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8 **BEFORE THE**  
**BOARD OF PHARMACY**  
9 **DEPARTMENT OF CONSUMER AFFAIRS**  
10 **STATE OF CALIFORNIA**

11 In the Matter of the Second Amended  
Accusation Against:

Case No. 4642

12 **OPTIMAL PHARMACIES INC. dba**  
13 **KOMOTO CUSTOM CARE PHARMACY**  
14 **(formerly Optimal Compounding**  
**Pharmacy); BRIAN K. KOMOTO,**  
15 **President; MARY KOMOTO, Secretary;**  
16 **PATRICK NELSON LEROY,**  
**PHARMACIST-IN-CHARGE (from July 5,**  
17 **2007 to November 10, 2014), KIRK**  
**FORREST SAKAMOTO, PHARMACIST-**  
18 **IN-CHARGE (from November 10, 2014 to**  
**Present)**  
19 **2110 Truxtun Avenue, Suite #300**  
**Bakersfield, CA 93301**  
20 **Original Pharmacy Permit No. PHY 46042**  
**Licensed Sterile Compounding License No.**  
**LSC 99071**

**SECOND AMENDED ACCUSATION**

21 **BRIAN K. KOMOTO**  
22 **1017 Ellington Street**  
**Delano, CA 93215**  
23 **Original Pharmacist License No. RPH 36353**

24 **PATRICK NELSON LEROY**  
**2110 Truxtun Avenue, Suite #300**  
**Bakersfield, CA 93301**  
25 **Original Pharmacist License No. RPH 58396**

26 and

27

28

1 **KIRK FORREST SAKAMOTO**  
2 **1017 Ellington Street**  
3 **Delano, CA 93215**  
4 **Original Pharmacist License No. RPH 35651**

5 Respondents.

6 Complainant alleges:

7 **PARTIES**

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

11 **Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy**

12 **Original Pharmacy Permit**

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

19 **Licensed Sterile Compounding License**

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

24 **Brian K. Komoto**

25 **Original Pharmacist License**

26 4. On or about August 13, 1981, the Board of Pharmacy issued Original Pharmacist  
27 License Number RPH 36353 to Brian K. Komoto (Respondent Komoto). The Original  
28 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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1 **Patrick Nelson Leroy**

2 **Original Pharmacist License**

3 5. On or about July 26, 2006, the Board of Pharmacy issued Original Pharmacist  
4 License Number RPH 58396 to Patrick Nelson Leroy (Respondent Leroy). The Original  
5 Pharmacist License was in full force and effect at all times relevant herein and will expire on June  
6 30, 2018, unless renewed.

7 **Kirk Forrest Sakamoto**

8 **Original Pharmacist License**

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

13 **JURISDICTION**

14 7. This Second Amended Accusation is brought before the Board of Pharmacy (Board),  
15 Department of Consumer Affairs, under the authority of the following laws. All section  
16 references are to the Business and Professions Code unless otherwise indicated.

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

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

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

26 11. Section 4300.1 of the Code states:

27 "The expiration, cancellation, forfeiture, or suspension of a board-issued license by  
28 operation of law or by order or decision of the board or a court of law, the placement of a license

1 on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board  
2 of jurisdiction to commence or proceed with any investigation of, or action or disciplinary  
3 proceeding against, the licensee or to render a decision suspending or revoking the license."

4 **STATUTORY PROVISIONS**

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

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

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

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

16 14. Section 4301 of the Code states:

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

20 . . . .

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

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

25 . . . .

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

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

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

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

15 “(2) Where the license is denied or revoked, the prohibition shall continue until the license  
16 is issued or reinstated.”

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

18 “No person shall prescribe, administer, or furnish a controlled substance for himself.”

### 19 REGULATORY PROVISIONS

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

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

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

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

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

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

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

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

12 "(2) Altering the strength of a drug

13 "(3) Combining components or active ingredients

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

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

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

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

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

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

3 “...

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

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

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

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

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

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

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

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

28

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

3           “(5) Documentation of the methodology used to determine appropriate expiration dates for  
4 compounded drug products.”

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

7           “Name and concentrations of ingredients contained in the sterile injectable product.”

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

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

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

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

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

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

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



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

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

12 “....”

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

15 “... ”

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

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

22 “(A) Aseptic technique.

23 “(B) Pharmaceutical calculations and terminology.

24 “(C) Sterile product compounding documentation.

25 “(D) Quality assurance procedures.

26 “(E) Aseptic preparation procedures.

27 “(F) Proper gowning and gloving technique.

28 “(G) General conduct in he controlled area.

1 “(H) Cleaning, sanitizing, and maintaining equipment used in the controlled  
2 area.

3 “(I) Sterilization techniques.

4 “(J) Container, equipment, and closure system selection.

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

11 “....”

