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

11 In the Matter of the Accusation Against:

Case No. 6068

12 **ANIMAL SOLUTIONS PHARMACY**
13 **INC.; CLARA FRANCES BROWN,**
OWNER

OAH No. 2017100614

14 **4775 Sonoma Hwy**
15 **Santa Rosa, CA 95409**

FIRST AMENDED ACCUSATION

16 **Pharmacy Permit No. PHY 51088 (Expired**
9/27/16; cancelled 9/28/16)

17 **ANIMAL SOLUTIONS PHARMACY**
18 **INC.; CLARA FRANCES BROWN,**
OWNER

19 **3313 Stony Point Rd.**
Santa Rosa, CA 95407

20 **Pharmacy Permit No. PHY 54438**

21 **CLARA FRANCES BROWN**
22 **3313 Stony Point Rd.**
Santa Rosa, CA 95407

23 **Pharmacist License No. RPH 37924**

24 **CHRISTOPHER ARTHUR NEWELL**
25 **971 Puget Dr. E**
Port Orchard, WA 98366

26 **Pharmacist License No. RPH 44486**

27 Respondents.
28

1 Complainant alleges:

2 PARTIES

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

6 2. On or about March 28, 2013, the Board of Pharmacy (“Board”) issued Pharmacy
7 Permit Number PHY 51088 to Animal Solutions Pharmacy Inc. (“Respondent Animal
8 Solutions”). Pharmacy Permit Number PHY 51088 expired on September 27, 2016, was
9 cancelled on September 28, 2016, and has not been renewed. On or about September 27, 2016,
10 the Board issued Pharmacy Permit Number PHY 54438 to Respondent Animal Solutions.
11 Pharmacy Permit Number PHY 54438 is in full force and effect, and will expire on September 1,
12 2018, unless renewed.

13 3. On or about September 6, 1983, the Board issued Pharmacist License Number RPH
14 37924 to Clara Frances Brown (“Respondent Brown”). The Pharmacist License was in full force
15 and effect at all times relevant to the charges brought in this First Amended Accusation and will
16 expire on July 31, 2019, unless renewed. Between March 28, 2013 and September 28, 2016,
17 Respondent Brown was the President, Sole Owner, Secretary, and Treasurer/Chief Financial
18 Officer of Respondent Animal Solutions. At all times relevant to the charges brought in this First
19 Amended Accusation against her, Respondent Brown functioned as Respondent Animal
20 Solution’s Pharmacist-in-Charge (“PIC”).

21 4. On or about August 9, 1991, the Board issued Pharmacist License Number RPH
22 44486 to Christopher Arthur Newell (“Respondent Newell”). The Pharmacist License was in full
23 force and effect at all times relevant to the charges brought in First Amended Accusation and will
24 expire on October 31, 2018, unless renewed. At all times relevant to the charges brought in this
25 First Amended Accusation against him, Respondent Newell was employed as a pharmacist at
26 Respondent Animal Solutions.

27 ////

28 ////

JURISDICTION

1
2 5. This First Amended Accusation is brought before the Board of Pharmacy,
3 Department of Consumer Affairs, under the authority of the following laws. All section
4 references are to the Business and Professions Code unless otherwise indicated.

5 6. **Section 118, subdivision (b)** states:

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

13 7. **Section 4300** of states, in part:

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

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

18 “(1) Suspending judgment.

19 “(2) Placing him or her upon probation.

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

21 “(4) Revoking his or her license.

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

24 ...

25 “(e) The proceedings under this article shall be conducted in accordance with Chapter 5
26 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board
27 shall have all the powers granted therein. The action shall be final, except that the propriety of
28

1 the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of
2 Civil Procedure.”

3 8. **Section 4307** of states, in part:

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

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

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

19”

20 RELEVANT STATUTES AND REGULATIONS

21 9. **Section 4301, subdivision (q)** states:

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

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

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28 ////

1 10. **Section 4038, subdivision (b)** states:

2 “(b) A “pharmacy technician trainee” is a person who is enrolled in a pharmacy technician
3 training program operated by a California public postsecondary education institution or by a
4 private postsecondary vocational institution approved by the Bureau for Private Postsecondary
5 and Vocational Education.”

6 11. **Section 4113, subdivision (c)** states:

7 “(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all
8 state and federal laws and regulations pertaining to the practice of pharmacy.”

9 12. **Section 4115, subdivisions (b) and (e)** state:

10 “(b) This section does not authorize the performance of any tasks specified in subdivision
11 (a) by a pharmacy technician without a pharmacist on duty.

12 ...

13 “(e) A person shall not act as a pharmacy technician without first being licensed by the
14 board as a pharmacy technician.

15 ”

16 13. **Section 4115.5** states, in part:

17 ...

18 “[(b)](5) A pharmacist supervising a pharmacy technician trainee participating in an
19 externship as described in subdivision (a) shall certify attendance for the pharmacy technician
20 trainee and certify that the pharmacy technician trainee has met the educational objectives
21 established by a California public postsecondary education institution or the private
22 postsecondary vocational institution in which the trainee is enrolled, as established by the
23 institution.

24 “(c)(1) Except as described in paragraph (2), an externship in which a pharmacy technician
25 trainee is participating as described in subdivision (a) shall be for a period of no more than 120
26 hours.

27 ”

28 /////

1 14. **Section 4342, subdivision (a)** states:

2 “(a) The board may institute any action or actions as may be provided by law and that, in its
3 discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not
4 conform to the standard and tests as to quality and strength, provided in the latest edition of the
5 United States Pharmacopoeia or the National Formulary, or that violate any provision of the
6 Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division
7 104 of the Health and Safety Code).”

8 15. **Health & Safety Code section 111250** states:

9 “Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or
10 decomposed substance.”

11 16. **Health & Safety Code section 111295** states:

12 “‘It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug
13 or device that is adulterated.”

14 17. **Health & Safety Code section 11165, subdivision (d)** states:

15 “(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled
16 substance, as defined in the controlled substances schedules in federal law and regulations,
17 specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of
18 Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following
19 information to the Department of Justice as soon as reasonably possible, but not more than seven
20 days after the date a controlled substance is dispensed, in a format specified by the Department of
21 Justice:

22 “(1) Full name, address, and, if available, telephone number of the ultimate user or research
23 subject, or contact information as determined by the Secretary of the United States Department of
24 Health and Human Services, and the gender, and date of birth of the ultimate user.

25 “(2) The prescriber’s category of licensure, license number, national provider identifier
26 (NPI) number, if applicable, the federal controlled substance registration number, and the state
27 medical license number of any prescriber using the federal controlled substance registration
28 number of a government-exempt facility.

1 “(3) Pharmacy prescription number, license number, NPI number, and federal controlled
2 substance registration number.

3 “(4) National Drug Code (NDC) number of the controlled substance dispensed.

4 “(5) Quantity of the controlled substance dispensed.

5 “(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th
6 revision (ICD-10) Code, if available.

7 “(7) Number of refills ordered.

8 “(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

9 “(9) Date of origin of the prescription.

10 “(10) Date of dispensing of the prescription.”

11 **18. Code of Regulations, title 16, section 1714, subdivision (d) states:**

12 “(d) Each pharmacist while on duty shall be responsible for the security of the prescription
13 department, including provisions for effective control against theft or diversion of dangerous
14 drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy
15 where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.”

16 **19. Code of Regulations, title 16, section 1718 states:**

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

20 “The controlled substances inventories required by Title 21, CFR, Section 1304 shall be
21 available for inspection upon request for at least 3 years after the date of the inventory.”

22 **20. Code of Regulations, title 16, section 1735.3, subdivisions (b) and (c) state:**

23 ...

24 “(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of
25 chemicals, bulk drug substances, drug products, and components used in compounding.

26 “(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug
27 Administration (FDA). All other chemicals, bulk drug substances, and drug products used to
28 compound drug preparations shall be obtained, whenever possible, from FDA- registered

1 suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in
2 English or translated into English, for chemicals, bulk drug substances, and drug products used in
3 compounding. Certificates of purity or analysis are not required for drug products that are
4 approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be
5 matched to the corresponding chemical, bulk drug substance, or drug products received.

6”

7 21. **Code of Regulations, title 16, section 1735.5, subdivision (b)** states:

8 “(b) The policies and procedures shall be reviewed and such review shall be documented on
9 an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated
10 whenever changes in policies and procedures are implemented.”

11 22. **Code of Regulations, title 16, section 1735.6** states, in part:

12 “(a) Any pharmacy engaged in compounding shall maintain written documentation
13 regarding the facilities and equipment necessary for safe and accurate compounding of
14 compounded drug preparations. This shall include records of maintenance and cleaning of the
15 facilities and equipment. Where applicable, this shall also include records of certification(s) of
16 facilities or equipment.

17 “(b) Any equipment used to compound drug preparations shall be stored, used, maintained,
18 and cleaned in accordance with manufacturers' specifications.

19 “(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug
20 preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on
21 a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy.
22 Documentation of each such calibration shall be recorded in a form which is not alterable and
23 these records of calibration shall be maintained and retained in the pharmacy.

24”

25 23. **Code of Regulations, title 16, section 1735.7** provides, in part:

26 “(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that
27 personnel involved in compounding have the skills and training required to properly and
28 accurately perform their assigned responsibilities and documentation demonstrating that all

1 personnel involved in compounding are trained in all aspects of policies and procedures. This
2 training shall include but is not limited to support personnel (e.g. institutional environmental
3 services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are
4 related to the compounding process.

5 “(b) The pharmacy shall develop and maintain an on-going competency evaluation process
6 for pharmacy personnel involved in compounding, and shall maintain documentation of any and
7 all training related to compounding undertaken by pharmacy personnel.

8”

9 24. **Code of Regulations, title 16, section 1735.8** provides, in part:

10 “(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies
11 and procedures, a written quality assurance plan designed to monitor and ensure the integrity,
12 potency, quality, and labeled strength of compounded drug preparations.

13 “(b) The quality assurance plan shall include written procedures for verification,
14 monitoring, and review of the adequacy of the compounding processes and shall also include
15 written documentation of review of those processes by qualified pharmacy personnel.

16 “(c) The quality assurance plan shall include written standards for qualitative and
17 quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and
18 labeled strength, including the frequency of testing. All qualitative and quantitative analysis
19 reports for compounded drug preparations shall be retained by the pharmacy and maintained
20 along with the compounding log and master formula document. The quality assurance plan shall
21 include a schedule for routine testing and analysis of specified compounded drug preparations to
22 ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

23 “(d) The quality assurance plan shall include a written procedure for scheduled action in the
24 event any compounded drug preparation is ever discovered to be outside minimum standards for
25 integrity, potency, quality, or labeled strength.

