

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

**In the Matter of the Accusation Against:**

**ANIMAL SOLUTIONS PHARMACY  
INC., CLARA FRANCES BROWN,  
OWNER**

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

**Pharmacy Permit No. PHY 51088 (Expired  
9/27/16; cancelled 9/28/216)**

**ANIMAL SOLUTIONS PHARMACY  
INC., CLARA FRANCES BROWN,  
OWNER**

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

**Pharmacy Permit No. PHY 54438**

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

**Pharmacist License No. RPH 37924**

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

**Pharmacist License No. RPH 44486**

**Respondents.**

**Case No. 6068**

**OAH No. 2017100614**

**STIPULATED SETTLEMENT AND  
DISCIPLINARY ORDER AS TO  
RESPONDENTS ANIMAL SOLUTIONS  
PHARMACY INC. AND CLARA  
FRANCES BROWN ONLY**

**DECISION AND ORDER**

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on July 10, 2018.

It is so ORDERED on June 11, 2018.

BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA

A handwritten signature in black ink, appearing to read "Victor Law", is written over a horizontal line.

By

Victor Law, R.Ph.  
Board President

1 XAVIER BECERRA  
Attorney General of California  
2 DIANN SOKOLOFF  
Supervising Deputy Attorney General  
3 CARTER OTT  
Deputy Attorney General  
4 State Bar No. 221660  
1515 Clay Street, 20th Floor  
5 P.O. Box 70550  
Oakland, CA 94612-0550  
6 Telephone: (510) 879-1349  
Facsimile: (510) 622-2270  
7 E-mail: Carter.Ott@doj.ca.gov  
*Attorneys for Complainant*

8  
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15 Pharmacy Permit No. PHY 51088 (Expired  
16 9/27/16; cancelled 9/28/16)

17 **ANIMAL SOLUTIONS PHARMACY**  
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19 3313 Stony Point Rd.  
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20 Pharmacy Permit No. PHY 54438

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

26 Pharmacist License No. RPH 44486

27 Respondents.  
28

1 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-  
2 entitled proceedings that the following matters are true:

3 PARTIES

4 1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy  
5 ("Board"). She brought this action solely in her official capacity and is represented in this matter  
6 by Xavier Becerra, Attorney General of the State of California, by Carter Ott, Deputy Attorney  
7 General.

8 2. Respondent Animal Solutions Pharmacy Inc.; Clara Frances Brown, Owner and  
9 Respondent Clara Frances Brown are represented in this proceeding by attorney Nicholas  
10 Jurkowitz, Fenton Law Group, LLP, 1990 S. Bundy Drive, Suite 777, Los Angeles, CA 90025.

11 3. On or about March 28, 2013, the Board issued Pharmacist Permit No. PHY 51088 to  
12 Respondent Animal Solutions Pharmacy Inc. ("Respondent Pharmacy"). Pharmacy Permit  
13 Number PHY 51088 expired on September 27, 2016, was cancelled on September 28, 2016, and  
14 has not been renewed. On or about September 27, 2016, the Board issued Pharmacy Permit  
15 Number PHY 54438 to Respondent Pharmacy. Pharmacy Permit Number PHY 54438 is in full  
16 force and effect, and will expire on September 1, 2018, unless renewed.

17 4. On or about September 6, 1983, the Board issued Pharmacist License Number RPH  
18 37924 to Respondent Clara Frances Brown ("Respondent Brown"). The Pharmacist License was  
19 in full force and effect at all times relevant to the charges brought in First Amended Accusation  
20 No. 6068 and will expire on July 31, 2019, unless renewed. Between March 28, 2013 and  
21 September 28, 2016, Respondent Brown was the President, Sole Owner, Secretary, and  
22 Treasurer/Chief Financial Officer of Respondent Pharmacy. At all times relevant to the charges  
23 brought in First Amended Accusation No. 6068 against her, Respondent Brown functioned as  
24 Respondent Animal Solution's Pharmacist-in-Charge ("PIC").

25 JURISDICTION

26 5. Accusation No. 6068 was filed before the Board on or about August 31, 2017, and  
27 Accusation No. 6068 and all other statutorily required documents were properly served on  
28 Respondents Pharmacy and Brown on September 7, 2017. Respondents Pharmacy and Brown

1 timely filed their Notice of Defense contesting the Accusation. The operative pleading, First  
2 Amended Accusation No. 6068, was filed and served on Respondents on or about February 16,  
3 2018. A copy of the First Amended Accusation No. 6068 is attached as Exhibit A and  
4 incorporated herein by reference.

5 ADVISEMENT AND WAIVERS

6 6. Respondents have carefully read, fully discussed with counsel, and understand the  
7 charges and allegations in First Amended Accusation No. 6068. Respondents have also carefully  
8 read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and  
9 Disciplinary Order.

10 7. Respondent is fully aware of its legal rights in this matter, including the right to a  
11 hearing on the charges and allegations in the Accusation; the right to confront and cross-examine  
12 the witnesses against them; the right to present evidence and to testify on its own behalf; the right  
13 to the issuance of subpoenas to compel the attendance of witnesses and the production of  
14 documents; the right to reconsideration and court review of an adverse decision; and all other  
15 rights accorded by the California Administrative Procedure Act and other applicable laws.