12 **COST RECOVERY**

13 25. Section 125.3 of the Code provides, in pertinent part, that the Board may request the  
14 administrative law judge to direct a licentiate found to have committed a violation or violations of  
15 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and  
16 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being  
17 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be  
18 included in a stipulated settlement.

19 **FIRST CAUSE FOR DISCIPLINE**

20 (Acting as a Manufacturer Without a Permit)

21 As to Respondent Pharmacy and Leroy

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

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

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

3 28. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for  
4 Respondents' sterile compounding permit. The inspection revealed that Respondents produced  
5 sterile compounded products for resale by "Systems North" identified as Integrated Care Systems.  
6 These compounded sterile injectable products were not sold to the ultimate consumer.  
7 Respondent Pharmacy and Leroy do not hold a manufacturing permit. Below are examples of the  
8 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/4meq/ml	4500	Systems North
9/30/2013	N00688800	Morphine sulfate 50mg/ml	1500	Systems North
10/2/2013	00660842	Sodium phosphates 3mmol/4meq/ml	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)

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

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

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

8                                           **THIRD CAUSE FOR DISCIPLINE**

9                                           (Pharmacy Practice-Orally transmitted Prescriptions)

10           32. Respondent Pharmacy and Leroy are subject to disciplinary action under section  
11 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section 1717,  
12 subdivision (c) in that Respondents failed to reduce an orally transmitted prescription to writing.  
13 The circumstances are as follows:

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

18                                           **FOURTH CAUSE FOR DISCIPLINE**

19                                           (Labeling Requirements for Injectable Products)

20           34. Respondent Pharmacy and Leroy are subject to disciplinary action under section  
21 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section  
22 1751.2, subdivision (b) in that Respondents failed to include the ingredients used in the sterile  
23 injectable product on the labels. The circumstances are as follows:

24           35. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection  
25 for Respondents' sterile compounding permit. The inspection revealed that Respondent  
26 Pharmacy and Leroy failed to have all of the ingredients used in lots numbers 03192010@7,  
27 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 powdr	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

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	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	Hyocyanine 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		Patrick 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
	Haloperidol 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

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

3 **SEVENTH CAUSE FOR DISCIPLINE**

4 (Compounding for Future Use-Beyond Use Dates)

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

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

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14 Lot number	Ingredient	Expiration date of raw ingredient	Assigned beyond use date of completed compound	Beyond use date on master formula if available	15 Pharmacist
16 07092010@24	lactic acid 88% USP	01/30/2010	01/05/2011		Brian Komoto
17	orange preserved water	04/29/2009	01/05/2011		Brian Komoto
18	sorbitol soln USP 70%	07/30/2010	01/05/2011		Brian Komoto
19 07092010@25	Hyocyanine 0.125mg/0.1ml drops	12/27/2010	01/05/2011		Brian Komoto
20 07132010@1	stevia liquid extract	09/30/2010	11/20/2010		Brian Komoto

21 **EIGHTH CAUSE FOR DISCIPLINE**

22 (Compounding for Future Use-Beyond Use Dates)

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

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



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

3	4	5	6	7	8
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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10 **NINTH CAUSE FOR DISCIPLINE**

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

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

16 45. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for  
17 Respondent Pharmacy's sterile compounding permit. This inspection revealed that Respondent  
18 Pharmacy and Respondent Leroy did not quarantine batch-produced compounded sterile  
19 injectable products such as sodium chloride 23.4% solution, lot number 05012014@53; copper  
20 glycinate 20%, lot number 02182014@26, and triamcinolone acetonide 6mg/ml, lot number  
21 06302014@13 until after the end product testing confirmed sterility and acceptable levels of  
22 pyrogens.

23 **TENTH CAUSE FOR DISCIPLINE**

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

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

1 that each person working in the designated area has the knowledge and skills necessary to  
2 perform their assigned tasks properly. Namely, California Code of Regulations, title 16, section  
3 1751.6, subdivision (e)(1). The required written program of training and performance evaluation  
4 must address the following: (A) Aseptic technique; (B) Pharmaceutical calculations and  
5 terminology; (C) Sterile product compounding documentation; (D) Quality assurance procedures;  
6 (E) Aseptic preparation procedures; (F) Proper gowning and gloving technique; (G) General  
7 conduct in the controlled area; (H) Cleaning, sanitizing and maintaining equipment used in the  
8 controlled area; (I) Sterilization techniques; and (J) Container, equipment, and closure selection.

9 The circumstances are as follows:

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

#### 14 **ELEVENTH CAUSE FOR DISCIPLINE**

15 (Failure to Train a Sterile Injectable Compounding Staff)

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

24 49. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for  
25 Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy  
26 and Respondent Leroy did not have completed training records for sterile compounding staff and  
27 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

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

5 **THIRTEENTH CAUSE FOR DISCIPLINE**

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

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

13 53. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for  
14 Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy  
15 and Respondent Leroy compounded 42 "prescriptions" for bevacizumab syringes. Komoto  
16 Custom Care Pharmacy compounded the 42 prescriptions of bevacizumab .05ml syringes from  
17 single dose vials of bevacizumab and failed to document the methodology used to establish a  
18 beyond use date that exceeded the manufacturer's and USP 797 guidelines. Respondent  
19 Pharmacy and Respondent Leroy also failed to document the methodology used to establish the  
20 90 day beyond use date given to compounded acetazolamide 100mg/ml injectable which  
21 exceeded the beyond use date of 14 days, or 28 days refrigerated established on the product's  
22 master formula.