26”

27 ////

28 ////

1 25. **Code of Regulations, title 16, section 1793.2** states:

2 “‘Nondiscretionary tasks’ as used in Business and Professions Code section 4115, include:

3 “(a) removing the drug or drugs from stock;

4 “(b) counting, pouring, or mixing pharmaceuticals;

5 “(c) placing the product into a container;

6 “(d) affixing the label or labels to the container;

7 “(e) packaging and repackaging.”

8 26. **Code of Regulations, title 16, section 1793.6** states:

9 “A course of training that meets the requirements of Business and Professions Code section
10 4202(a)(2) is:

11 “(a) Any pharmacy technician training program accredited by the American Society of
12 Health-System Pharmacists,

13 “(b) Any pharmacy technician training program provided by a branch of the federal armed
14 services for which the applicant possesses a certificate of completion, or

15 “(c) Any other course that provides a training period of at least 240 hours of instruction
16 covering at least the following:

17 “(1) Knowledge and understanding of different pharmacy practice settings.

18 “(2) Knowledge and understanding of the duties and responsibilities of a pharmacy
19 technician in relationship to other pharmacy personnel and knowledge of standards and ethics,
20 laws and regulations governing the practice of pharmacy.

21 “(3) Knowledge and ability to identify and employ pharmaceutical and medical terms,
22 abbreviations and symbols commonly used in prescribing, dispensing and record keeping of
23 medications.

24 “(4) Knowledge of and the ability to carry out calculations required for common dosage
25 determination, employing both the metric and apothecary systems.

26 “(5) Knowledge and understanding of the identification of drugs, drug dosages, routes of
27 administration, dosage forms and storage requirements.

28

1 “(6) Knowledge of and ability to perform the manipulative and record-keeping functions
2 involved in and related to dispensing prescriptions.

3 “(7) Knowledge of and ability to perform procedures and techniques relating to
4 manufacturing, packaging, and labeling of drug products.”

5 **27. Code of Regulations, title 16, section 1793.7, subdivision (b)** states:

6 “(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in
7 such a relationship that the supervising pharmacist is fully aware of all activities involved in the
8 preparation and dispensing of medications, including the maintenance of appropriate records.”

9 **28. Code of Federal Regulations, title 21, section 1304.11** states, in part:

10 “(a) General requirements. Each inventory shall contain a complete and accurate record of
11 all controlled substances on hand on the date the inventory is taken, and shall be maintained in
12 written, typewritten, or printed form at the registered location. An inventory taken by use of an
13 oral recording device must be promptly transcribed. Controlled substances shall be deemed to be
14 “on hand” if they are in the possession of or under the control of the registrant, including
15 substances returned by a customer, ordered by a customer but not yet invoiced, stored in a
16 warehouse on behalf of the registrant, and substances in the possession of employees of the
17 registrant and intended for distribution as complimentary samples. A separate inventory shall be
18 made for each registered location and each independent activity registered, except as provided in
19 paragraph (e)(4) of this section. In the event controlled substances in the possession or under the
20 control of the registrant are stored at a location for which he/she is not registered, the substances
21 shall be included in the inventory of the registered location to which they are subject to control or
22 to which the person possessing the substance is responsible. The inventory may be taken either as
23 of opening of business or as of the close of business on the inventory date and it shall be indicated
24 on the inventory.

25 ...

26 “(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a
27 new inventory of all stocks of controlled substances on hand at least every two years. The
28

1 biennial inventory may be taken on any date which is within two years of the previous biennial
2 inventory date.

3”

4 COST RECOVERY

5 29. Section 125.3 provides, in part, that the Board may request the administrative law
6 judge to direct a licensee found to have committed a violation or violations of the licensing act to
7 pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

8 FIRST CAUSE FOR DISCIPLINE

9 (Failure to Secure Pharmacy)

10 (Cal. Code of Regs., title 16, § 1714, subd. (d))

11 (Respondents Animal Solutions Pharmacy and Brown)

12 30. Respondents Animal Solutions and Brown have subjected their Pharmacy Permits
13 and Pharmacist License, respectively, to disciplinary action for failing to secure the prescription
14 department, including restricting access to the key to the pharmacy. (Cal. Code of Regs., title 16,
15 § 1714, subd. (d)). In particular:

16 a. During a February 3, 2016 inspection, a Board inspector discovered that an
17 Animal Solutions pharmacist allowed a pharmacy technician, G.C., access to the key to the
18 licensed pharmacy space and G.C. entered when no pharmacist was present.

19 b. During a February 3, 2016 inspection, a Board inspector discovered a pharmacist
20 allowed storage of prescriptions to be dispensed in a drawer which was not located in the licensed
21 pharmacy.

22 SECOND CAUSE FOR DISCIPLINE

23 (Non-Licensed Individual Acting as Pharmacist Technician Without Supervision)

24 (Bus. & Prof. Code § 4115, subs. (b) and (e); and

25 Cal. Code of Regs., title 16, §§ 1793.2 and 1793.7, subd. (b))

26 (Respondents Animal Solutions Pharmacy, Brown, and Newell)

27 31. Respondents Animal Solutions, Brown, and Newell have subjected their Pharmacy
28 Permits and Pharmacists Licenses, respectively, to disciplinary action for permitting a non-
licensed individual to act as a pharmacy technician without the supervision of a pharmacist. (Bus.
& Prof. Code § 4115, subs. (b) and (e); and Cal. Code of Regs., title 16, §§ 1793.2 and 1793.7,
subd. (b)). In particular, during a February 3, 2016 inspection, Respondents allowed a non-

1 licensed individual, G.C., to let herself into the pharmacy with a pharmacist's key and perform
2 technician tasks without the supervision of a pharmacist. These tasks included removing drugs
3 from stock, weighing drugs on a balance, mixing pharmaceuticals, and placing the product into a
4 container. Respondent Brown also approved compounded products made by G.C. and H.K., two
5 unlicensed individuals, who worked at the pharmacy as pharmacy technicians without pharmacist
6 supervision.

7 THIRD CAUSE FOR DISCIPLINE

8 (Certifications and Approvals for Trainee Program)
9 (Bus. & Prof. Code §§ 4038, subd. (b) and 4115.5, subd. (b)(5) and (c)(1); and
10 Cal. Code of Regs., title 16, § 1793.6)
11 (Respondents Animal Solutions Pharmacy and Brown)

12 32. Respondents Animal Solutions and Brown have subjected their Pharmacy Permits
13 and Pharmacist License, respectively, to disciplinary action for having a non-licensed individual
14 scheduled to work at the pharmacy as a "technician trainee" without documenting the alleged
15 trainee's attendance, the trainee's meeting educational objectives, and without establishing a
16 approved and compliant training program. (Bus. & Prof. Code §§ 4038, subd. (b) and 4115.5,
17 subd. (b)(5) and (c)(1); and Cal. Code of Regs., title 16, § 1793.6). In particular, during a
18 February 3, 2016 inspection, a Board inspector learned that the pharmacy had G.C., a non-
19 licensed individual, scheduled to work as a "technician trainee" without having any paperwork to
20 show enrollment in any approved technician training program. G.C. opened the pharmacy and
21 went to work without a pharmacist on duty. G.C. had worked at the pharmacy as a technician
22 trainee for over 14 months.

23 FOURTH CAUSE FOR DISCIPLINE

24 (Failing to Conduct and Document Annual Policy and Procedure Review)
25 (Cal. Code of Regs., title 16, § 1735.5, subd. (b))
26 (Respondents Animal Solutions Pharmacy and Brown)

27 33. Respondents Animal Solutions and Brown have subjected their Pharmacy Permits
28 and Pharmacist License, respectively, to disciplinary action for failing to review and document,
on an annual basis, the pharmacy's policies and procedures. (Cal. Code of Regs., title 16, §
1735.5, subd. (b)). In particular, during a February 3, 2016 inspection, a Board inspector found

1 that the pharmacy lacked any evidence of an annual review of compounding policies and
2 procedures.

3
4 FIFTH CAUSE FOR DISCIPLINE

(Documentation and Calibration of Compounding Equipment)
(Cal. Code of Regs., title 16, § 1735.6, subds. (a), (b), and (c))
5 (Respondents Animal Solutions Pharmacy and Brown)

6 34. Respondents Animal Solutions and Brown have subjected their Pharmacy Permits
7 and Pharmacist License, respectively, to disciplinary action for failing to maintain written
8 documentation regarding the facilities and equipment necessary for safe and accurate
9 compounding of compounded drug preparations and failing to maintain and calibrate
10 compounding equipment. (Cal. Code of Regs., title 16, § 1735.6, subds. (a), (b), and (c)). In
11 particular, during a February 3, 2016 inspection, a Board inspector discovered that the pharmacy
12 lacked documentation of certification, maintenance, or proper storage regarding the equipment
13 used for compounding. In addition, the pharmacy's scale lacked documentation of daily
14 calibration.

15
16 SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Written Quality Assurance Plan)
(Cal. Code of Regs., title 16, § 1735.8, subds. (a), (b), (c), and (d))
17 (Respondents Animal Solutions Pharmacy and Brown)

18 35. Respondents Animal Solutions and Brown have subjected their Pharmacy Permits
19 and Pharmacist License, respectively, to disciplinary action for failing to maintain a written
20 quality assurance plan. (Cal. Code of Regs., title 16, § 1735.8, subds. (a), (b), (c), and (d)). In
21 particular, during a February 3, 2016 inspection, a Board inspector discovered that the pharmacy
22 lacked any written quality assurance program for compounded products.

23
24 SEVENTH CAUSE FOR DISCIPLINE

(Failure to Document Training and Competency)
(Cal. Code of Regs., title 16, § 1735.7, subds. (a) and (b))
25 (Respondents Animal Solutions Pharmacy and Brown)

26 36. Respondents Animal Solutions and Brown have subjected their Pharmacy Permits
27 and Pharmacist License, respectively, to disciplinary action for failing to maintain documentation
28 demonstrating that personnel involved in compounding have the skills and training required to

1 properly and accurately perform their assigned responsibilities and documentation demonstrating
2 that all personnel involved in compounding are trained in all aspects of policies and procedures,
3 as well as failing to develop and maintain an on-going competency evaluation process for
4 pharmacy personnel involved in compounding and maintain documentation of any and all
5 training related to compounding undertaken by pharmacy personnel. (Cal. Code of Regs., title
6 16, § 1735.7, subds. (a) and (b)). In particular, during a February 3, 2016 inspection, a Board
7 inspector discovered that the pharmacy lacked any documentation of initial training and or
8 ongoing competencies for any of its staff that compounded.