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

18 CULPABILITY

19 9. Respondents understand and agree that the charges and allegations in in First  
20 Amended Accusation No. 6068, if proven at a hearing, constitute cause for imposing discipline  
21 upon their Pharmacy Permits and Pharmacist License.

22 10. For the purpose of resolving the First Amended Accusation without the expense and  
23 uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could  
24 establish a factual basis for the charges in the First Amended Accusation, and that Respondents  
25 hereby give up their right to contest those charges.

26 11. Respondents agree that their Pharmacy Permits and Pharmacist License are subject to  
27 discipline and they agree to be bound by the Board's probationary terms as set forth in the  
28 Disciplinary Order below.



1       **1.     Obey All Laws**

2       Respondent Brown shall obey all state and federal laws and regulations.

3       Respondent Brown shall report any of the following occurrences to the Board, in writing,  
4       within seventy-two (72) hours of such occurrence:

- 5       •     an arrest or issuance of a criminal complaint for violation of any provision of the  
6             Pharmacy Law, state and federal food and drug laws, or state and federal controlled  
7             substances laws
- 8       •     a plea of guilty or nolo contendere in any state or federal criminal proceeding to any  
9             criminal complaint, information or indictment
- 10      •     a conviction of any crime
- 11      •     discipline, citation, or other administrative action filed by any state or federal agency  
12             which involves Respondent Brown's Pharmacist License or which is related to the  
13             practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing,  
14             or charging for any drug, device or controlled substance.

15      Failure to timely report such occurrence shall be considered a violation of probation.

16      **2.     Report to the Board**

17      Respondent Brown shall report to the Board quarterly, on a schedule as directed by the  
18      Board or its designee. The report shall be made either in person or in writing, as directed.  
19      Among other requirements, Respondent Brown shall state in each report under penalty of perjury  
20      whether there has been compliance with all the terms and conditions of probation. Failure to  
21      submit timely reports in a form as directed shall be considered a violation of probation. Any  
22      period(s) of delinquency in submission of reports as directed may be added to the total period of  
23      probation. Moreover, if the final probation report is not made as directed, probation shall be  
24      automatically extended until such time as the final report is made and accepted by the Board.

25      **3.     Interview with the Board**

26      Upon receipt of reasonable prior notice, Respondent Brown shall appear in person for  
27      interviews with the Board or its designee, at such intervals and locations as are determined by the  
28      Board or its designee. Failure to appear for any scheduled interview without prior notification to

1 Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its  
2 designee during the period of probation, shall be considered a violation of probation.

3 **4. Cooperate with Board Staff**

4 Respondent Brown shall cooperate with the Board's inspection program and with the  
5 Board's monitoring and investigation of Respondent Brown's compliance with the terms and  
6 conditions of her probation. Failure to cooperate shall be considered a violation of probation.

7 **5. Continuing Education**

8 Respondent Brown shall provide evidence of efforts to maintain skill and knowledge as a  
9 pharmacist as directed by the Board or its designee.

10 **6. Notice to Employers**

11 During the period of probation, Respondent Brown shall notify all present and prospective  
12 employers of the decision in Case Number 6068 and the terms, conditions and restrictions  
13 imposed on Respondent Brown by the decision, as follows:

14 Within thirty (30) days of the effective date of this Decision, and within fifteen (15) days of  
15 Respondent Brown undertaking any new employment, Respondent Brown shall cause her direct  
16 supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during  
17 Respondent Brown's tenure of employment) and owner to report to the Board in writing  
18 acknowledging that the listed individual(s) has/have read the decision in case number 2015  
19 68092, and terms and conditions imposed thereby. It shall be Respondent Brown's responsibility  
20 to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the  
21 Board.

22 If Respondent Brown works for or is employed by or through a pharmacy employment  
23 service, Respondent Brown must notify her direct supervisor, pharmacist-in-charge, and owner at  
24 every entity licensed by the Board of the terms and conditions of the Decision in Case Number  
25 6068 in advance of Respondent Brown commencing work at each licensed entity. A record of  
26 this notification must be provided to the Board upon request.

27 Furthermore, within thirty (30) days of the effective date of this Decision, and within fifteen  
28 (15) days of Respondent Brown undertaking any new employment by or through a pharmacy



1 employment service, Respondent Brown shall cause her direct supervisor with the pharmacy  
2 employment service to report to the Board in writing acknowledging that she has read the  
3 Decision in Case Number 6068 and the terms and conditions imposed thereby. It shall be  
4 Respondent Brown's responsibility to ensure that her employer(s) and/or supervisor(s) submit  
5 timely acknowledgment(s) to the Board.

6 Failure to timely notify present or prospective employer(s) or to cause that/those  
7 employer(s) to submit timely acknowledgments to the Board shall be considered a violation of  
8 probation.

9 "Employment" within the meaning of this provision shall include any full-time,  
10 part-time, temporary, relief or pharmacy management service as a pharmacist or any  
11 position for which a pharmacist license is a requirement or criterion for employment,  
12 whether the respondent is an employee, independent contractor or volunteer.