23 **FOURTEENTH CAUSE FOR DISCIPLINE**

24 (Compounding Commercially Available Products without Documented Medical Need)

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

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

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

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11 56. The August 12, 2014 inspection further revealed that Respondent Pharmacy and  
12 Respondent Leroy compounded FDA approved the following commercially available products  
13 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

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

19 **FIFTEENTH CAUSE FOR DISCIPLINE**

20 (Compounding Commercially Available Products without Documented Medical Need)

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

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

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

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

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

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

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

9 **SIXTEENTH CAUSE FOR DISCIPLINE**

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

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

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

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

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1 **SEVENTEETH CAUSE FOR DISCIPLINE**

2 (Dispensing Controlled Substance Prescription Written for Self)

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

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

13

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

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1	02/21/2014	C00703728	N.Z.	buprenorphine	N.Z. DVM	30
	02/25/2014	C00704032	K.S.	stanozolol	K.S. DVM	30
2	03/06/2014	C00705129	K.J.	buprenorphine	K.J. DVM	30
	03/12/2014	C00705584	L. DVM	stanozolol	L. DVM	30
3	03/13/2014	C00705806	B.DVM	stanozolol	B.DVM	60
	04/02/2014	C00707860	K.J.	buprenorphine	K.J.	15
4	04/10/2014	C00708820	L., DVM	stanozolol	L., DVM	30
	04/14/2014	C00709207	D.V.	stanozolol	D.V. DVM	50
5	04/14/2014	C00709269	A. DVM	stanozolol	A.DVM	90
6	04/24/2014	C00710445	K.B.	testosterone cypionate	Bouldoukian, K	250
	04/25/2014	C00710655	K.S.	stanozolo	K.S. DVM	30
7	04/25/2014	C00710660	J.C.	stanozolol	J.C. DVM	30
	04/25/2014	C00710768	S.S.	stanozolol	S.S. DVM	90
8	04/25/2014	C00710769	S.S.	stanozolol	S.S. DVM	30
	05/06/2014	C00719900	T.F.	stanozolol	T.F. DVM	50
9	05/20/2014	C00713420	K.J.	buprenorphine	K.J. DVM	15
	05/30/2014	C00714673	A. DVM	stanozolol	A. DVM	90
10	06/02/2014	C00715019	N.Z.	buprenorphine	N.Z. DVM	60
	06/18/2014	C00717149	K.J.	buprenorphine	K.J. DVM	15
11	06/25/2014	C00717913	L.M.	stanozolol	Martin, Larry DVM	30
12	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 Statutes (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**

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

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

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

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

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

6 **DISCIPLINE CONSIDERATIONS**

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

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

17 71. To determine the degree of discipline, if any, to be imposed on Respondent Leroy,  
18 Complainant alleges that on or about August 29, 2013, in a prior action, the Board of Pharmacy  
19 issued Citation Number CI 2012 58065 and ordered Respondent Leroy to pay a citation fine of  
20 \$500.00. That Citation is now final and is incorporated by reference as if fully set forth.

21 **PRAYER**

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

24 1. Revoking or suspending Original Pharmacy Permit Number PHY 46042, issued to  
25 Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy;

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

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

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

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

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

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

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

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

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

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

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

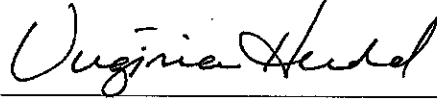
21           13. Prohibiting Kirk Forrest Sakamoto from serving as a manager, administrator, owner,  
22 member, officer, director, associate, or partner of a licensee for five years if Licensed Sterile  
23 Compounding License Number 99071 is placed on probation or until Licensed Sterile  
24 Compounding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

27           14. Ordering Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy, Brian K.  
28 Komoto, Patrick Nelson Leroy and Kirk Forrest Sakamoto to pay the Board of Pharmacy the

1 reasonable costs of the investigation and enforcement of this case, pursuant to Business and  
2 Professions Code section 125.3; and

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

4 DATED: 9/14/16



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

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E-mail: MichaelB.Brown@doj.ca.gov  
7 *Attorneys for Complainant*

8 **BEFORE THE**  
**BOARD OF PHARMACY**  
9 **DEPARTMENT OF CONSUMER AFFAIRS**  
10 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 4642