9 EIGHTH CAUSE FOR DISCIPLINE

(Expired Bulk Chemicals)

(Bus. & Prof. Code § 4342, subd. (a); and

Health & Safety Code §§ 111250 and 111295)

(Respondents Animal Solutions Pharmacy and Brown)

12 37. Respondents Animal Solutions and Brown have subjected their Pharmacy Permits
13 and Pharmacist License, respectively, to disciplinary action for maintaining and holding
14 pharmaceutical preparations and drugs that do not conform to the standards and tests as to quality
15 and strength and violate Division 10 of the Health and Safety Code in that they are adulterated.
16 (Bus. & Prof. Code § 4342, subd. (a); and Health & Safety Code §§ 111250 and 111295). In
17 particular, during a February 3, 2016 inspection, a Board inspector discovered that the pharmacy
18 had, for use in compounding, expired bulk chemicals, including, hydrochloric acid 37%, tuna
19 flavor power, organic red apple chips, chondroitin sulfate powder, and lecithin isopropyl
20 palmitate solution.

21 NINTH CAUSE FOR DISCIPLINE

(Failing to Maintain Records of Destruction of Drugs)

(Cal. Code of Regs., title 16, § 1735.3, subd. (b))

(Respondents Animal Solutions Pharmacy and Brown)

24 38. Respondents Animal Solutions and Brown have subjected their Pharmacy Permits
25 and Pharmacist License, respectively, to disciplinary action for failing to maintain records of the
26 proper destruction of chemicals, bulk drug substances, drug products, and components used in
27 compounding. (Cal. Code of Regs., title 16, § 1735.3, subd. (b)). In particular, during a February
28 3, 2016 inspection, a Board inspector discovered that the pharmacy lacked an active waste

1 disposal policy and procedure for use and disposal of caustic materials and did not have a contract
2 with a licensed facility to take away caustic chemicals and other expired chemicals.

3
4 TENTH CAUSE FOR DISCIPLINE

(Failure to Acquire and Retain Certificates of Analysis)
5 (Cal. Code of Regs., title 16, § 1735.3, subd. (c))
(Respondents Animal Solutions Pharmacy and Brown)

6 39. Respondents Animal Solutions and Brown have subjected their Pharmacy Permits
7 and Pharmacist License, respectively, to disciplinary action for failing to acquire and retain
8 certificates of analysis with regard to two large boxes of active pharmaceutical ingredients
9 discovered during a February 3, 2016 inspection. (Cal. Code of Regs., title 16, § 1735.3, subd.
10 (c)).

11 ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Inventories of Controlled Substances)
12 (Code of Federal Regs., title 21, § 1304.11, subds. (a) and (c); and
13 Cal. Code of Regs., title 16, § 1718)
(Respondents Animal Solutions Pharmacy and Brown)

14 40. Respondents Animal Solutions and Brown have subjected their Pharmacy Permits
15 and Pharmacist License, respectively, to disciplinary action for failing to maintain inventories of
16 the pharmacy's controlled substances. (Code of Federal Regs., title 21, § 1304.11, subds. (a) and
17 (c); and Cal. Code of Regs., title 16, § 1718). In particular, during a February 3, 2016 inspection,
18 a Board inspector discovered that the pharmacy lacked a biennial controlled substance inventory
19 and an initial controlled substance inventory.

20 TWELFTH CAUSE FOR DISCIPLINE

(Failure to Report to CURES)
21 (Health & Safety Code § 11165, subd. (d))
22 (Respondents Animal Solutions Pharmacy and Brown)

23 41. Respondents Animal Solutions and Brown have subjected their Pharmacy Permits
24 and Pharmacist License, respectively, to disciplinary action for failing to report required
25 information to CURES (also known as the Controlled Substance Utilization Review and
26 Evaluation System) for the pharmacy's prescription of Schedule II, Schedule III, and Schedule IV
27 controlled substances. (Health & Safety Code § 11165, subd. (d)). In particular, the pharmacy
28

1 has dispensed and sold Schedule II, Schedule III, and Schedule IV controlled substances but has
2 not reported data to CURES since the pharmacy's original license was issued in March 2013.

3
4 THIRTEENTH CAUSE FOR DISCIPLINE

(Impeding an Investigation)

(Bus. & Prof. Code §§ 4080, 4081, and 4301, subd. (q))

5 (Respondents Animal Solutions Pharmacy and Brown)

6 42. Respondents Animal Solutions and Brown have subjected their Pharmacy Permits
7 and Pharmacist License, respectively, to disciplinary action for engaging in conduct that subverts
8 or attempts to subvert an investigation of the Board. (Bus. & Prof. Code §§ 4080, 4081, and
9 4301, subd. (q)). In particular, Respondents Animal Solutions and Brown, while Respondent
10 Brown was acting as the pharmacy's PIC, did not send the Board's inspector a requested
11 controlled substance inventory within 14 days of the initial inspection on February 3, 2016, or
12 when requested a month later on March 8, 2016, or when requested later on May 31, 2016.
13 Contrary to the law, Respondents Animal Solutions and Brown failed to produce any controlled
14 substances inventory.

15
16 FOURTEENTH CAUSE FOR DISCIPLINE

(Pharmacist-in-Charge)

(Bus. & Prof. Code § 4113, subds. (a) and (c))

17 (Respondents Animal Solutions Pharmacy and Brown)

18 43. Respondents Animal Solutions and Brown have subjected their Pharmacy Permits
19 and Pharmacist License, respectively, to disciplinary action for failing to designate a pharmacist-
20 in-charge responsible for the pharmacy's compliance with all state and federal laws and
21 regulations pertaining to the practice of pharmacy. (Bus. & Prof. Code § 4113, subds. (a) and
22 (c)). In particular, PIC Brown did not ensure compliance with all state and federal laws and
23 regulations pertaining to the practice of pharmacy, as described in paragraphs 30 through 42,
24 above.

25 OTHER MATTERS

26 44. Pursuant to Section 4307, if discipline is imposed on Pharmacy Permit Numbers PHY
27 51088 and PHY 54438 issued to Animal Solutions Pharmacy Inc., Animal Solutions Pharmacy
28 Inc. shall be prohibited from serving as manager, administrator, owner, member, officer, director,

1 associate, or partner of a licensee for five years if Pharmacy Permit Numbers PHY 51088 and
2 PHY 54438 are placed on probation or until Pharmacy Permit Numbers PHY 51088 and PHY
3 54438 are reinstated if they are revoked.

4 45. Pursuant to Section 4307, if discipline is imposed on Pharmacy Permit Numbers PHY
5 51088 and PHY 54438 issued to Animal Solutions Pharmacy Inc. while Clara Frances Brown has
6 been an officer and/or owner and had knowledge of or knowingly participated in any conduct for
7 which the licensee was disciplined, Clara Frances Brown shall be prohibited from serving as a
8 manager, administrator, owner, member, officer, director, associate, or partner of a licensee for
9 five years if Pharmacy Permit Numbers PHY 51088 and PHY 54438 are placed on probation or
10 until Pharmacy Permit Numbers PHY 51088 and PHY 54438 are reinstated if they are revoked.

11 PRAYER

12 WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this
13 First Amended Accusation, and that following the hearing, the Board of Pharmacy issue a
14 decision:

15 1. Revoking or suspending Pharmacy Permit Number PHY 51088, issued to Respondent
16 Animal Solutions Pharmacy Inc.;

17 2. Revoking or suspending Pharmacy Permit Number PHY 54438, issued to Respondent
18 Animal Solutions Pharmacy Inc.;

19 3. Revoking or suspending Pharmacist License Number RPH 37924, issued to
20 Respondent Clara Frances Brown;

21 4. Revoking or suspending Pharmacist License Number RPH 44486, issued to
22 Respondent Christopher Arthur Newell;

23 5. Prohibiting Respondent Clara Frances Brown from serving as a manager,
24 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
25 Pharmacy Permit Numbers PHY 51088 and/or PHY 54438 are placed on probation or until
26 Pharmacy Permit Number PHY 51088 and/or PHY 54438 are reinstated if Pharmacy Permit
27 Number PHY 51088 and/or PHY 54438 issued to Respondent Animal Solutions Pharmacy Inc. is
28 revoked;

1 6. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the
2 investigation and enforcement of this case, pursuant to Business and Professions Code section
3 125.3; and

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

5
6
7 DATED: _____

2/15/18



8 VIRGINIA HEROLD
9 Executive Officer
10 Board of Pharmacy
11 Department of Consumer Affairs
12 State of California
13 *Complainant*

11
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8
9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11
12 In the Matter of the Accusation Against:

13 **ANIMAL SOLUTIONS PHARMACY**
14 **INC.; CLARA FRANCES BROWN,**
OWNER
15 **4775 Sonoma Hwy**
Santa Rosa, CA 95409

16 **Pharmacy Permit No. PHY 51088 (Expired**
17 **9/27/16; cancelled 9/28/16)**

18 **CLARA FRANCES BROWN**
19 **3313 Stony Point Rd.**
Santa Rosa, CA 95407

20 **Pharmacist License No. RPH 37924**

21 **CHRISTOPHER ARTHUR NEWELL**
22 **971 Puget Dr. E**
Port Orchard, WA 98366

23 **Pharmacist License No. RPH 44486**

24 Respondents.

Case No. 6068

OAH No. 2017100614

NOTICE OF ERRATA

[Gov. Code §§ 11504, 11505, subd. (b)]

1 By this Notice of Errata, Complainant hereby corrects the following of typographical
2 errors in the Accusation:

<u>Page and Line</u>	<u>Errata</u>
3 4 5 6 1:20	“472 Crivelli Dr., Sonoma, CA 95476” to “971 Puget Dr. E, Port Orchard, WA 98366”
7 1:20, 2:13, and 18:9	“Scott” to “Arthur”

8
9 A corrected version of Accusation is attached as Exhibit A.