13 **7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as**  
14 **Designated Representative-in-Charge, or Serving as a Consultant**

15 During the period of probation, Respondent Brown shall not supervise any intern  
16 pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity  
17 licensed by the Board nor serve as a consultant unless otherwise specified in this order.  
18 Assumption of any such unauthorized supervision responsibilities shall be considered a violation  
19 of probation. Respondent Brown may remain the pharmacist-in-charge at Respondent Pharmacy  
20 only.

21 **8. Reimbursement of Board Costs**

22 As a condition precedent to successful completion of probation, Respondent Brown shall  
23 pay to the Board its costs of investigation and prosecution in the amount of \$6,675.45, jointly and  
24 severally with Respondent Pharmacy. Respondents shall make the payments on a payment plan  
25 approved by the Board.

26 There shall be no deviation from this schedule absent prior written approval by the Board or  
27 its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of  
28 probation.

1 The filing of bankruptcy by either or both Respondents shall not relieve Respondents of  
2 their responsibility to reimburse the Board its costs of investigation and prosecution.

3 **9. Probation Monitoring Costs**

4 Respondent Brown shall pay any costs associated with probation monitoring as determined  
5 by the Board each and every year of probation. Such costs shall be payable to the board on a  
6 schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as  
7 directed shall be considered a violation of probation.

8 **10. Status of License**

9 Respondent Brown shall, at all times while on probation, maintain an active, current license  
10 with the Board, including any period during which suspension or probation is tolled. Failure to  
11 maintain an active, current license shall be considered a violation of probation.

12 If Respondent Brown's license expires or is cancelled by operation of law or otherwise at  
13 any time during the period of probation, including any extensions thereof due to tolling or  
14 otherwise, upon renewal or reapplication Respondent Brown's license shall be subject to all terms  
15 and conditions of this probation not previously satisfied.

16 **11. License Surrender While on Probation/Suspension**

17 Following the effective date of this Decision, should Respondent Brown cease practice due  
18 to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,  
19 Respondent Brown may tender her license to the Board for surrender. The Board or its designee  
20 shall have the discretion whether to grant the request for surrender or take any other action it  
21 deems appropriate and reasonable. Upon formal acceptance of the surrender of the license,  
22 Respondent Brown will no longer be subject to the terms and conditions of probation. This  
23 surrender constitutes a record of discipline and shall become a part of Respondent Brown's  
24 license history with the Board.

25 Upon acceptance of the surrender, Respondent Brown shall relinquish her pocket and wall  
26 license to the Board within ten (10) days of notification by the Board that the surrender is  
27 accepted. Respondent Brown may not reapply for any license from the Board for three (3) years  
28 from the effective date of the surrender. Respondent Brown shall meet all requirements

1 applicable to the license sought as of the date the application for that license is submitted to the  
2 board, including any outstanding costs.

3 **12. Notification of a Change in Name, Residence Address, Mailing Address or**  
4 **Employment**

5 Respondent Brown shall notify the Board in writing within ten (10) days of any change of  
6 employment. Said notification shall include the reasons for leaving, the address of the new  
7 employer, the name of the supervisor and owner, and the work schedule if known. Respondent  
8 Brown shall further notify the Board in writing within ten (10) days of a change in name,  
9 residence address, mailing address, or phone number.

10 Failure to timely notify the Board of any change in employer(s), name(s), address(es), or  
11 phone number(s) shall be considered a violation of probation.

12 **13. Tolling of Probation**

13 Except during periods of suspension, Respondent shall, at all times while on probation, be  
14 employed as a pharmacist in California for a minimum of forty (40) hours per calendar month.  
15 Any month during which this minimum is not met shall toll the period of probation, *i.e.*, the  
16 period of probation shall be extended by one month for each month during which this minimum is  
17 not met. During any such period of tolling of probation, Respondent Brown must nonetheless  
18 comply with all terms and conditions of probation.

19 Should Respondent Brown, regardless of residency, for any reason (including vacation)  
20 cease practicing as a pharmacist for a minimum of forty (40) hours per calendar month in  
21 California, respondent must notify the board in writing within ten (10) days of the cessation of  
22 practice, and must further notify the board in writing within ten (10) days of the resumption of  
23 practice. Any failure to provide such notification(s) shall be considered a violation of probation.

24 It is a violation of probation for Respondent Brown's probation to remain tolled pursuant to  
25 the provisions of this condition for a total period, counting consecutive and non-consecutive  
26 months, exceeding thirty-six (36) months.

27 "Cessation of practice" means any calendar month during which Respondent  
28 Brown is not practicing as a pharmacist for at least forty (40) hours, as defined by

1 Business and Professions Code section 4000 *et seq.* "Resumption of practice" means  
2 any calendar month during which Respondent Brown is practicing as a pharmacist for  
3 at least forty (40) hours as a pharmacist as defined by Business and Professions Code  
4 section 4000 *et seq.*

#### 5 **14. Violation of Probation**

6 If a Respondent Brown has not complied with any term or condition of probation, the Board  
7 shall have continuing jurisdiction over Respondent Brown, and probation shall automatically be  
8 extended, until all terms and conditions have been satisfied or the Board has taken other action as  
9 deemed appropriate to treat the failure to comply as a violation of probation, to terminate  
10 probation, and to impose the penalty that was stayed.