12 **OPTIMAL PHARMACIES INC. dba**  
**KOMOTO CUSTOM CARE PHARMACY**  
13 **(formerly Optimal Compounding**  
**Pharmacy); BRIAN K. KOMOTO,**  
14 **President; MARY KOMOTO, Secretary;**  
**PATRICK NELSON LEROY,**  
15 **PHARMACIST-IN- CHARGE**  
**2110 Truxtun Avenue, Suite #300**  
16 **Bakersfield, CA 93301**  
**Original Pharmacy Permit No. PHY 46042**  
17 **Licensed Sterile Compounding License No.**  
**LSC 99071**

**FIRST AMENDED ACCUSATION**

18 **BRIAN K. KOMOTO**  
19 **1017 Ellington Street**  
**Delano, CA 93215**  
20 **Original Pharmacist License No. RPH 36353**

21 and

22 **PATRICK NELSON LEROY**  
23 **2110 Truxtun Avenue, Suite #300**  
**Bakersfield, CA 93301**  
24 **Original Pharmacist License No. RPH 58396**

25 Respondents.

26 ///

27 ///

28 ///

1 Complainant alleges:

2 **PARTIES**

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

5 **Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy**

6 **Original Pharmacy Permit**

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

13 **Licensed Sterile Compounding License**

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

19 **Brian K. Komoto**

20 **Original Pharmacist License**

21 4. On or about August 13, 1981, the Board of Pharmacy issued Original Pharmacist  
22 License Number RPH 36353 to Brian K. Komoto (Respondent Komoto). The Original  
23 Pharmacist License was in full force and effect at all times relevant herein and will expire on July  
24 31, 2017, unless renewed.

25 **Patrick Nelson Leroy**

26 **Original Pharmacist License**

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

1 Pharmacist License was in full force and effect at all times relevant herein and will expire on June  
2 30, 2016, unless renewed.

3 **JURISDICTION**

4 6. This Accusation is brought before the Board of Pharmacy (Board), Department of  
5 Consumer Affairs, under the authority of the following laws. All section references are to the  
6 Business and Professions Code unless otherwise indicated.

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

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

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

16 10. Section 4300.1 of the Code states:

17 "The expiration, cancellation, forfeiture, or suspension of a board-issued license by  
18 operation of law or by order or decision of the board or a court of law, the placement of a license  
19 on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board  
20 of jurisdiction to commence or proceed with any investigation of, or action or disciplinary  
21 proceeding against, the licensee or to render a decision suspending or revoking the license."

22 **STATUTORY PROVISIONS**

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

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

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

28 ///



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

7           13. Section 4301 of the Code states:

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

11           ....

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

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

16           ....

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

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

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

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

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

5 “(2) Where the license is denied or revoked, the prohibition shall continue until the license  
6 is issued or reinstated.”

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

8 “No person shall prescribe, administer, or furnish a controlled substance for himself.”

9 **REGULATORY PROVISIONS**

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

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

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

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

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

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

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

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- “(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.”

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

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

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

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

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

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

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

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

19 “(5) Documentation of the methodology used to determine appropriate expiration dates for  
20 compounded drug products.”

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

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

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

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

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

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

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

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

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

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

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

28 “....”

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

3           “...

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

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

10                           “(A) Aseptic technique.

11                           “(B) Pharmaceutical calculations and terminology.

12                           “(C) Sterile product compounding documentation.

13                           “(D) Quality assurance procedures.

14                           “(E) Aseptic preparation procedures.

15                           “(F) Proper gowning and gloving technique.

16                           “(G) General conduct in the controlled area.

17                           “(H) Cleaning, sanitizing, and maintaining equipment used in the controlled  
18 area.

19                           “(I) Sterilization techniques.

20                           “(J) Container, equipment, and closure system selection.

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

27           “....”

28       ///

1 **COST RECOVERY**

2 24. Section 125.3 of the Code provides, in pertinent part, that the Board may request the  
3 administrative law judge to direct a licentiate found to have committed a violation or violations of  
4 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and  
5 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being  
6 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be  
7 included in a stipulated settlement.

8 **FIRST CAUSE FOR DISCIPLINE**

9 (Acting as a Manufacturer Without a Permit)

10 As to Respondent Pharmacy and Leroy

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

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

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

26

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

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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/4meq/ml	4500	Systems North
9/30/2013	N00688800	Morphine sulfate 50mg/ml	1500	Systems North
10/2/2013	00660842	Sodium phosphates 3mmol/4meq/ml	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,



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

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

7 **FOURTH CAUSE FOR DISCIPLINE**

8 (Labeling Requirements for Injectable Products)

9 33. Respondent Pharmacy and Leroy are subject to disciplinary action under section  
10 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section  
11 1751.2, subdivision (b) in that Respondents failed to include the ingredients used in the sterile  
12 injectable product on the labels. The circumstances are as follows:

13 34. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection  
14 for Respondents' sterile compounding permit. The inspection revealed that Respondent  
15 Pharmacy and Leroy failed to have all of the ingredients used in lots numbers 03192010@7,  
16 04302010@5, 06102010@22 and 06182010@8 included on the labels.