10
11 Dated: February 8, 2018

Respectfully submitted,

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28
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8
9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:

Case No. 6068

12 **ANIMAL SOLUTIONS PHARMACY**
13 **INC.; CLARA FRANCES BROWN,**
OWNER

A C C U S A T I O N

14 **4775 Sonoma Hwy**
15 **Santa Rosa, CA 95409**

16 **Pharmacy Permit No. PHY 51088 (Expired**
9/27/16; cancelled 9/28/16)

17 **CLARA FRANCES BROWN**
18 **3313 Stony Point Rd.**
Santa Rosa, CA 95407

19 **Pharmacist License No. RPH 37924**

20 **CHRISTOPHER ARTHUR NEWELL**
21 **971 Puget Dr. E**
Port Orchard, WA 98366

22 **Pharmacist License No. RPH 44486**

23 Respondents.

24
25 Complainant alleges:

26 PARTIES

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

1 2. On or about March 28, 2013, the Board of Pharmacy (“Board”) issued Pharmacy
2 Permit Number PHY 51088 to Animal Solutions Pharmacy Inc. (“Respondent Animal
3 Solutions”). The Pharmacy Permit expired on September 27, 2016, was cancelled on September
4 28, 2016, and has not been renewed.

5 3. On or about September 6, 1983, the Board issued Pharmacist License Number RPH
6 37924 to Clara Frances Brown (“Respondent Brown”). The Pharmacist License was in full force
7 and effect at all times relevant to the charges brought in this Accusation and will expire on July
8 31, 2017, unless renewed. Between March 28, 2013 and September 28, 2016, Respondent Brown
9 was the President, Sole Owner, Secretary, and Treasurer/Chief Financial Officer of Respondent
10 Animal Solutions. At all times relevant to the charges brought in this Accusation against her,
11 Respondent Brown functioned as Respondent Animal Solution’s Pharmacist-in-Charge (“PIC”).

12 4. On or about August 9, 1991, the Board issued Pharmacist License Number RPH
13 44486 to Christopher Arthur Newell (“Respondent Newell”). The Pharmacist License was in full
14 force and effect at all times relevant to the charges brought in Accusation and will expire on
15 October 31, 2018, unless renewed. At all times relevant to the charges brought in this Accusation
16 against him, Respondent Newell was employed as a pharmacist at Respondent Animal Solutions.

17 JURISDICTION

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

21 6. **Section 118, subdivision (b)** states:

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

1 7. **Section 4300** of states, in part:

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

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

6 “(1) Suspending judgment.

7 “(2) Placing him or her upon probation.

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

9 “(4) Revoking his or her license.

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

12 ...

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

18 8. **Section 4307** of states, in part:

19 “(a) Any person who has been denied a license or whose license has been revoked or is
20 under suspension, or who has failed to renew his or her license while it was under suspension, or
21 who has been a manager, administrator, owner, member, officer, director, associate, partner, or
22 any other person with management or control of any partnership, corporation, trust, firm, or
23 association whose application for a license has been denied or revoked, is under suspension or has
24 been placed on probation, and while acting as the manager, administrator, owner, member,
25 officer, director, associate, partner, or any other person with management or control had
26 knowledge of or knowingly participated in any conduct for which the license was denied,
27 revoked, suspended, or placed on probation, shall be prohibited from serving as a manager,

28

1 administrator, owner, member, officer, director, associate, partner, or in any other position with
2 management or control of a licensee as follows:

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”

8 RELEVANT STATUTES AND REGULATIONS

9 9. **Section 4301, subdivision (q)** states:

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

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

15 10. **Section 4038, subdivision (b)** states:

16 “(b) A “pharmacy technician trainee” is a person who is enrolled in a pharmacy technician
17 training program operated by a California public postsecondary education institution or by a
18 private postsecondary vocational institution approved by the Bureau for Private Postsecondary
19 and Vocational Education.”

20 11. **Section 4113, subdivision (c)** states:

21 “(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all
22 state and federal laws and regulations pertaining to the practice of pharmacy.”

23 12. **Section 4115, subdivisions (b) and (e)** state:

24 “(b) This section does not authorize the performance of any tasks specified in subdivision
25 (a) by a pharmacy technician without a pharmacist on duty.

26 . . .

27 “(e) A person shall not act as a pharmacy technician without first being licensed by the
28 board as a pharmacy technician.

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13. **Section 4115.5** states, in part:

...

“(b)(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by a California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.

“(c)(1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no more than 120 hours.

....”

14. **Section 4342, subdivision (a)** states:

“(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).”

15. **Health & Safety Code section 111250** states:

“Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.”

16. **Health & Safety Code section 111295** states:

“It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.”

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1 **17. Health & Safety Code section 11165, subdivision (d)** states:

2 “(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled
3 substance, as defined in the controlled substances schedules in federal law and regulations,
4 specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of
5 Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following
6 information to the Department of Justice as soon as reasonably possible, but not more than seven
7 days after the date a controlled substance is dispensed, in a format specified by the Department of
8 Justice:

9 “(1) Full name, address, and, if available, telephone number of the ultimate user or research
10 subject, or contact information as determined by the Secretary of the United States Department of
11 Health and Human Services, and the gender, and date of birth of the ultimate user.

12 “(2) The prescriber’s category of licensure, license number, national provider identifier
13 (NPI) number, if applicable, the federal controlled substance registration number, and the state
14 medical license number of any prescriber using the federal controlled substance registration
15 number of a government-exempt facility.

16 “(3) Pharmacy prescription number, license number, NPI number, and federal controlled
17 substance registration number.

18 “(4) National Drug Code (NDC) number of the controlled substance dispensed.

19 “(5) Quantity of the controlled substance dispensed.

20 “(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th
21 revision (ICD-10) Code, if available.

22 “(7) Number of refills ordered.

23 “(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

24 “(9) Date of origin of the prescription.

25 “(10) Date of dispensing of the prescription.”

26 **18. Code of Regulations, title 16, section 1714, subdivision (d)** states:

27 “(d) Each pharmacist while on duty shall be responsible for the security of the prescription
28 department, including provisions for effective control against theft or diversion of dangerous

1 drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy
2 where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.”

3 19. **Code of Regulations, title 16, section 1718** states:

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

7 “The controlled substances inventories required by Title 21, CFR, Section 1304 shall be
8 available for inspection upon request for at least 3 years after the date of the inventory.”

9 20. **Code of Regulations, title 16, section 1735.3, subdivisions (b) and (c)** state:

10 . . .

11 “(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of
12 chemicals, bulk drug substances, drug products, and components used in compounding.

13 “(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug
14 Administration (FDA). All other chemicals, bulk drug substances, and drug products used to
15 compound drug preparations shall be obtained, whenever possible, from FDA- registered
16 suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in
17 English or translated into English, for chemicals, bulk drug substances, and drug products used in
18 compounding. Certificates of purity or analysis are not required for drug products that are
19 approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be
20 matched to the corresponding chemical, bulk drug substance, or drug products received.

21”

22 21. **Code of Regulations, title 16, section 1735.5, subdivision (b)** states:

23 “(b) The policies and procedures shall be reviewed and such review shall be documented on
24 an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated
25 whenever changes in policies and procedures are implemented.”

26 22. **Code of Regulations, title 16, section 1735.6** states, in part:

27 “(a) Any pharmacy engaged in compounding shall maintain written documentation
28 regarding the facilities and equipment necessary for safe and accurate compounding of

1 compounded drug preparations. This shall include records of maintenance and cleaning of the
2 facilities and equipment. Where applicable, this shall also include records of certification(s) of
3 facilities or equipment.

4 “(b) Any equipment used to compound drug preparations shall be stored, used, maintained,
5 and cleaned in accordance with manufacturers' specifications.

6 “(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug
7 preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on
8 a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy.
9 Documentation of each such calibration shall be recorded in a form which is not alterable and
10 these records of calibration shall be maintained and retained in the pharmacy.

11”

12 23. **Code of Regulations, title 16, section 1735.7** provides, in part:

13 “(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that
14 personnel involved in compounding have the skills and training required to properly and
15 accurately perform their assigned responsibilities and documentation demonstrating that all
16 personnel involved in compounding are trained in all aspects of policies and procedures. This
17 training shall include but is not limited to support personnel (e.g. institutional environmental
18 services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are
19 related to the compounding process.

20 “(b) The pharmacy shall develop and maintain an on-going competency evaluation process
21 for pharmacy personnel involved in compounding, and shall maintain documentation of any and
22 all training related to compounding undertaken by pharmacy personnel.

23”

24 24. **Code of Regulations, title 16, section 1735.8** provides, in part:

25 “(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies
26 and procedures, a written quality assurance plan designed to monitor and ensure the integrity,
27 potency, quality, and labeled strength of compounded drug preparations.

28

1 “(b) The quality assurance plan shall include written procedures for verification,
2 monitoring, and review of the adequacy of the compounding processes and shall also include
3 written documentation of review of those processes by qualified pharmacy personnel.

4 “(c) The quality assurance plan shall include written standards for qualitative and
5 quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and
6 labeled strength, including the frequency of testing. All qualitative and quantitative analysis
7 reports for compounded drug preparations shall be retained by the pharmacy and maintained
8 along with the compounding log and master formula document. The quality assurance plan shall
9 include a schedule for routine testing and analysis of specified compounded drug preparations to
10 ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

11 “(d) The quality assurance plan shall include a written procedure for scheduled action in the
12 event any compounded drug preparation is ever discovered to be outside minimum standards for
13 integrity, potency, quality, or labeled strength.

14 “...”

15 **25. Code of Regulations, title 16, section 1793.2 states:**

16 “‘Nondiscretionary tasks’ as used in Business and Professions Code section 4115, include:

17 “(a) removing the drug or drugs from stock;

18 “(b) counting, pouring, or mixing pharmaceuticals;

19 “(c) placing the product into a container;

20 “(d) affixing the label or labels to the container;

21 “(e) packaging and repackaging.”

22 **26. Code of Regulations, title 16, section 1793.6 states:**

23 “A course of training that meets the requirements of Business and Professions Code section
24 4202(a)(2) is:

25 “(a) Any pharmacy technician training program accredited by the American Society of
26 Health-System Pharmacists,

27 “(b) Any pharmacy technician training program provided by a branch of the federal armed
28 services for which the applicant possesses a certificate of completion, or

1 “(c) Any other course that provides a training period of at least 240 hours of instruction
2 covering at least the following:

3 “(1) Knowledge and understanding of different pharmacy practice settings.

4 “(2) Knowledge and understanding of the duties and responsibilities of a pharmacy
5 technician in relationship to other pharmacy personnel and knowledge of standards and ethics,
6 laws and regulations governing the practice of pharmacy.