11 If Respondent Brown violates probation in any respect, the Board, after giving Respondent  
12 Brown notice and an opportunity to be heard, may revoke probation and carry out the disciplinary  
13 order that was stayed. Notice and opportunity to be heard are not required for those provisions  
14 stating that a violation thereof may lead to automatic termination of the stay and/or revocation of  
15 the license. If a petition to revoke probation or an accusation is filed against Respondent Brown  
16 during probation, the Board shall have continuing jurisdiction and the period of probation shall be  
17 automatically extended until the petition to revoke probation or accusation is heard and decided,  
18 and the charges and allegations in First Amended Accusation No. 6068 shall be deemed true and  
19 correct.

#### 20 **15. Completion of Probation**

21 Upon written notice by the Board or its designee indicating successful completion of  
22 probation, Respondent Brown's license will be fully restored.

#### 23 **16. Remedial Education**

24 Within thirty (30) days of the effective date of this Decision, Respondent shall submit to the  
25 Board or its designee, for prior approval, an appropriate program of remedial education related to  
26 compounding, law, and the duties of the pharmacist-in-charge. The program of remedial  
27 education shall consist of at least forty (40) hours, with 10 hours completed per year, at least; fifty  
28 percent of the remedial education shall be attended by Respondent Brown in person; and all

1 remedial education will be at Respondent Brown's own expense. All remedial education shall be  
2 in addition to, and shall not be credited toward, continuing education (CE) courses used for  
3 license renewal purposes.

4 Failure to timely submit or complete the approved remedial education shall be considered a  
5 violation of probation. The period of probation will be automatically extended until such  
6 remedial education is successfully completed and written proof, in a form acceptable to the  
7 Board, is provided to the Board or its designee.

8 Following the completion of each course, the Board or its designee may require Respondent  
9 Brown, at her own expense, to take an approved examination to test the Respondent Brown's  
10 knowledge of the course. If Respondent Brown does not achieve a passing score on the  
11 examination, this failure shall be considered a violation of probation. Any such examination  
12 failure shall require Respondent Brown to take another course approved by the Board in the same  
13 subject area.

#### 14 **17. No Ownership of Licensed Premises**

15 Respondent Brown shall not acquire any new ownership, legal or beneficial interest nor  
16 serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any  
17 additional business, firm, partnership, or corporation licensed by the Board. If Respondent  
18 Brown currently owns or has any legal or beneficial interest in, or serves as a manager,  
19 administrator, member, officer, director, trustee, associate, or partner of any business, firm,  
20 partnership, or corporation currently or hereinafter licensed by the Board, Respondent Brown  
21 may continue to serve in such capacity or hold that interest, but only to the extent of that position  
22 or interest as of the effective date of this Decision. Violation of this restriction shall be  
23 considered a violation of probation.

#### 24 **18. Ethics Course**

25 Within sixty (60) calendar days of the effective date of this Decision, Respondent Brown  
26 shall enroll in a course in ethics, at Respondent Brown's expense, approved in advance by the  
27 board or its designee. Failure to initiate the course during the first year of probation, and  
28 complete it within the second year of probation, is a violation of probation.

1 Respondent Brown shall submit a certificate of completion to the Board or its designee  
2 within five days after completing the course.

3 **DISCIPLINARY ORDER FOR RESPONDENT PHARMACY**

4 IT IS HEREBY ORDERED that Pharmacy Permit Nos. PHY 51088 and 54438 issued to  
5 Animal Solutions Pharmacy Inc.; Clara Frances Brown, Owner are revoked. However, the  
6 revocation is stayed and Respondent Pharmacy is placed on probation for four (4) years on the  
7 following terms and conditions.

8 **1. Obey All Laws**

9 Respondent Pharmacy shall obey all state and federal laws and regulations,

10 Respondent Pharmacy shall report any of the following occurrences to the Board, in  
11 writing, within seventy-two (72) hours of such occurrence:

- 12 • an arrest or issuance of a criminal complaint for violation of any provision of the  
13 Pharmacy Law, state and federal food and drug laws, or state and federal controlled  
14 substances laws
- 15 • a plea of guilty or nolo contendere in any state or federal criminal proceeding to any  
16 criminal complaint, information or indictment
- 17 • a conviction of any crime
- 18 • discipline, citation, or other administrative action filed by any state or federal agency  
19 which involves Respondent Pharmacy's Pharmacy Permits or which is related to the  
20 practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing,  
21 or charging for any drug, device or controlled substance.

22 Failure to timely report such occurrence shall be considered a violation of probation.

23 **2. Report to the Board**

24 Respondent Pharmacy shall report to the Board quarterly, on a schedule as directed by the  
25 Board or its designee. The report shall be made either in person or in writing, as directed.  
26 Among other requirements, Respondent Pharmacy shall state in each report under penalty of  
27 perjury whether there has been compliance with all the terms and conditions of probation. Failure  
28 to submit timely reports in a form as directed shall be considered a violation of probation. Any

1 period(s) of delinquency in submission of reports as directed may be added to the total period of  
2 probation. Moreover, if the final probation report is not made as directed, probation shall be  
3 automatically extended until such time as the final report is made and accepted by the Board.

