testosterone / lactose trituration 10% pow	None provided (lot number indicates this product was made on 09/04/2009 by the pharmacy)	01/08/2011		Patrick Leroy
	base, PCCA emollient cream	11/30//2010	01/09/2011		Patrick Leroy

07122010@31	testosterone cypionate USP	11/21/2010	01/08/2011		Patrick Leroy
	benzyl benzonate USP	09/30/2010	01/08/2011		Patrick Leroy
	sesame oil NF	06/12/2010	01/08/2012		Partick Leroy
07122010@33	sulfadiazine excipients stock solution	08/23/2009	01/08/2011		Patrick Leroy
07132010@1	stevia liquid extract	09/30/2010	11/20/2010		Brian Komoto
07132010@2	lactose NF monohydrate	08/15/2010	01/09/2011		Patrick Leroy
07132010@6	stevia liquid extract	09/30/2010	11/20/2010		Patrick Leroy
07132010@8	methylcellulose USP	06/30/2009	01/09/2011		Patrick Leroy
07132010@9	syrup, simple flavored syrup	12/13/2008	01/09/2011		Patrick Leroy
	carboxymethylcellulose (preserved) 1% sol	08/07/2010	01/09/2011		Patrick Leroy
07132010@11	ABHR 1/12.5/2/10 gel	09/24/2008	10/11/2010		Patrick Leroy
	Haloperidiol 4mg/ml soln.	11/03/2008	10/11/2010		Patrick Leroy
	Hyoscyamine 0.125mg/0.1ml drop	11/26/2008	10/11/2010		Patrick Leroy
	Lorazepam anhydrous 1mg/0.1mg drop	09/07/2010	10/11/2010		Patrick Leroy
	morphine sulfate 5mg/0.1ml	11/12/2008	10/11/2010		Patrick Leroy
07132010@13	Syrup, simple flavored syrup	12/31/2008	9/11/2010		Patrick Leroy
07132010@15	benzyl benzoate USP	09/30/2010	01/9/2011		Patrick Leroy
07132010@21	butylatedhydroxy-toluene NF	05/30/2010	09/11/2010		Patrick Leroy
	emollient cream base	11/30/2008	09/11/2010		Patrick Leroy
07132010@22	lactose NF monohydrate	08/15/2010	01/09/2011		Patrick Leroy
07132010@23	pluronic F127 20% gel	08/24/2010	01/09/2011		Patrick Leroy
07132010@24	ethoxy diglycol agent	08/20/2010	01/09/2011		Patrick Leroy
07132010@25	Powdered sugar powder	03/31/2010	01/09/2011		Patrick Leroy
	Levothyroxine trituration 1:1000 powder	12/29/2010	01/09/2011		Patrick Leroy
07132010@26	Powdered sugar powder	03/31/2010	01/09/2011		Patrick Leroy
	Levothyroxine trituration 1:1000 powder	12/29/2010	01/09/2011		Patrick Leroy

07132010@27	aminophylline USP anhydrous	11/30/2010	01/09/2011		Patrick Leroy
	base, PCCA emollient cream	11/30//2010	01/09/2011		Patrick Leroy
07132010@32	lactose NF monohydrate	08/15/2010	01/09/2011		Patrick Leroy

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

28. Respondent Pharmacy and Leroy are subject to disciplinary action under section 4301, subdivisions (j) in that Respondents violated laws of other states. The circumstances are as follows:

29. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that between July 5, 2010 and July 7, 2010, Respondents provided 17 Legend products to customers in Arizona, New Mexico, Nevada, Texas, Oregon, Washington, New York and South Dakota without obtaining the proper pharmacy licenses from these states.

SEVENTH CAUSE FOR DISCIPLINE

(Compounding for Future Use-Beyond Use Dates)

30. Respondent Komoto is subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1735.2, subdivision (h) in that Respondent Komoto failed to give an expiration date representing the date beyond that it should not be used. The circumstances are as follows:

31. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondent Komoto allowed compounded products lot numbers 07092010@24, 07092010@25 and 07132010@1 to be assigned beyond dates use dates exceeding the expiration date of one of more ingredients.

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Lot number	Ingredient	Expiration date of raw ingredient	Assigned beyond use date of completed compound	Beyond use date on master formula if available	Pharmacist
07092010@24	lactic acid 88% USP	01/30/2010	01/05/2011		Brian Komoto
	orange preserved water	04/29/2009	01/05/2011		Brian Komoto
	sorbitol soln USP 70%	07/30/2010	01/05/2011		Brian Komoto
07092010@25	Hyocyamine 0.125mg/0.1ml drops	12/27/2010	01/05/2011		Brian Komoto
07132010@1	stevia liquid extract	09/30/2010	11/20/2010		Brian Komoto

EIGHTH CAUSE FOR DISCIPLINE

(Compounding for Future Use-Beyond Use Dates)

32. Respondent Leroy is subject to disciplinary action under section 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1735.2, subdivision (h) in that Respondent Leroy failed to give an expiration date representing the date beyond that it should not be used. The circumstances are as follows:

33. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection for Respondents' sterile compounding permit. The inspection revealed that Respondent Leroy allowed compounded products lot numbers 04302010@5 to be assigned beyond dates use dates exceeding the expiration date of one of more ingredients.

Lot number	Ingredient	Expiration date of raw ingredient	Assigned beyond use date of completed compound	Beyond use date on master formula if available	Pharmacist
04302010@5	benzyl benzoate USP	09/30/2010	10/27/2010	07/29/2010	Mike Adam Urmston
	sesame oil	06/12/2010	10/27/2010	07/29/2010	Mike Adam Urmston

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DISCIPLINE CONSIDERATIONS

34. To determine the degree of discipline, if any, to be imposed on Respondent Brian K. Komoto, Complainant alleges that on or about March 19, 2008, in a prior action, the Board of Pharmacy issued Citation Number CI 2007 35296 and ordered Respondent Komoto to pay a citation fine of $1,200.00. 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 Original Pharmacy Permit Number PHY 46042, issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy;

2. Revoking or suspending Licensed Sterile Compounding License Number 99071, issued to Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy;

3. Revoking or suspending Original Pharmacist License Number RPH 36353, issued to Brian K. Komoto;

4. Revoking or suspending Original Pharmacist License Number RPH 58396, issued to Patrick Nelson Leroy;

5. Ordering Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy, Brian K. Komoto and Patrick Nelson Leroy 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.

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DATED: 5/8/14

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

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