7 “(3) Knowledge and ability to identify and employ pharmaceutical and medical terms,
8 abbreviations and symbols commonly used in prescribing, dispensing and record keeping of
9 medications.

10 “(4) Knowledge of and the ability to carry out calculations required for common dosage
11 determination, employing both the metric and apothecary systems.

12 “(5) Knowledge and understanding of the identification of drugs, drug dosages, routes of
13 administration, dosage forms and storage requirements.

14 “(6) Knowledge of and ability to perform the manipulative and record-keeping functions
15 involved in and related to dispensing prescriptions.

16 “(7) Knowledge of and ability to perform procedures and techniques relating to
17 manufacturing, packaging, and labeling of drug products.”

18 **27. Code of Regulations, title 16, section 1793.7, subdivision (b) states:**

19 “(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in
20 such a relationship that the supervising pharmacist is fully aware of all activities involved in the
21 preparation and dispensing of medications, including the maintenance of appropriate records.”

22 **28. Code of Federal Regulations, title 21, section 1304.11 states, in part:**

23 “(a) General requirements. Each inventory shall contain a complete and accurate record of
24 all controlled substances on hand on the date the inventory is taken, and shall be maintained in
25 written, typewritten, or printed form at the registered location. An inventory taken by use of an
26 oral recording device must be promptly transcribed. Controlled substances shall be deemed to be
27 “on hand” if they are in the possession of or under the control of the registrant, including
28 substances returned by a customer, ordered by a customer but not yet invoiced, stored in a

1 warehouse on behalf of the registrant, and substances in the possession of employees of the
2 registrant and intended for distribution as complimentary samples. A separate inventory shall be
3 made for each registered location and each independent activity registered, except as provided in
4 paragraph (e)(4) of this section. In the event controlled substances in the possession or under the
5 control of the registrant are stored at a location for which he/she is not registered, the substances
6 shall be included in the inventory of the registered location to which they are subject to control or
7 to which the person possessing the substance is responsible. The inventory may be taken either as
8 of opening of business or as of the close of business on the inventory date and it shall be indicated
9 on the inventory.

10 . . .

11 “(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a
12 new inventory of all stocks of controlled substances on hand at least every two years. The
13 biennial inventory may be taken on any date which is within two years of the previous biennial
14 inventory date.

15”

16 COST RECOVERY

17 29. Section 125.3 provides, in part, that the Board may request the administrative law
18 judge to direct a licentiate found to have committed a violation or violations of the licensing act to
19 pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

20 FIRST CAUSE FOR DISCIPLINE

21 (Failure to Secure Pharmacy)
22 (Cal. Code of Regs., title 16, § 1714, subd. (d))
(Respondents Animal Solutions Pharmacy and Brown)

23 30. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and
24 Pharmacist License, respectively, to disciplinary action for failing to secure the prescription

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27 ////

28 ////

1 department, including restricting access to the key to the pharmacy. (Cal. Code of Regs., title 16,
2 § 1714, subd. (d)). In particular:

3 a. During a February 3, 2016 inspection, a Board inspector discovered that an
4 Animal Solutions pharmacist allowed a pharmacy technician, G.C., access to the key to the
5 licensed pharmacy space and G.C. entered when no pharmacist was present.

6 b. During a February 3, 2016 inspection, a Board inspector discovered a pharmacist
7 allowed storage of prescriptions to be dispensed in a drawer which was not located in the licensed
8 pharmacy.

9 SECOND CAUSE FOR DISCIPLINE

10 (Non-Licensed Individual Acting as Pharmacist Technician Without Supervision)
11 (Bus. & Prof. Code § 4115, subds. (b) and (e); and
12 Cal. Code of Regs., title 16, §§ 1793.2 and 1793.7, subd. (b))
13 (Respondents Animal Solutions Pharmacy, Brown, and Newell)

14 31. Respondents Animal Solutions, Brown, and Newell have subjected their Pharmacy
15 Permit and Pharmacists Licenses, respectively, to disciplinary action for permitting a non-
16 licensed individual to act as a pharmacy technician without the supervision of a pharmacist. (Bus.
17 & Prof. Code § 4115, subds. (b) and (e); and Cal. Code of Regs., title 16, §§ 1793.2 and 1793.7,
18 subd. (b)). In particular, during a February 3, 2016 inspection, Respondents allowed a non-
19 licensed individual, G.C., to let herself into the pharmacy with a pharmacist's key and perform
20 technician tasks without the supervision of a pharmacist. These tasks included removing drugs
21 from stock, weighing drugs on a balance, mixing pharmaceuticals, and placing the product into a
22 container. Respondent Brown also approved compounded products made by G.C. and H.K., two
unlicensed individuals, who worked at the pharmacy as pharmacy technicians without pharmacist
supervision.

23 THIRD CAUSE FOR DISCIPLINE

24 (Certifications and Approvals for Trainee Program)
25 (Bus. & Prof. Code §§ 4038, subd. (b) and 4115.5, subd. (b)(5) and (c)(1); and
26 Cal. Code of Regs., title 16, § 1793.6)
27 (Respondents Animal Solutions Pharmacy and Brown)

28 32. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and
Pharmacist License, respectively, to disciplinary action for having a non-licensed individual
scheduled to work at the pharmacy as a "technician trainee" without documenting the alleged

1 trainee's attendance, the trainee's meeting educational objectives, and without establishing a
2 approved and compliant training program. (Bus. & Prof. Code §§ 4038, subd. (b) and 4115.5,
3 subd. (b)(5) and (c)(1); and Cal. Code of Regs., title 16, § 1793.6). In particular, during a
4 February 3, 2016 inspection, a Board inspector learned that the pharmacy had G.C., a non-
5 licensed individual, scheduled to work as a "technician trainee" without having any paperwork to
6 show enrollment in any approved technician training program. G.C. opened the pharmacy and
7 went to work without a pharmacist on duty. G.C. had worked at the pharmacy as a technician
8 trainee for over 14 months.

9
10 FOURTH CAUSE FOR DISCIPLINE

11 (Failing to Conduct and Document Annual Policy and Procedure Review)
12 (Cal. Code of Regs., title 16, § 1735.5, subd. (b))
13 (Respondents Animal Solutions Pharmacy and Brown)

14 33. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and
15 Pharmacist License, respectively, to disciplinary action for failing to review and document, on an
16 annual basis, the pharmacy's policies and procedures. (Cal. Code of Regs., title 16, § 1735.5,
17 subd. (b)). In particular, during a February 3, 2016 inspection, a Board inspector found that the
18 pharmacy lacked any evidence of an annual review of compounding policies and procedures.

19 FIFTH CAUSE FOR DISCIPLINE

20 (Documentation and Calibration of Compounding Equipment)
21 (Cal. Code of Regs., title 16, § 1735.6, subds. (a), (b), and (c))
22 (Respondents Animal Solutions Pharmacy and Brown)

23 34. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and
24 Pharmacist License, respectively, to disciplinary action for failing to maintain written
25 documentation regarding the facilities and equipment necessary for safe and accurate
26 compounding of compounded drug preparations and failing to maintain and calibrate
27 compounding equipment. (Cal. Code of Regs., title 16, § 1735.6, subds. (a), (b), and (c)). In
28 particular, during a February 3, 2016 inspection, a Board inspector discovered that the pharmacy
lacked documentation of certification, maintenance, or proper storage regarding the equipment
used for compounding. In addition, the pharmacy's scale lacked documentation of daily
calibration.

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SIXTH CAUSE FOR DISCIPLINE
(Failure to Maintain Written Quality Assurance Plan)
(Cal. Code of Regs., title 16, § 1735.8, subs. (a), (b), (c), and (d))
(Respondents Animal Solutions Pharmacy and Brown)

35. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and Pharmacist License, respectively, to disciplinary action for failing to maintain a written quality assurance plan. (Cal. Code of Regs., title 16, § 1735.8, subs. (a), (b), (c), and (d)). In particular, during a February 3, 2016 inspection, a Board inspector discovered that the pharmacy lacked any written quality assurance program for compounded products.

SEVENTH CAUSE FOR DISCIPLINE
(Failure to Document Training and Competency)
(Cal. Code of Regs., title 16, § 1735.7, subs. (a) and (b))
(Respondents Animal Solutions Pharmacy and Brown)

36. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and Pharmacist License, respectively, to disciplinary action for failing to maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures, as well as failing to develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding and maintain documentation of any and all training related to compounding undertaken by pharmacy personnel. (Cal. Code of Regs., title 16, § 1735.7, subs. (a) and (b)). In particular, during a February 3, 2016 inspection, a Board inspector discovered that the pharmacy lacked any documentation of initial training and or ongoing competencies for any of its staff that compounded.

EIGHTH CAUSE FOR DISCIPLINE
(Expired Bulk Chemicals)
(Bus. & Prof. Code § 4342, subd. (a); and
Health & Safety Code §§ 111250 and 111295)
(Respondents Animal Solutions Pharmacy and Brown)

37. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and Pharmacist License, respectively, to disciplinary action for maintaining and holding pharmaceutical preparations and drugs that do not conform to the standards and tests as to quality

1 and strength and violate Division 10 of the Health and Safety Code in that they are adulterated.
2 (Bus. & Prof. Code § 4342, subd. (a); and Health & Safety Code §§ 111250 and 111295). In
3 particular, during a February 3, 2016 inspection, a Board inspector discovered that the pharmacy
4 had, for use in compounding, expired bulk chemicals, including, hydrochloric acid 37%, tuna
5 flavor power, organic red apple chips, chondroitin sulfate powder, and lecithin isopropyl
6 palmitate solution.

7
8 NINTH CAUSE FOR DISCIPLINE
9 (Failing to Maintain Records of Destruction of Drugs)
10 (Cal. Code of Regs., title 16, § 1735.3, subd. (b))
11 (Respondents Animal Solutions Pharmacy and Brown)

12 38. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and
13 Pharmacist License, respectively, to disciplinary action for failing to maintain records of the
14 proper destruction of chemicals, bulk drug substances, drug products, and components used in
15 compounding. (Cal. Code of Regs., title 16, § 1735.3, subd. (b)). In particular, during a February
16 3, 2016 inspection, a Board inspector discovered that the pharmacy lacked an active waste
17 disposal policy and procedure for use and disposal of caustic materials and did not have a contract
18 with a licensed facility to take away caustic chemicals and other expired chemicals.