### 4 **3. Interview with the Board**

5 Upon receipt of reasonable prior notice, Respondent Pharmacy shall appear in person for  
6 interviews with the Board or its designee, at such intervals and locations as are determined by the  
7 board or its designee. Failure to appear for any scheduled interview without prior notification to  
8 Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its  
9 designee during the period of probation, shall be considered a violation of probation.

### 10 **4. Cooperate with Board Staff**

11 Respondent Pharmacy shall cooperate with the Board's inspection program and with the  
12 Board's monitoring and investigation of Respondent Pharmacy's compliance with the terms and  
13 conditions of their probation. Failure to cooperate shall be considered a violation of probation.

### 14 **5. Reimbursement of Board Costs**

15 As a condition precedent to successful completion of probation, Respondent Pharmacy shall  
16 pay to the Board its costs of investigation and prosecution in the amount of \$6,675.45, jointly and  
17 severally with Respondent Brown. Respondents shall make the payments on a payment plan  
18 approved by the Board.

19 There shall be no deviation from this schedule absent prior written approval by the Board or  
20 its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of  
21 probation.

22 The filing of bankruptcy by either or both Respondents shall not relieve Respondents of  
23 their responsibility to reimburse the Board its costs of investigation and prosecution.

### 24 **6. Probation Monitoring Costs**

25 Respondent Pharmacy shall pay any costs associated with probation monitoring as  
26 determined by the Board each and every year of probation. Such costs shall be payable to the  
27 board on a schedule as directed by the Board or its designee. Failure to pay such costs by the  
28 deadline(s) as directed shall be considered a violation of probation.

1           7.     **Status of License**

2           Respondent Pharmacy shall, at all times while on probation, maintain current licensure with  
3     the Board. If Respondent Pharmacy submits an application to the Board, and the application is  
4     approved, for a change of location, change of permit or change of ownership, the Board shall  
5     retain continuing jurisdiction over the license, and Respondent Pharmacy shall remain on  
6     probation as determined by the Board. Failure to maintain current licensure shall be considered a  
7     violation of probation.

8           If Respondent Pharmacy's license expires or is cancelled by operation of law or otherwise  
9     at any time during the period of probation, including any extensions thereof or otherwise, upon  
10    renewal or reapplication Respondent Pharmacy's license shall be subject to all terms and  
11    conditions of this probation not previously satisfied.

12           8.     **License Surrender While on Probation/Suspension**

13           Following the effective date of this Decision, should Respondent Pharmacy discontinue  
14    business, Respondent Pharmacy may tender the premises license to the board for surrender. The  
15    Board or its designee shall have the discretion whether to grant the request for surrender or take  
16    any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of  
17    the license, Respondent Pharmacy will no longer be subject to the terms and conditions of  
18    probation.

19           Upon acceptance of the surrender, Respondent Pharmacy shall relinquish the premises wall  
20    and renewal license to the Board within ten (10) days of notification by the Board that the  
21    surrender is accepted. Respondent Pharmacy shall further submit a completed Discontinuance of  
22    Business form according to Board guidelines and shall notify the Board of the records inventory  
23    transfer.

24           Respondent Pharmacy shall also, by the effective date of this Decision, arrange for the  
25    continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written  
26    notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that  
27    identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating  
28    as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five



1 days of its provision to the pharmacy's ongoing patients, Respondent Pharmacy shall provide a  
2 copy of the written notice to the Board. For the purposes of this provision, "ongoing patients"  
3 means those patients for whom the pharmacy has on file a prescription with one or more refills  
4 outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60)  
5 days.

6 Respondent Pharmacy may not apply for any new licensure from the Board for three (3)  
7 years from the effective date of the surrender. Respondent Pharmacy shall meet all requirements  
8 applicable to the license sought as of the date the application for that license is submitted to the  
9 Board.

10 Respondent Pharmacy further stipulates that it shall reimburse the board for its costs of  
11 investigation and prosecution prior to the acceptance of the surrender.

12 **9. Notice to Employees**

13 Respondent Pharmacy shall, upon or before the effective date of this Decision, ensure that  
14 all employees involved in permit operations are made aware of all the terms and conditions of  
15 probation, either by posting a notice of the terms and conditions, circulating such notice, or both.  
16 If the notice required by this provision is posted, it shall be posted in a prominent place and shall  
17 remain posted throughout the probation period. Respondent Pharmacy shall ensure that any  
18 employees hired or used after the effective date of this Decision are made aware of the terms and  
19 conditions of probation by posting a notice, circulating a notice, or both. Additionally,  
20 Respondent Pharmacy shall submit written notification to the Board, within fifteen (15) days of  
21 the effective date of this Decision, that this term has been satisfied. Failure to submit such  
22 notification to the Board shall be considered a violation of probation.

23 "Employees" as used in this provision includes all full-time, part-time,  
24 volunteer, temporary and relief employees and independent contractors employed or  
25 hired at any time during probation.

26 **10. Owners and Officers: Knowledge of the Law**

27 Respondent Pharmacy shall provide, within thirty (30) days after the effective date of this  
28 Decision, signed and dated statements from its owner(s), including any owner or holder of ten

1 percent (10%) or more of the interest in Respondent Pharmacy or Respondent Pharmacy's stock,  
2 and any officer, stating under penalty of perjury that said individuals have read and are familiar  
3 with state and federal laws and regulations governing the practice of pharmacy. The failure to  
4 timely provide said statements under penalty of perjury shall be considered a violation of  
5 probation.