17 **FIFTH CAUSE FOR DISCIPLINE**

18 (Compounding for Future Use-Beyond Use Dates)

19 35. Respondent Pharmacy and Leroy are subject to disciplinary action under section  
20 4301, subdivisions (j) and (o) for violating California Code of Regulations, title 16, section  
21 1735.2, subdivision (h) in that Respondents failed to give an expiration date representing the date  
22 beyond that it should not be used. The circumstances are as follows:

23 36. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection  
24 for Respondents' sterile compounding permit. The inspection revealed that Respondents allowed  
25 compounded products lot numbers 03192010@7, 04302010@5, 06092010@24, 06102010@22,  
26 06182010@8, 07012010@15, 07082010@29, 07092010@24, 07092010@25, 07122010@27,  
27 07122010@31, 07122010@33, 07132010@1, 07132010@2, 07132010@6, 07132010@8,  
28 07132010@9, 07132010@11, 07132010@13, 07132010@15, 07132010@21, 07132010@22,

1 07132010@23, 07132010@24, 07132010@25, 07132010@26, 07132010@27, and  
 2 07132010@32, to be assigned beyond use dates exceeding the expiration date of one or more  
 3 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 powdr	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 powdr 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	Hyocyanine 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

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		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
	Haloperidol 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				
1	07132010@26	Powdered sugar powder	03/31/2010	01/09/2011	Patrick Leroy
2		Levothyroxine trituration 1:1000 powder	12/29/2010	01/09/2011	Patrick Leroy
3		aminophylline USP anhydrous	11/30/2010	01/09/2011	Patrick Leroy
4	07132010@27	base, PCCA emollient cream	11/30//2010	01/09/2011	Patrick Leroy
5		lactose NF monohydrate	08/15/2010	01/09/2011	Patrick Leroy
6	07132010@32				

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8 **SIXTH CAUSE FOR DISCIPLINE**

9 (Unprofessional Conduct)

10 37. Respondent Pharmacy and Leroy are subject to disciplinary action under section  
11 4301, subdivisions (j) in that Respondents violated laws of other states. The circumstances are as  
12 follows:

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

18 **SEVENTH CAUSE FOR DISCIPLINE**

19 (Compounding for Future Use-Beyond Use Dates)

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

24 40. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection  
25 for Respondents' sterile compounding permit. The inspection revealed that Respondent Komoto  
26 allowed compounded products lot numbers 07092010@24, 07092010@25 and 07132010@1 to  
27 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	Hyocyanine 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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1 **NINTH CAUSE FOR DISCIPLINE**

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

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

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

14 **TENTH CAUSE FOR DISCIPLINE**

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

17 45. Respondent Pharmacy and Leroy are subject to disciplinary action under California  
18 Code of Regulations, title 16, section 1751.6, subdivision (e)(1) in that Respondents failed to  
19 establish and follow a written program of training and performance evaluation designed to ensure  
20 that each person working in the designated area has the knowledge and skills necessary to  
21 perform their assigned tasks properly. Namely, California Code of Regulations, title 16, section  
22 1751.6, subdivision (e)(1). The required written program of training and performance evaluation  
23 must address the following: (A) Aseptic technique; (B) Pharmaceutical calculations and  
24 terminology; (C) Sterile product compounding documentation; (D) Quality assurance procedures;  
25 (E) Aseptic preparation procedures; (F) Proper gowning and gloving technique; (G) General  
26 conduct in the controlled area; (H) Cleaning, sanitizing and maintaining equipment used in the  
27 controlled area; (I) Sterilization techniques; and (J) Container, equipment, and closure selection.  
28 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

1	Olsen					4/1/14-PATT
2	Rovilyn Estanislao	TCH131775		04/07/14-ATE	6/23/14	06/10/14-OAT 04/07/14-PATT (incomplete documentation)
3	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)
4	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)

7 PATT= Personal Aseptic Technique (Media fill)  
8 ATE= Aseptic Technique Exam  
9 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)

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

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

**THIRTEENTH CAUSE FOR DISCIPLINE**

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

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



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

3 52. On or about August 12, 2014, a Board Inspector conducted a renewal inspection for  
4 Respondents' sterile compounding permit. This inspection revealed that Respondent Pharmacy  
5 and Respondent Leroy compounded 42 "prescriptions" for bevacizumab syringes. Komoto  
6 Custom Care Pharmacy compounded the 42 prescriptions of bevacizumab .05ml syringes from  
7 single dose vials of bevacizumab and failed to document the methodology used to establish a  
8 beyond use date that exceeded the manufacturer's and USP 797 guidelines. Respondent  
9 Pharmacy and Respondent Leroy also failed to document the methodology used to establish the  
10 90 day beyond use date given to compounded acetazolamide 100mg/ml injectable which  
11 exceeded the beyond use date of 14 days, or 28 days refrigerated established on the product's  
12 master formula.