19 TENTH CAUSE FOR DISCIPLINE
20 (Failure to Acquire and Retain Certificates of Analysis)
21 (Cal. Code of Regs., title 16, § 1735.3, subd. (c))
22 (Respondents Animal Solutions Pharmacy and Brown)

23 39. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and
24 Pharmacist License, respectively, to disciplinary action for failing to acquire and retain
25 certificates of analysis with regard to two large boxes of active pharmaceutical ingredients
26 discovered during a February 3, 2016 inspection. (Cal. Code of Regs., title 16, § 1735.3, subd.
27 (c)).
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ELEVENTH CAUSE FOR DISCIPLINE
(Failure to Maintain Inventories of Controlled Substances)
(Code of Federal Regs., title 21, § 1304.11, subds. (a) and (c); and
Cal. Code of Regs., title 16, § 1718)
(Respondents Animal Solutions Pharmacy and Brown)

40. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and Pharmacist License, respectively, to disciplinary action for failing to maintain inventories of the pharmacy’s controlled substances. (Code of Federal Regs., title 21, § 1304.11, subds. (a) and (c); and Cal. Code of Regs., title 16, § 1718). In particular, during a February 3, 2016 inspection, a Board inspector discovered that the pharmacy lacked a biennial controlled substance inventory and an initial controlled substance inventory.

TWELFTH CAUSE FOR DISCIPLINE
(Failure to Report to CURES)
(Health & Safety Code § 11165, subd. (d))
(Respondents Animal Solutions Pharmacy and Brown)

41. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and Pharmacist License, respectively, to disciplinary action for failing to report required information to CURES (also known as the Controlled Substance Utilization Review and Evaluation System) for the pharmacy’s prescription of Schedule II, Schedule III, and Schedule IV controlled substances. (Health & Safety Code § 11165, subd. (d)). In particular, the pharmacy has dispensed and sold Schedule II, Schedule III, and Schedule IV controlled substances but has not reported data to CURES since the pharmacy’s original license was issued in March 2013.

THIRTEENTH CAUSE FOR DISCIPLINE
(Impeding an Investigation)
(Bus. & Prof. Code §§ 4080, 4081, and 4301, subd. (q))
(Respondents Animal Solutions Pharmacy and Brown)

42. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and Pharmacist License, respectively, to disciplinary action for engaging in conduct that subverts or attempts to subvert an investigation of the Board. (Bus. & Prof. Code §§ 4080, 4081, and 4301, subd. (q)). In particular, Respondents Animal Solutions and Brown, while Respondent Brown was acting as the pharmacy’s PIC, did not send the Board’s inspector a requested controlled substance inventory within 14 days of the initial inspection on February 3, 2016, or when

1 requested a month later on March 8, 2016, or when requested later on May 31, 2016. Contrary to
2 the law, Respondents Animal Solutions and Brown failed to produce any controlled substances
3 inventory.

4
5 FOURTEENTH CAUSE FOR DISCIPLINE
6 (Pharmacist-in-Charge)
7 (Bus. & Prof. Code § 4113, subds. (a) and (c))
8 (Respondents Animal Solutions Pharmacy and Brown)

9 43. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and
10 Pharmacist License, respectively, to disciplinary action for failing to designate a pharmacist-in-
11 charge responsible for the pharmacy's compliance with all state and federal laws and regulations
12 pertaining to the practice of pharmacy. (Bus. & Prof. Code § 4113, subds. (a) and (c)). In
13 particular, PIC Brown did not ensure compliance with all state and federal laws and regulations
14 pertaining to the practice of pharmacy, as described in paragraphs 30 through 42, above.

15 OTHER MATTERS

16 44. Pursuant to Section 4307, if discipline is imposed on Pharmacy Permit Number PHY
17 51088 issued to Animal Solutions Pharmacy Inc., Animal Solutions Pharmacy Inc. shall be
18 prohibited from serving as manager, administrator, owner, member, officer, director, associate, or
19 partner of a licensee for five years if Pharmacy Permit Number PHY 51088 is placed on
20 probation or until Pharmacy Permit Number PHY 51088 is reinstated if it is revoked.

21 45. Pursuant to Section 4307, if discipline is imposed on Pharmacy Permit Number PHY
22 51088 issued to Animal Solutions Pharmacy Inc. while Clara Frances Brown has been an officer
23 and/or owner and had knowledge of or knowingly participated in any conduct for which the
24 licensee was disciplined, Clara Frances Brown shall be prohibited from serving as a manager,
25 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
26 Pharmacy Permit Number PHY 51088 is placed on probation or until Pharmacy Permit Number
27 PHY 51088 is reinstated if it is revoked.

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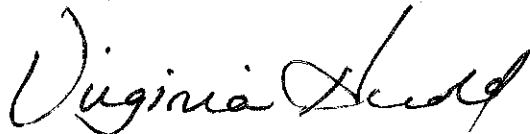
PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 51088, issued to Respondent Animal Solutions Pharmacy Inc.;
2. Revoking or suspending Pharmacist License Number RPH 37924, issued to Respondent Clara Frances Brown;
3. Revoking or suspending Pharmacist License Number RPH 44486, issued to Respondent Christopher Arthur Newell;
4. Prohibiting Respondent Clara Frances Brown from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51088 is placed on probation of until Pharmacy Permit Number PHY 51088 is reinstated if Pharmacy Permit Number PHY 51088 issued to Respondent Animal Solutions Pharmacy Inc. is revoked;
5. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and
6. Taking such other and further action as deemed necessary and proper.

DATED: _____

2/9/18



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

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

11 In the Matter of the Accusation Against:

Case No. 6068

12 **ANIMAL SOLUTIONS PHARMACY**
13 **INC.; CLARA FRANCES BROWN,**
OWNER
14 **4775 Sonoma Hwy**
Santa Rosa, CA 95409

ACCUSATION

15 **Pharmacy Permit No. PHY 51088 (Expired**
16 **9/27/16; cancelled 9/28/16)**

17 **CLARA FRANCES BROWN**
18 **3313 Stony Point Rd.**
Santa Rosa, CA 95407

19 **Pharmacist License No. RPH 37924**

20 **CHRISTOPHER SCOTT NEWELL**
21 **472 Crivelli Dr.**
Sonoma, CA 95476

22 **Pharmacist License No. RPH 44486**

23 Respondents.

24
25 Complainant alleges:

26 PARTIES

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

1 2. On or about March 28, 2013, the Board of Pharmacy ("Board") issued Pharmacy
2 Permit Number PHY 51088 to Animal Solutions Pharmacy Inc. ("Respondent Animal
3 Solutions"). The Pharmacy Permit expired on September 27, 2016, was cancelled on September
4 28, 2016, and has not been renewed.

5 3. On or about September 6, 1983, the Board issued Pharmacist License Number RPH
6 37924 to Clara Frances Brown ("Respondent Brown"). The Pharmacist License was in full force
7 and effect at all times relevant to the charges brought in this Accusation and will expire on July
8 31, 2017, unless renewed. Between March 28, 2013 and September 28, 2016, Respondent Brown
9 was the President, Sole Owner, Secretary, and Treasurer/Chief Financial Officer of Respondent
10 Animal Solutions. At all times relevant to the charges brought in this Accusation against her,
11 Respondent Brown functioned as Respondent Animal Solution's Pharmacist-in-Charge ("PIC").

12 4. On or about August 9, 1991, the Board issued Pharmacist License Number RPH
13 44486 to Christopher Scott Newell ("Respondent Newell"). The Pharmacist License was in full
14 force and effect at all times relevant to the charges brought in Accusation and will expire on
15 October 31, 2018, unless renewed. At all times relevant to the charges brought in this Accusation
16 against him, Respondent Newell was employed as a pharmacist at Respondent Animal Solutions.

17 JURISDICTION

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

21 6. **Section 118, subdivision (b)** states:

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

1 7. **Section 4300** of states, in part:

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

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

6 “(1) Suspending judgment.

7 “(2) Placing him or her upon probation.

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

9 “(4) Revoking his or her license.

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

12 ...

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

18 8. **Section 4307** of states, in part:

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

1 administrator, owner, member, officer, director, associate, partner, or in any other position with
2 management or control of a licensee as follows:

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”

8 RELEVANT STATUTES AND REGULATIONS

9 9. **Section 4301, subdivision (q)** states:

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

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

15 10. **Section 4038, subdivision (b)** states:

16 “(b) A “pharmacy technician trainee” is a person who is enrolled in a pharmacy technician
17 training program operated by a California public postsecondary education institution or by a
18 private postsecondary vocational institution approved by the Bureau for Private Postsecondary
19 and Vocational Education.”

20 11. **Section 4113, subdivision (c)** states:

21 “(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all
22 state and federal laws and regulations pertaining to the practice of pharmacy.”

23 12. **Section 4115, subdivisions (b) and (e)** state:

24 “(b) This section does not authorize the performance of any tasks specified in subdivision
25 (a) by a pharmacy technician without a pharmacist on duty.

26 . . .

27 “(e) A person shall not act as a pharmacy technician without first being licensed by the
28 board as a pharmacy technician.

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13. **Section 4115.5** states, in part:

...

“(b)(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by a California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.

“(c)(1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no more than 120 hours.

....”

14. **Section 4342, subdivision (a)** states:

“(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).”

15. **Health & Safety Code section 111250** states:

“Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.”

16. **Health & Safety Code section 111295** states:

“It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.”

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1 17. **Health & Safety Code section 11165, subdivision (d)** states:

2 “(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled
3 substance, as defined in the controlled substances schedules in federal law and regulations,
4 specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of
5 Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following
6 information to the Department of Justice as soon as reasonably possible, but not more than seven
7 days after the date a controlled substance is dispensed, in a format specified by the Department of
8 Justice:

9 “(1) Full name, address, and, if available, telephone number of the ultimate user or research
10 subject, or contact information as determined by the Secretary of the United States Department of
11 Health and Human Services, and the gender, and date of birth of the ultimate user.

12 “(2) The prescriber’s category of licensure, license number, national provider identifier
13 (NPI) number, if applicable, the federal controlled substance registration number, and the state
14 medical license number of any prescriber using the federal controlled substance registration
15 number of a government-exempt facility.

16 “(3) Pharmacy prescription number, license number, NPI number, and federal controlled
17 substance registration number.

18 “(4) National Drug Code (NDC) number of the controlled substance dispensed.

19 “(5) Quantity of the controlled substance dispensed.

20 “(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th
21 revision (ICD-10) Code, if available.