#### 6 **11. Posted Notice of Probation**

7 Respondent Pharmacy shall prominently post a probation notice provided by the Board in a  
8 place conspicuous and readable to the public. The probation notice shall remain posted during  
9 the entire period of probation.

10 Respondent Pharmacy shall not, directly or indirectly, engage in any conduct or make any  
11 statement which is intended to mislead or is likely to have the effect of misleading any patient,  
12 customer, member of the public, or other person(s) as to the nature of and reason for the probation  
13 of the licensed entity.

14 Failure to post such notice shall be considered a violation of probation.

#### 15 **12. Violation of Probation**

16 If Respondent Pharmacy has not complied with any term or condition of probation, the  
17 Board shall have continuing jurisdiction over Respondent Pharmacy's license, and probation shall  
18 be automatically extended until all terms and conditions have been satisfied or the Board has  
19 taken other action as deemed appropriate to treat the failure to comply as a violation of probation,  
20 to terminate probation, and to impose the penalty that was stayed.

21 If Respondent Pharmacy violates probation in any respect, the Board, after giving  
22 Respondent Pharmacy notice and an opportunity to be heard, may revoke probation and carry out  
23 the disciplinary order that was stayed. Notice and opportunity to be heard are not required for  
24 those provisions stating that a violation thereof may lead to automatic termination of the stay  
25 and/or revocation of the license. If a petition to revoke probation or an accusation is filed against  
26 Respondent Pharmacy during probation, the Board shall have continuing jurisdiction and the  
27 period of probation shall be automatically extended until the petition to revoke probation or

28 ////

13. Completion of Probation

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent Pharmacy's license will be fully restored.

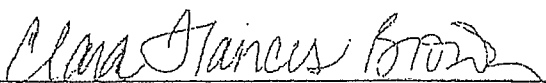
14. Consultant Pharmacist Review of Pharmacy Operations

During the period of probation, Respondent Pharmacy shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by Respondent Pharmacy with state and federal laws and regulations governing the practice of pharmacy. The consultant shall be a pharmacist licensed by and not on probation with the Board and whose name shall be submitted to the Board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. During the period of probation, the Board or its designee retains the discretion to reduce the frequency of the pharmacist consultant's review of Respondent Pharmacy's operations. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

ACCEPTANCE

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

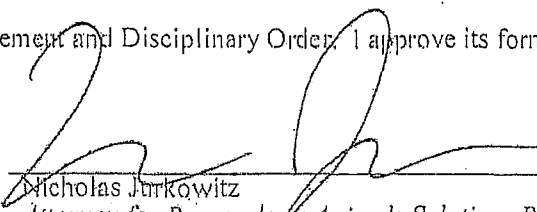
DATED: \_\_\_\_\_

  
Clara Frances Brown  
ANIMAL SOLUTIONS PHARMACY INC.; CLARA  
FRANCES BROWN, OWNER  
CLARA FRANCES BROWN

I have read and fully discussed with Respondents Animal Solutions Pharmacy Inc.; Clara Frances Brown, Owner and Clara Frances Brown the terms and conditions and other matters

1 I have read and fully discussed with Respondents Animal Solutions Pharmacy Inc.; Clara  
2 Frances Brown, Owner and Clara Frances Brown the terms and conditions and other matters  
3 contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and  
4 content.

5 DATED: 4-4-18

  
6 Nicholas Jurkowitz  
7 Attorney for Respondents Animal Solutions Pharmacy  
8 Inc.; Clara Frances Brown, Owner and Clara Frances  
9 Brown

10 ENDORSEMENT

11 The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully  
12 submitted for consideration by the Board of Pharmacy.

13 Dated:

Respectfully submitted,

14 XAVIER BECERRA  
15 Attorney General of California  
16 DIANN SOKOLOFF  
17 Supervising Deputy Attorney General

18 CARTER OTT  
19 Deputy Attorney General  
20 Attorneys for Complainant

21 SF2017901117  
22 90928692.docx

1 I have read and fully discussed with Respondents Animal Solutions Pharmacy Inc.; Clara  
2 Frances Brown, Owner and Clara Frances Brown the terms and conditions and other matters  
3 contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and  
4 content.

5 DATED: \_\_\_\_\_

Nicholas Jurkowitz  
*Attorney for Respondents Animals Solutions Pharmacy  
Inc.; Clara Frances Brown, Owner and Clara Frances  
Brown*

8  
9 ENDORSEMENT

10 The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully  
11 submitted for consideration by the Board of Pharmacy.