13 **FOURTEENTH CAUSE FOR DISCIPLINE**

14 (Compounding Commercially Available Products without Documented Medical Need)

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

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

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

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1 55. The August 12, 2014 inspection further revealed that Respondent Pharmacy and  
 2 Respondent Leroy compounded FDA approved the following commercially available products  
 3 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

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

9 **FIFTEENTH CAUSE FOR DISCIPLINE**

10 (Dispensing Controlled Substance Prescription Written for Self)

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

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

Date	Rx Number	Patient	Controlled substance	Prescriber	Quantity
9/3/2013	C00685808	S.S.	stanazolol	S.S. DVM	150
9/3/2013	C00685810	S.S.	stanazolol	S.S. DVM	20
9/10/2013	C00686695	P.D.	stanazolol	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.	stanazolol	J.C. DVM	30
10/30/2013	C00691899	T.F.	stanazolol	T.F. DVM	50
10/31/2013	C00692051	P.A.	stanazolol	P.A. DVM	90
11/4/2013	C00692350	G.D.	stanazolol	G.D. DVM	50
11/13/2013	C00693399	K.J.	stanazolol	K.J. DVM	120
11/13/2013	C00693446	G.D.	stanazolol	G.D.	30

					DVM	
1	11/14/2013	C00693479	B.O.	testosterone	Bouldoukian, K. MD	225
	11/18/2013	C00693865	G.L.	buprenorphine	G.L.VMD	400
2	11/19/2013	C00683957	L.	stanozolol	L.	30
	11/20/2013	C00694066	J.R.	testosterone	J.R. DVM	100
3	11/20/2013	C00694135	N.Z.	buprenorphine	N.Z. DVM	30
	11/25/2013	C00693957	L.	stanozolol	L.	30
4	12/18/2013	C00696961	K.J.	buprenorphine	K.J. DVM	30
	12/20/2013	C00697149	K.S.	stanozolol	K.S. DVM	30
5	01/16/2014	C00699721	K.J.	buprenorphine	K.J. DVM	60
	01/31/2014	C00701454	B.O.	testosterone cypionate	Bouldoukian, K. MD	225
6	02/05/2014	C00702113	K.J.	buprenorphine	K.J. DVM	30
	02/15/2014	C00703059	S.S.	stanozolol	S.S. DVM	90
8	02/14/2014	C00702061	S.S.	stanozolol	S.S. DVM	30
	02/20/2014	C00703683	J.C.	stanozolol	J.C. DVM	30
9	02/21/2014	C00703728	N.Z.	buprenorphine	N.Z. DVM	30
	02/25/2014	C00704032	K.S.	stanozolol	K.S. DVM	30
10	03/06/2014	C00705129	K.J.	buprenorphine	K.J. DVM	30
	03/12/2014	C00705584	L. DVM	stanozolol	L. DVM	30
11	03/13/2014	C00705806	B.DVM	stanozolol	B.DVM	60
	04/02/2014	C00707860	K.J.	buprenorphine	K.J.	15
12	04/10/2014	C00708820	L., DVM	stanozolol	L., DVM	30
	04/14/2014	C00709207	D.V.	stanozolol	D.V. DVM	50
13	04/14/2014	C00709269	A. DVM	stanozolol	A.DVM	90
	04/24/2014	C00710445	K.B.	testosterone cypionate	Bouldoukian, K	250
14	04/25/2014	C00710655	K.S.	stanozolol	K.S. DVM	30
15	04/25/2014	C00710660	J.C.	stanozolol	J.C. DVM	30
	04/25/2014	C00710768	S.S.	stanozolol	S.S. DVM	90
16	04/25/2014	C00710769	S.S.	stanozolol	S.S. DVM	30
	05/06/2014	C00719900	T.F.	stanozolol	T.F. DVM	50
17	05/20/2014	C00713420	K.J.	buprenorphine	K.J. DVM	15
	05/30/2014	C00714673	A. DVM	stanozolol	A. DVM	90
18	06/02/2014	C00715019	N.Z.	buprenorphine	N.Z. DVM	60
	06/18/2014	C00717149	K.J.	buprenorphine	K.J. DVM	15
19	06/25/2014	C00717913	L.M.	stanozolol	Martin, Larry DVM	30
20	07/21/2014	C90000147	G.D.	stanozolol	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,*

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

3 59. The Conclusions of Law found violations of Colorado Revised Statutes (CRS) section  
4 12-42.5-123 for Unprofessional Conduct and section 12-42.5-303 for violations of Wholesaler  
5 License Requirements, as follows: Between March 1, 2011 and March 1, 2013, Respondent  
6 Pharmacy distributed 51 prescription drugs and controlled substances to licensed prescribers in  
7 Colorado in response to requests from those prescribers, but without prescription orders.