22 “(7) Number of refills ordered.

23 “(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

24 “(9) Date of origin of the prescription.

25 “(10) Date of dispensing of the prescription.”

26 18. **Code of Regulations, title 16, section 1714, subdivision (d)** states:

27 “(d) Each pharmacist while on duty shall be responsible for the security of the prescription
28 department, including provisions for effective control against theft or diversion of dangerous

1 drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy
2 where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.”

3 **19. Code of Regulations, title 16, section 1718 states:**

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

7 “The controlled substances inventories required by Title 21, CFR, Section 1304 shall be
8 available for inspection upon request for at least 3 years after the date of the inventory.”

9 **20. Code of Regulations, title 16, section 1735.3, subdivisions (b) and (c) state:**

10 ...

11 “(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of
12 chemicals, bulk drug substances, drug products, and components used in compounding.

13 “(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug
14 Administration (FDA). All other chemicals, bulk drug substances, and drug products used to
15 compound drug preparations shall be obtained, whenever possible, from FDA- registered
16 suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in
17 English or translated into English, for chemicals, bulk drug substances, and drug products used in
18 compounding. Certificates of purity or analysis are not required for drug products that are
19 approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be
20 matched to the corresponding chemical, bulk drug substance, or drug products received.

21 ...”

22 **21. Code of Regulations, title 16, section 1735.5, subdivision (b) states:**

23 “(b) The policies and procedures shall be reviewed and such review shall be documented on
24 an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated
25 whenever changes in policies and procedures are implemented.”

26 **22. Code of Regulations, title 16, section 1735.6 states, in part:**

27 “(a) Any pharmacy engaged in compounding shall maintain written documentation
28 regarding the facilities and equipment necessary for safe and accurate compounding of

1 compounded drug preparations. This shall include records of maintenance and cleaning of the
2 facilities and equipment. Where applicable, this shall also include records of certification(s) of
3 facilities or equipment.

4 “(b) Any equipment used to compound drug preparations shall be stored, used, maintained,
5 and cleaned in accordance with manufacturers' specifications.

6 “(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug
7 preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on
8 a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy.
9 Documentation of each such calibration shall be recorded in a form which is not alterable and
10 these records of calibration shall be maintained and retained in the pharmacy.

11”

12 23. **Code of Regulations, title 16, section 1735.7** provides, in part:

13 “(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that
14 personnel involved in compounding have the skills and training required to properly and
15 accurately perform their assigned responsibilities and documentation demonstrating that all
16 personnel involved in compounding are trained in all aspects of policies and procedures. This
17 training shall include but is not limited to support personnel (e.g. institutional environmental
18 services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are
19 related to the compounding process.

20 “(b) The pharmacy shall develop and maintain an on-going competency evaluation process
21 for pharmacy personnel involved in compounding, and shall maintain documentation of any and
22 all training related to compounding undertaken by pharmacy personnel.

23”

24 24. **Code of Regulations, title 16, section 1735.8** provides, in part:

25 “(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies
26 and procedures, a written quality assurance plan designed to monitor and ensure the integrity,
27 potency, quality, and labeled strength of compounded drug preparations.

28

1 “(b) The quality assurance plan shall include written procedures for verification,
2 monitoring, and review of the adequacy of the compounding processes and shall also include
3 written documentation of review of those processes by qualified pharmacy personnel.

4 “(c) The quality assurance plan shall include written standards for qualitative and
5 quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and
6 labeled strength, including the frequency of testing. All qualitative and quantitative analysis
7 reports for compounded drug preparations shall be retained by the pharmacy and maintained
8 along with the compounding log and master formula document. The quality assurance plan shall
9 include a schedule for routine testing and analysis of specified compounded drug preparations to
10 ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

11 “(d) The quality assurance plan shall include a written procedure for scheduled action in the
12 event any compounded drug preparation is ever discovered to be outside minimum standards for
13 integrity, potency, quality, or labeled strength.

14 “...”

15 25. **Code of Regulations, title 16, section 1793.2** states:

16 “‘Nondiscretionary tasks’ as used in Business and Professions Code section 4115, include:

17 “(a) removing the drug or drugs from stock;

18 “(b) counting, pouring, or mixing pharmaceuticals;

19 “(c) placing the product into a container;

20 “(d) affixing the label or labels to the container;

21 “(e) packaging and repackaging.”

22 26. **Code of Regulations, title 16, section 1793.6** states:

23 “A course of training that meets the requirements of Business and Professions Code section
24 4202(a)(2) is:

25 “(a) Any pharmacy technician training program accredited by the American Society of
26 Health-System Pharmacists,

27 “(b) Any pharmacy technician training program provided by a branch of the federal armed
28 services for which the applicant possesses a certificate of completion, or

1 “(c) Any other course that provides a training period of at least 240 hours of instruction
2 covering at least the following:

3 “(1) Knowledge and understanding of different pharmacy practice settings.

4 “(2) Knowledge and understanding of the duties and responsibilities of a pharmacy
5 technician in relationship to other pharmacy personnel and knowledge of standards and ethics,
6 laws and regulations governing the practice of pharmacy.

7 “(3) Knowledge and ability to identify and employ pharmaceutical and medical terms,
8 abbreviations and symbols commonly used in prescribing, dispensing and record keeping of
9 medications.

10 “(4) Knowledge of and the ability to carry out calculations required for common dosage
11 determination, employing both the metric and apothecary systems.

12 “(5) Knowledge and understanding of the identification of drugs, drug dosages, routes of
13 administration, dosage forms and storage requirements.

14 “(6) Knowledge of and ability to perform the manipulative and record-keeping functions
15 involved in and related to dispensing prescriptions.

16 “(7) Knowledge of and ability to perform procedures and techniques relating to
17 manufacturing, packaging, and labeling of drug products.”

18 **27. Code of Regulations, title 16, section 1793.7, subdivision (b) states:**

19 “(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in
20 such a relationship that the supervising pharmacist is fully aware of all activities involved in the
21 preparation and dispensing of medications, including the maintenance of appropriate records.”

22 **28. Code of Federal Regulations, title 21, section 1304.11 states, in part:**

23 “(a) General requirements. Each inventory shall contain a complete and accurate record of
24 all controlled substances on hand on the date the inventory is taken, and shall be maintained in
25 written, typewritten, or printed form at the registered location. An inventory taken by use of an
26 oral recording device must be promptly transcribed. Controlled substances shall be deemed to be
27 “on hand” if they are in the possession of or under the control of the registrant, including
28 substances returned by a customer, ordered by a customer but not yet invoiced, stored in a

1 warehouse on behalf of the registrant, and substances in the possession of employees of the
2 registrant and intended for distribution as complimentary samples. A separate inventory shall be
3 made for each registered location and each independent activity registered, except as provided in
4 paragraph (e)(4) of this section. In the event controlled substances in the possession or under the
5 control of the registrant are stored at a location for which he/she is not registered, the substances
6 shall be included in the inventory of the registered location to which they are subject to control or
7 to which the person possessing the substance is responsible. The inventory may be taken either as
8 of opening of business or as of the close of business on the inventory date and it shall be indicated
9 on the inventory.

10 ...

11 “(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a
12 new inventory of all stocks of controlled substances on hand at least every two years. The
13 biennial inventory may be taken on any date which is within two years of the previous biennial
14 inventory date.

15”

16 COST RECOVERY

17 29. Section 125.3 provides, in part, that the Board may request the administrative law
18 judge to direct a licentiate found to have committed a violation or violations of the licensing act to
19 pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

20 FIRST CAUSE FOR DISCIPLINE

21 (Failure to Secure Pharmacy)

22 (Cal. Code of Regs., title 16, § 1714, subd. (d))

23 (Respondents Animal Solutions Pharmacy and Brown)

24 30. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and
25 Pharmacist License, respectively, to disciplinary action for failing to secure the prescription

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1 department, including restricting access to the key to the pharmacy. (Cal. Code of Regs., title 16,
2 § 1714, subd. (d)). In particular:

3 a. During a February 3, 2016 inspection, a Board inspector discovered that an
4 Animal Solutions pharmacist allowed a pharmacy technician, G.C., access to the key to the
5 licensed pharmacy space and G.C. entered when no pharmacist was present.

6 b. During a February 3, 2016 inspection, a Board inspector discovered a pharmacist
7 allowed storage of prescriptions to be dispensed in a drawer which was not located in the licensed
8 pharmacy.

9 SECOND CAUSE FOR DISCIPLINE

10 (Non-Licensed Individual Acting as Pharmacist Technician Without Supervision)

11 (Bus. & Prof. Code § 4115, subds. (b) and (e); and

12 Cal. Code of Regs., title 16, §§ 1793.2 and 1793.7, subd. (b))

13 (Respondents Animal Solutions Pharmacy, Brown, and Newell)

14 31. Respondents Animal Solutions, Brown, and Newell have subjected their Pharmacy
15 Permit and Pharmacists Licenses, respectively, to disciplinary action for permitting a non-
16 licensed individual to act as a pharmacy technician without the supervision of a pharmacist. (Bus.
17 & Prof. Code § 4115, subds. (b) and (e); and Cal. Code of Regs., title 16, §§ 1793.2 and 1793.7,
18 subd. (b)). In particular, during a February 3, 2016 inspection, Respondents allowed a non-
19 licensed individual, G.C., to let herself into the pharmacy with a pharmacist's key and perform
20 technician tasks without the supervision of a pharmacist. These tasks included removing drugs
21 from stock, weighing drugs on a balance, mixing pharmaceuticals, and placing the product into a
22 container. Respondent Brown also approved compounded products made by G.C. and H.K., two
23 unlicensed individuals, who worked at the pharmacy as pharmacy technicians without pharmacist
24 supervision.

25 THIRD CAUSE FOR DISCIPLINE

26 (Certifications and Approvals for Trainee Program)

27 (Bus. & Prof. Code §§ 4038, subd. (b) and 4115.5, subd. (b)(5) and (c)(1); and

28 Cal. Code of Regs., title 16, § 1793.6)

(Respondents Animal Solutions Pharmacy and Brown)

32. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and
Pharmacist License, respectively, to disciplinary action for having a non-licensed individual
scheduled to work at the pharmacy as a "technician trainee" without documenting the alleged

1 trainee's attendance, the trainee's meeting educational objectives, and without establishing a
2 approved and compliant training program. (Bus. & Prof. Code §§ 4038, subd. (b) and 4115.5,
3 subd. (b)(5) and (c)(1); and Cal. Code of Regs., title 16, § 1793.6). In particular, during a
4 February 3, 2016 inspection, a Board inspector learned that the pharmacy had G.C., a non-
5 licensed individual, scheduled to work as a "technician trainee" without having any paperwork to
6 show enrollment in any approved technician training program. G.C. opened the pharmacy and
7 went to work without a pharmacist on duty. G.C. had worked at the pharmacy as a technician
8 trainee for over 14 months.