12 Dated:

13 4/5/18

Respectfully submitted,

14 XAVIER BECERRA  
Attorney General of California  
15 DIANN SOKOLOFF  
Supervising Deputy Attorney General

16 

17 CARTER OTT  
18 Deputy Attorney General  
Attorneys for Complainant

19  
20  
21 SF2017901117  
22 90928692.docx

**Exhibit A**

**First Amended Accusation No. 6068**

1 XAVIER BECERRA  
Attorney General of California  
2 DIANN SOKOLOFF  
Supervising Deputy Attorney General  
3 CARTER OTT  
Deputy Attorney General  
4 State Bar No. 221660  
1515 Clay Street, 20th Floor  
5 P.O. Box 70550  
Oakland, CA 94612-0550  
6 Telephone: (510) 879-1349  
Facsimile: (510) 622-2270  
7 E-mail: Carter.Ott@doj.ca.gov  
*Attorneys for Complainant*

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

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

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

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

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

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

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

“(1) Suspending judgment.

“(2) Placing him or her upon probation.

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

“(4) Revoking his or her license.

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

...

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

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.”

27 /////

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))

(Respondents Animal Solutions Pharmacy and Brown)

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

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

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

21 SECOND CAUSE FOR DISCIPLINE

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

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

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

(Respondents Animal Solutions Pharmacy, Brown, and Newell)

24 31. Respondents Animal Solutions, Brown, and Newell have subjected their Pharmacy  
25 Permits and Pharmacists Licenses, respectively, to disciplinary action for permitting a non-  
26 licensed individual to act as a pharmacy technician without the supervision of a pharmacist. (Bus.  
27 & Prof. Code § 4115, subds. (b) and (e); and Cal. Code of Regs., title 16, §§ 1793.2 and 1793.7,  
28 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

(Certifications and Approvals for Trainee Program)

8 (Bus. & Prof. Code §§ 4038, subd. (b) and 4115.5, subd. (b)(5) and (c)(1); and  
9 Cal. Code of Regs., title 16, § 1793.6)

(Respondents Animal Solutions Pharmacy and Brown)

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

21 FOURTH CAUSE FOR DISCIPLINE

22 (Failing to Conduct and Document Annual Policy and Procedure Review)

23 (Cal. Code of Regs., title 16, § 1735.5, subd. (b))

(Respondents Animal Solutions Pharmacy and Brown)

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

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)  
5 (Cal. Code of Regs., title 16, § 1735.6, subds. (a), (b), and (c))  
(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)  
17 (Cal. Code of Regs., title 16, § 1735.8, subds. (a), (b), (c), and (d))  
(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)  
25 (Cal. Code of Regs., title 16, § 1735.7, subds. (a) and (b))  
(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)

10 (Bus. & Prof. Code § 4342, subd. (a); and  
11 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

22 (Failing to Maintain Records of Destruction of Drugs)

23 (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

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

TENTH CAUSE FOR DISCIPLINE

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

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

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 Permits 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 Permits 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

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



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

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9  
10  
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1 XAVIER BECERRA  
Attorney General of California  
2 DIANN SOKOLOFF  
Supervising Deputy Attorney General  
3 CARTER OTT  
Deputy Attorney General  
4 State Bar No. 221660  
1515 Clay Street, 20th Floor  
5 P.O. Box 70550  
Oakland, CA 94612-0550  
6 Telephone: (510) 879-1349  
Facsimile: (510) 622-2270  
7 E-mail: Carter.Ott@doj.ca.gov  
*Attorneys for Complainant*

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,**  
15 **OWNER**  
16 **4775 Sonoma Hwy**  
**Santa Rosa, CA 95409**

17 **Pharmacy Permit No. PHY 51088 (Expired**  
**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.  
25  
26  
27  
28

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 1:20	4 "472 Crivelli Dr., Sonoma, CA 95476" to "971 Puget Dr. E, Port 5 Orchard, WA 98366"
6 1:20, 2:13, and 18:9	7 "Scott" to "Arthur"

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

10 Dated: February 9, 2018

11 Respectfully submitted,

12 XAVIER BECERRA  
13 Attorney General of California  
14 DIANN SOKOLOFF  
15 Supervising Deputy Attorney General

16 

17 CARTER OTT  
18 Deputy Attorney General  
19 *Attorneys for Complainant*

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21 90908019.docx

1 XAVIER BECERRA  
Attorney General of California  
2 DIANN SOKOLOFF  
Supervising Deputy Attorney General  
3 CARTER OTT  
Deputy Attorney General  
4 State Bar No. 221660  
1515 Clay Street, 20th Floor  
5 P.O. Box 70550  
Oakland, CA 94612-0550  
6 Telephone: (510) 879-1349  
Facsimile: (510) 622-2270  
7 E-mail: Carter.Ott@doj.ca.gov  
*Attorneys for Complainant*

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**  
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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.

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

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

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

## JURISDICTION

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

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

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

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.

1       ....”

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

3       ...

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

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

13       ....”

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

15       “(a) The board may institute any action or actions as may be provided by law and that, in its  
16   discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not  
17   conform to the standard and tests as to quality and strength, provided in the latest edition of the  
18   United States Pharmacopoeia or the National Formulary, or that violate any provision of the  
19   Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division  
20   104 of the Health and Safety Code).”

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

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

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

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

27       ////

28       ////



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.

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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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)  
(Bus. & Prof. Code § 4115, subds. (b) and (e); and  
11 Cal. Code of Regs., title 16, §§ 1793.2 and 1793.7, subd. (b))  
(Respondents Animal Solutions Pharmacy, Brown, and Newell)

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

23 THIRD CAUSE FOR DISCIPLINE

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

26 32. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and  
27 Pharmacist License, respectively, to disciplinary action for having a non-licensed individual  
28 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))  
11 (Respondents Animal Solutions Pharmacy and Brown)

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.