8 **OTHER MATTERS**

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

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

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

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

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

11 **DISCIPLINE CONSIDERATIONS**

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

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

22 66. To determine the degree of discipline, if any, to be imposed on Respondent Leroy,  
23 Complainant alleges that on or about August 29, 2013, in a prior action, the Board of Pharmacy  
24 issued Citation Number CI 2012 58065 and ordered Respondent Leroy to pay a citation fine of  
25 \$500.00. That Citation is now final and is incorporated by reference as if fully set forth.

26 **PRAYER**

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

1           1.     Revoking or suspending Original Pharmacy Permit Number PHY 46042, issued to  
2 Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy;

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

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

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

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

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

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

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

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

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

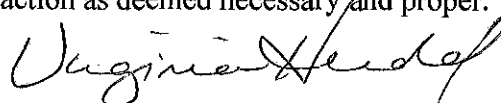
11 10. Prohibiting Patrick Nelson Leroy from serving as a manager, administrator, owner,  
12 member, officer, director, associate, or partner of a licensee for five years if Licensed Sterile  
13 Compounding License Number 99071 is placed on probation or until Licensed Sterile  
14 Compounding License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

17 11. Ordering Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy, Brian K.  
18 Komoto and Patrick Nelson Leroy to pay the Board of Pharmacy the reasonable costs of the  
19 investigation and enforcement of this case, pursuant to Business and Professions Code section  
20 125.3; and

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

22 DATED: \_\_\_\_\_

4/21/16



23 VIRGINIA HEROLD  
24 Executive Officer  
25 Board of Pharmacy  
26 Department of Consumer Affairs  
27 State of California  
28 *Complainant*

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7 *Attorneys for Complainant*

8 **BEFORE THE**  
**BOARD OF PHARMACY**  
9 **DEPARTMENT OF CONSUMER AFFAIRS**  
10 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 4642

12 **OPTIMAL PHARMACIES INC. dba**  
**KOMOTO CUSTOM CARE PHARMACY**  
13 **(formerly Optimal Compounding**  
**Pharmacy); BRIAN K. KOMOTO,**  
14 **President; MARY KOMOTO, Secretary;**  
**PATRICK NELSON LEROY,**  
15 **PHARMACIST-IN- CHARGE**  
**2110 Truxtun Avenue, Suite #300**  
16 **Bakersfield, CA 93301**  
**Original Pharmacy Permit No. PHY 46042**  
17 **Licensed Sterile Compounding License No.**  
**LSC 99071**

**A C C U S A T I O N**

18 **BRIAN K. KOMOTO**  
19 **1017 Ellington Street**  
**Delano, CA 93215**  
20 **Original Pharmacist License No. RPH 36353**

21 **and**

22 **PATRICK NELSON LEROY**  
**2110 Truxtun Avenue, Suite #300**  
23 **Bakersfield, CA 93301**  
24 **Original Pharmacist License No. RPH 58396**

25 Respondents.

26 ///

27 ///

28 ///



1 Complainant alleges:

2 **PARTIES**

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

5 **Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy**

6 **Original Pharmacy Permit**

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

13 **Licensed Sterile Compounding License**

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

19 **Brian K. Komoto**

20 **Original Pharmacist License**

21 4. On or about August 13, 1981, the Board of Pharmacy issued Original Pharmacist  
22 License Number RPH 36353 to Brian K. Komoto (Respondent Komoto). The Original  
23 Pharmacist License was in full force and effect at all times relevant herein and will expire on July  
24 31, 2015, unless renewed.

25 **Patrick Nelson Leroy**

26 **Original Pharmacist License**

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

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

3 **JURISDICTION**

4 6. This Accusation is brought before the Board of Pharmacy (Board), Department of  
5 Consumer Affairs, under the authority of the following laws. All section references are to the  
6 Business and Professions Code unless otherwise indicated.

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

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

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

16 10. Section 4300.1 of the Code states:

17 "The expiration, cancellation, forfeiture, or suspension of a board-issued license by  
18 operation of law or by order or decision of the board or a court of law, the placement of a license  
19 on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board  
20 of jurisdiction to commence or proceed with any investigation of, or action or disciplinary  
21 proceeding against, the licensee or to render a decision suspending or revoking the license."

22 **STATUTORY PROVISIONS**

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

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

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

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

7 13. Section 4301 of the Code states:

8 "The board shall take action against any holder of a license who is guilty of unprofessional  
9 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

10 Unprofessional conduct shall include, but is not limited to, any of the following:

11 . . . .

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

14 . . . .

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

19 **REGULATORY PROVISIONS**

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

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

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

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

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

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

14 **COST RECOVERY**

15 17. Section 125.3 of the Code provides, in pertinent part, that the Board may request the  
16 administrative law judge to direct a licentiate found to have committed a violation or violations of  
17 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and  
18 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being  
19 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be  
20 included in a stipulated settlement.