9
10 FOURTH CAUSE FOR DISCIPLINE

(Failing to Conduct and Document Annual Policy and Procedure Review)
(Cal. Code of Regs., title 16, § 1735.5, subd. (b))
(Respondents Animal Solutions Pharmacy and Brown)

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12 33. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and
13 Pharmacist License, respectively, to disciplinary action for failing to review and document, on an
14 annual basis, the pharmacy's policies and procedures. (Cal. Code of Regs., title 16, § 1735.5,
15 subd. (b)). In particular, during a February 3, 2016 inspection, a Board inspector found that the
16 pharmacy lacked any evidence of an annual review of compounding policies and procedures.

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18 FIFTH CAUSE FOR DISCIPLINE

(Documentation and Calibration of Compounding Equipment)
(Cal. Code of Regs., title 16, § 1735.6, subs. (a), (b), and (c))
(Respondents Animal Solutions Pharmacy and Brown)

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20 34. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and
21 Pharmacist License, respectively, to disciplinary action for failing to maintain written
22 documentation regarding the facilities and equipment necessary for safe and accurate
23 compounding of compounded drug preparations and failing to maintain and calibrate
24 compounding equipment. (Cal. Code of Regs., title 16, § 1735.6, subs. (a), (b), and (c)). In
25 particular, during a February 3, 2016 inspection, a Board inspector discovered that the pharmacy
26 lacked documentation of certification, maintenance, or proper storage regarding the equipment
27 used for compounding. In addition, the pharmacy's scale lacked documentation of daily
28 calibration.

SIXTH CAUSE FOR DISCIPLINE
(Failure to Maintain Written Quality Assurance Plan)
(Cal. Code of Regs., title 16, § 1735.8, subds. (a), (b), (c), and (d))
(Respondents Animal Solutions Pharmacy and Brown)

35. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and Pharmacist License, respectively, to disciplinary action for failing to maintain a written quality assurance plan. (Cal. Code of Regs., title 16, § 1735.8, subds. (a), (b), (c), and (d)). In particular, during a February 3, 2016 inspection, a Board inspector discovered that the pharmacy lacked any written quality assurance program for compounded products.

SEVENTH CAUSE FOR DISCIPLINE
(Failure to Document Training and Competency)
(Cal. Code of Regs., title 16, § 1735.7, subds. (a) and (b))
(Respondents Animal Solutions Pharmacy and Brown)

36. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and Pharmacist License, respectively, to disciplinary action for failing to maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures, as well as failing to develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding and maintain documentation of any and all training related to compounding undertaken by pharmacy personnel. (Cal. Code of Regs., title 16, § 1735.7, subds. (a) and (b)). In particular, during a February 3, 2016 inspection, a Board inspector discovered that the pharmacy lacked any documentation of initial training and or ongoing competencies for any of its staff that compounded.

EIGHTH CAUSE FOR DISCIPLINE
(Expired Bulk Chemicals)
(Bus. & Prof. Code § 4342, subd. (a); and
Health & Safety Code §§ 111250 and 111295)
(Respondents Animal Solutions Pharmacy and Brown)

37. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and Pharmacist License, respectively, to disciplinary action for maintaining and holding pharmaceutical preparations and drugs that do not conform to the standards and tests as to quality

1 and strength and violate Division 10 of the Health and Safety Code in that they are adulterated.
2 (Bus. & Prof. Code § 4342, subd. (a); and Health & Safety Code §§ 111250 and 111295). In
3 particular, during a February 3, 2016 inspection, a Board inspector discovered that the pharmacy
4 had, for use in compounding, expired bulk chemicals, including, hydrochloric acid 37%, tuna
5 flavor power, organic red apple chips, chondroitin sulfate powder, and lecithin isopropyl
6 palmitate solution.

7
8 NINTH CAUSE FOR DISCIPLINE

9 (Failing to Maintain Records of Destruction of Drugs)
10 (Cal. Code of Regs., title 16, § 1735.3, subd. (b))
11 (Respondents Animal Solutions Pharmacy and Brown)

12 38. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and
13 Pharmacist License, respectively, to disciplinary action for failing to maintain records of the
14 proper destruction of chemicals, bulk drug substances, drug products, and components used in
15 compounding. (Cal. Code of Regs., title 16, § 1735.3, subd. (b)). In particular, during a February
16 3, 2016 inspection, a Board inspector discovered that the pharmacy lacked an active waste
17 disposal policy and procedure for use and disposal of caustic materials and did not have a contract
18 with a licensed facility to take away caustic chemicals and other expired chemicals.

19 TENTH CAUSE FOR DISCIPLINE

20 (Failure to Acquire and Retain Certificates of Analysis)
21 (Cal. Code of Regs., title 16, § 1735.3, subd. (c))
22 (Respondents Animal Solutions Pharmacy and Brown)

23 39. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and
24 Pharmacist License, respectively, to disciplinary action for failing to acquire and retain
25 certificates of analysis with regard to two large boxes of active pharmaceutical ingredients
26 discovered during a February 3, 2016 inspection. (Cal. Code of Regs., title 16, § 1735.3, subd.
27 (c)).

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ELEVENTH CAUSE FOR DISCIPLINE
(Failure to Maintain Inventories of Controlled Substances)
(Code of Federal Regs., title 21, § 1304.11, subs. (a) and (c); and
Cal. Code of Regs., title 16, § 1718)
(Respondents Animal Solutions Pharmacy and Brown)

40. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and Pharmacist License, respectively, to disciplinary action for failing to maintain inventories of the pharmacy's controlled substances. (Code of Federal Regs., title 21, § 1304.11, subs. (a) and (c); and Cal. Code of Regs., title 16, § 1718). In particular, during a February 3, 2016 inspection, a Board inspector discovered that the pharmacy lacked a biennial controlled substance inventory and an initial controlled substance inventory.

TWELFTH CAUSE FOR DISCIPLINE
(Failure to Report to CURES)
(Health & Safety Code § 11165, subd. (d))
(Respondents Animal Solutions Pharmacy and Brown)

41. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and Pharmacist License, respectively, to disciplinary action for failing to report required information to CURES (also known as the Controlled Substance Utilization Review and Evaluation System) for the pharmacy's prescription of Schedule II, Schedule III, and Schedule IV controlled substances. (Health & Safety Code § 11165, subd. (d)). In particular, the pharmacy has dispensed and sold Schedule II, Schedule III, and Schedule IV controlled substances but has not reported data to CURES since the pharmacy's original license was issued in March 2013.

THIRTEENTH CAUSE FOR DISCIPLINE
(Impeding an Investigation)
(Bus. & Prof. Code §§ 4080, 4081, and 4301, subd. (q))
(Respondents Animal Solutions Pharmacy and Brown)

42. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and Pharmacist License, respectively, to disciplinary action for engaging in conduct that subverts or attempts to subvert an investigation of the Board. (Bus. & Prof. Code §§ 4080, 4081, and 4301, subd. (q)). In particular, Respondents Animal Solutions and Brown, while Respondent Brown was acting as the pharmacy's PIC, did not send the Board's inspector a requested controlled substance inventory within 14 days of the initial inspection on February 3, 2016, or when

1 requested a month later on March 8, 2016, or when requested later on May 31, 2016. Contrary to
2 the law, Respondents Animal Solutions and Brown failed to produce any controlled substances
3 inventory.

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5 FOURTEENTH CAUSE FOR DISCIPLINE
6 (Pharmacist-in-Charge)
7 (Bus. & Prof. Code § 4113, subs. (a) and (c))
8 (Respondents Animal Solutions Pharmacy and Brown)

9 43. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and
10 Pharmacist License, respectively, to disciplinary action for failing to designate a pharmacist-in-
11 charge responsible for the pharmacy's compliance with all state and federal laws and regulations
12 pertaining to the practice of pharmacy. (Bus. & Prof. Code § 4113, subs. (a) and (c)). In
13 particular, PIC Brown did not ensure compliance with all state and federal laws and regulations
14 pertaining to the practice of pharmacy, as described in paragraphs 30 through 42, above.

15 OTHER MATTERS

16 44. Pursuant to Section 4307, if discipline is imposed on Pharmacy Permit Number PHY
17 51088 issued to Animal Solutions Pharmacy Inc., Animal Solutions Pharmacy Inc. shall be
18 prohibited from serving as manager, administrator, owner, member, officer, director, associate, or
19 partner of a licensee for five years if Pharmacy Permit Number PHY 51088 is placed on
20 probation or until Pharmacy Permit Number PHY 51088 is reinstated if it is revoked.

21 45. Pursuant to Section 4307, if discipline is imposed on Pharmacy Permit Number PHY
22 51088 issued to Animal Solutions Pharmacy Inc. while Clara Frances Brown has been an officer
23 and/or owner and had knowledge of or knowingly participated in any conduct for which the
24 licensee was disciplined, Clara Frances Brown shall be prohibited from serving as a manager,
25 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
26 Pharmacy Permit Number PHY 51088 is placed on probation or until Pharmacy Permit Number
27 PHY 51088 is reinstated if it is revoked.

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P R A Y E R

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

1. Revoking or suspending Pharmacy Permit Number PHY 51088, issued to Respondent Animal Solutions Pharmacy Inc.;

2. Revoking or suspending Pharmacist License Number RPH 37924, issued to Respondent Clara Frances Brown;

3. Revoking or suspending Pharmacist License Number RPH 44486, issued to Respondent Christopher Scott Newell;

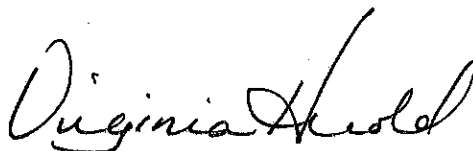
4. Prohibiting Respondent Clara Frances Brown from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51088 is placed on probation of until Pharmacy Permit Number PHY 51088 is reinstated if Pharmacy Permit Number PHY 51088 issued to Respondent Animal Solutions Pharmacy Inc. is revoked;

5. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: _____

8/31/17



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

SF2017901117