17 FIFTH CAUSE FOR DISCIPLINE

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

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, subds. (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.



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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)  
(Cal. Code of Regs., title 16, § 1735.3, subd. (b))  
(Respondents Animal Solutions Pharmacy and Brown)

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

17  
18 TENTH CAUSE FOR DISCIPLINE

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

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

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1 ELEVENTH CAUSE FOR DISCIPLINE

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

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

12 TWELFTH CAUSE FOR DISCIPLINE

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

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

23 THIRTEENTH CAUSE FOR DISCIPLINE

24 (Impeding an Investigation)  
25 (Bus. & Prof. Code §§ 4080, 4081, and 4301, subd. (q))  
26 (Respondents Animal Solutions Pharmacy and Brown)

27 42. Respondents Animal Solutions and Brown have subjected their Pharmacy Permit and  
28 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

(Pharmacist-in-Charge)

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

6 (Respondents Animal Solutions Pharmacy and Brown)

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

13 OTHER MATTERS

14 44. Pursuant to Section 4307, if discipline is imposed on Pharmacy Permit Number PHY  
15 51088 issued to Animal Solutions Pharmacy Inc., Animal Solutions Pharmacy Inc. shall be  
16 prohibited from serving as manager, administrator, owner, member, officer, director, associate, or  
17 partner of a licensee for five years if Pharmacy Permit Number PHY 51088 is placed on  
18 probation or until Pharmacy Permit Number PHY 51088 is reinstated if it is revoked.

19 45. Pursuant to Section 4307, if discipline is imposed on Pharmacy Permit Number PHY  
20 51088 issued to Animal Solutions Pharmacy Inc. while Clara Frances Brown has been an officer  
21 and/or owner and had knowledge of or knowingly participated in any conduct for which the  
22 licensee was disciplined, Clara Frances Brown shall be prohibited from serving as a manager,  
23 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if  
24 Pharmacy Permit Number PHY 51088 is placed on probation or until Pharmacy Permit Number  
25 PHY 51088 is reinstated if it is revoked.

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1 PRAYER

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

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

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


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

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

15 5. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the  
16 investigation and enforcement of this case, pursuant to Business and Professions Code section  
17 125.3; and

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

19  
20  
21 DATED: 2/9/18



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

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1 XAVIER BECERRA  
Attorney General of California  
2 DIANN SOKOLOFF  
Supervising Deputy Attorney General  
3 CARTER OTT  
Deputy Attorney General  
4 State Bar No. 221660  
1515 Clay Street, 20th Floor  
5 P.O. Box 70550  
Oakland, CA 94612-0550  
6 Telephone: (510) 879-1349  
Facsimile: (510) 622-2270  
7 E-mail: Carter.Ott@doj.ca.gov  
*Attorneys for Complainant*

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 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.

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

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

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

#### JURISDICTION

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

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

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

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

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

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

“(1) Suspending judgment.

“(2) Placing him or her upon probation.

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

“(4) Revoking his or her license.

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

...

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

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

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



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.

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 licensee 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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27 /////

28 /////

29 /////



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

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

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

#### SECOND CAUSE FOR DISCIPLINE

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

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

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

(Respondents Animal Solutions Pharmacy, Brown, and Newell)

31. Respondents Animal Solutions, Brown, and Newell have subjected their Pharmacy Permit 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, subds. (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-licensed individual, G.C., to let herself into the pharmacy with a pharmacist's key and perform technician tasks without the supervision of a pharmacist. These tasks included removing drugs from stock, weighing drugs on a balance, mixing pharmaceuticals, and placing the product into a 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.

#### THIRD CAUSE FOR DISCIPLINE

(Certifications and Approvals for Trainee Program)

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

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))  
11 (Respondents Animal Solutions Pharmacy and Brown)

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.

17 FIFTH CAUSE FOR DISCIPLINE

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

19  
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

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

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)

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

TENTH CAUSE FOR DISCIPLINE

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

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

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

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

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

OTHER MATTERS

44. Pursuant to Section 4307, if discipline is imposed on Pharmacy Permit Number PHY 51088 issued to Animal Solutions Pharmacy Inc., Animal Solutions Pharmacy Inc. shall be prohibited from serving as 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 or until Pharmacy Permit Number PHY 51088 is reinstated if it is revoked.

45. Pursuant to Section 4307, if discipline is imposed on Pharmacy Permit Number PHY 51088 issued to Animal Solutions Pharmacy Inc. while Clara Frances Brown has been an officer and/or owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Clara Frances Brown shall be prohibited 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 or until Pharmacy Permit Number 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;

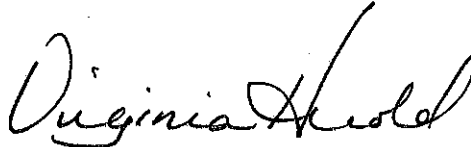
3. Revoking or suspending Pharmacist License Number RPH 44486, issued to Respondent Christopher Scott Newell;

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