21 **FIRST CAUSE FOR DISCIPLINE**

22 (Acting as a Manufacturer Without a Permit)

23 As to Respondent Pharmacy and Leroy

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

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1 **FOURTH CAUSE FOR DISCIPLINE**

2 (Labeling Requirements for Injectable Products)

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

7 25. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection  
8 for Respondents' sterile compounding permit. The inspection revealed that Respondent  
9 Pharmacy and Leroy failed to have all of the ingredients used in lots numbers 03192010@7,  
10 04302010@5, 06102010@22 and 06182010@8 included on the labels.

11 **FIFTH CAUSE FOR DISCIPLINE**

12 (Compounding for Future Use-Beyond Use Dates)

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

17 27. On or about July 13 and 14, 2011, a Board Inspector conducted a renewal inspection  
18 for Respondents' sterile compounding permit. The inspection revealed that Respondents allowed  
19 compounded products lot numbers 03192010@7, 04302010@5, 06092010@24, 06102010@22,  
20 06182010@8, 07012010@15, 07082010@29, 07092010@24, 07092010@25, 07122010@27,  
21 07122010@31, 07122010@33, 07132010@1, 07132010@2, 07132010@6, 07132010@8,  
22 07132010@9, 07132010@11, 07132010@13, 07132010@15, 07132010@21, 07132010@22,  
23 07132010@23, 07132010@24, 07132010@25, 07132010@26, 07132010@27, and  
24 07132010@32, to be assigned beyond use dates exceeding the expiration date of one or more  
25 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	Hyocyanine 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

1	07122010@31	testosterone cypionate USP	11/21/2010	01/08/2011		Patrick Leroy
2		benzyl benzonate USP	09/30/2010	01/08/2011		Patrick Leroy
3		sesame oil NF	06/12/2010	01/08/2012		Patrick Leroy
4	07122010@33	sulfadiazine excipients stock solution	08/23/2009	01/08/2011		Patrick Leroy
5	07132010@1	stevia liquid extract	09/30/2010	11/20/2010		Brian Komoto
6	07132010@2	lactose NF monohydrate	08/15/2010	01/09/2011		Patrick Leroy
7	07132010@6	stevia liquid extract	09/30/2010	11/20/2010		Patrick Leroy
8	07132010@8	methylcellulose USP	06/30/2009	01/09/2011		Patrick Leroy
9	07132010@9	syrup, simple flavored syrup	12/13/2008	01/09/2011		Patrick Leroy
10		carboxymethylcellulose (preserved) 1% sol	08/07/2010	01/09/2011		Patrick Leroy
11	07132010@11	ABHR 1/12.5/2/10 gel	09/24/2008	10/11/2010		Patrick Leroy
12		Haloperidol 4mg/ml soln.	11/03/2008	10/11/2010		Patrick Leroy
13		Hyoscyamine 0.125mg/0.1ml drop	11/26/2008	10/11/2010		Patrick Leroy
14		Lorazepam anhydrous 1mg/0.1mg drop	09/07/2010	10/11/2010		Patrick Leroy
15		morphine sulfate 5mg/0.1ml	11/12/2008	10/11/2010		Patrick Leroy
16	07132010@13	Syrup, simple flavored syrup	12/31/2008	9/11/2010		Patrick Leroy
17	07132010@15	benzyl benzoate USP	09/30/2010	01/9/2011		Patrick Leroy
18	07132010@21	butylatedhydroxy- toluene NF	05/30/2010	09/11/2010		Patrick Leroy
19		emollient cream base	11/30/2008	09/11/2010		Patrick Leroy
20						
21	07132010@22	lactose NF monohydrate	08/15/2010	01/09/2011		Patrick Leroy
22	07132010@23	pluronic F127 20% gel	08/24/2010	01/09/2011		Patrick Leroy
23	07132010@24	ethoxy diglycol agent	08/20/2010	01/09/2011		Patrick Leroy
24	07132010@25	Powdered sugar powder	03/31/2010	01/09/2011		Patrick Leroy
25		Levothyroxine trituration 1:1000 powder	12/29/2010	01/09/2011		Patrick Leroy
26	07132010@26	Powdered sugar powder	03/31/2010	01/09/2011		Patrick Leroy
27		Levothyroxine trituration 1:1000 powder	12/29/2010	01/09/2011		Patrick Leroy
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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	Hyocyanine 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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1 **DISCIPLINE CONSIDERATIONS**

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

7 **PRAYER**

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

10 1. Revoking or suspending Original Pharmacy Permit Number PHY 46042, issued to  
11 Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy;

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

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

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

18 5. Ordering Optimal Pharmacies Inc. dba Komoto Custom Care Pharmacy, Brian K.  
19 Komoto and Patrick Nelson Leroy to pay the Board of Pharmacy the reasonable costs of the  
20 investigation and enforcement of this case, pursuant to Business and Professions Code section  
21 125.3; and

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

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DATED:

5/8/14

*Virginia Herold*

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

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