

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

In the Matter of the Amended Accusation Against:

**BET FARM LLC, dba
BET PHARM LLC,
GREEN WORLD PHARMACY, LLC, SOLE OWNER
ROBERT H. DOUGLAS, MEMBER/MANAGER OF
GREEN WORLD PHARMACY, LLC.**

**Nonresident Pharmacy Permit No. NRP 1759, and
Nonresident Sterile Compounding Permit No. NSC 100946**

Respondent

Agency Case No. 7212

OAH No. 2022060207

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 26, 2023.

It is so ORDERED on June 26, 2023.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

A handwritten signature in black ink, appearing to read "Seung W. Oh". The signature is fluid and cursive, with the first name "Seung" and last name "Oh" clearly visible.

Seung W. Oh, Pharm.D.
Board President

1 ROB BONTA
Attorney General of California
2 ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
3 ANAHITA S. CRAWFORD
Deputy Attorney General
4 State Bar No. 209545
1300 I Street, Suite 125
5 P.O. Box 944255
Sacramento, CA 94244-2550
6 Telephone: (916) 210-6099
Facsimile: (916) 327-8643
7 *Attorneys for Complainant*

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

12 In the Matter of the Amended Accusation
13 Against:

Case No. 7212

14 **BET Pharm LLC**
Green World Pharmacy, LLC, Sole Owner
15 Robert H. Douglas, Member/Manager of Green
World Pharmacy, LLC.
16 **1501 Bull Lea Rd., Ste 102B**
17 **Lexington, Ky 40511**

OAH No. 2022060207

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER**

18 Nonresident Pharmacy Permit No. NRP 1759

19 Nonresident Sterile Compounding Permit
20 Number NSC 100946

21 Respondent.

22
23 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
24 entitled proceedings that the following matters are true:

25 **PARTIES**

26 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy
27 (Board). She brought this action solely in her official capacity and is represented in this matter by
28

1 Rob Bonta, Attorney General of the State of California, by Anahita S. Crawford, Deputy Attorney
2 General.

3 2. Respondent BET Pharm LLC, with Green World Pharmacy, LLC, as the sole owner
4 and Robert H. Douglas as Manager/Member of Green World Pharmacy, LLC was represented in
5 this proceeding by attorney Douglas R. Ottenwess, Paul, Plevin, Sullivan & Connaughton, LLP,
6 whose address was 101 West Broadway Ninth Floor, San Diego, CA 92101-8285. After a
7 merger, effective January 2023, Respondent continues to be represented by Douglas R.
8 Ottenwess, with the law firm of Quarles & Brady, LLP, whose address remains 101 West
9 Broadway Ninth Floor, San Diego, CA 92101-8285.

10 3. On or about June 22, 2016, the Board issued Nonresident Pharmacy Permit No. NRP
11 1759 to BET Pharm LLC, with Green World Pharmacy, LLC, as the sole owner and Robert H.
12 Douglas as Manager/Member of Green World Pharmacy, LLC (Respondent). The Nonresident
13 Pharmacy Permit was in full force and effect at all times relevant to the charges brought in
14 Amended Accusation No. 7212, and will expire on June 1, 2022, unless renewed.

15 4. On or about June 22, 2021, the Board issued Nonresident Sterile Compounding
16 Permit No. NSC 100946 to BET Pharm LLC, with Green World Pharmacy, LLC, as the sole
17 owner and Robert H. Douglas as Manager/Member of Green World Pharmacy, LLC
18 (Respondent). The Nonresident Sterile Compounding Permit was in full force and effect at all
19 times relevant to the charges brought in Amended Accusation No. 7212, and will expire on June
20 1, 2022, unless renewed.

21 **JURISDICTION**

22 5. Amended Accusation No. 7212 was filed before the Board, and is currently pending
23 against Respondent. The Amended Accusation and all other statutorily required documents were
24 properly served on Respondent on March 20, 2023. Respondent previously timely filed its Notice
25 of Defense, which also serves to contest the Amended Accusation.

26 6. A copy of Amended Accusation No. 7212 is attached as exhibit A and incorporated
27 herein by reference.

28 ///

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28

- 2
- 3
- 4
- 5

6
7
8
9
10
11
12

13
14

15

16
17
18
19

20
21
22
23

24
25
26
27

28

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Nonresident Pharmacy Permit No. NRP 1759 and Nonresident Sterile Compounding Permit No. NSC 100946, issued to Respondent BET Farm Inc. doing business as BET Pharm LLC with Robert H. Douglas as Manager are revoked. However, the revocations are stayed and Respondent is placed on probation for three (3) years on the following terms and conditions:

1 **1. Definition: Respondent**

2 For the purposes of these terms and conditions, “respondent” shall refer to Respondent BET
3 Pharm LLC, with Green World Pharmacy, LLC, as the sole owner and Robert H. Douglas as
4 Manager/Member of Green World Pharmacy, LLC. All terms and conditions stated herein shall
5 bind and be applicable to the licensed premises and to all owners, managers, officers,
6 administrators, members, directors, trustees, associates, or partners thereof. For purposes of
7 compliance with any term or condition, any report, submission, filing, payment, or appearance
8 required to be made by respondent to or before the board or its designee shall be made by an
9 owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

10 **2. Obey All Laws**

11 Respondent shall obey all state and federal laws and regulations.

12 Respondent shall report any of the following occurrences to the board, in writing, within
13 seventy-two (72) hours of such occurrence:

- 14 • an arrest or issuance of a criminal complaint for violation of any provision of the
15 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
16 substances laws;
- 17 • a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal
18 proceeding to any criminal complaint, information or indictment;
- 19 • a conviction of any crime; or
- 20 • discipline, citation, or other administrative action filed by any state or federal agency
21 which involves respondent’s Nonresident Pharmacy Permit or Nonresident Sterile
22 Compounding Pharmacy Permit or which is related to the practice of pharmacy or the
23 manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous
24 drug, and/or dangerous device or controlled substance.

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

26 **3. Report to the Board**

27 Respondent shall report to the board quarterly, on a schedule as directed by the board or its
28 designee. The report shall be made either in person or in writing, as directed. Among other

1 requirements, respondent shall state in each report under penalty of perjury whether there has
2 been compliance with all the terms and conditions of probation. Failure to submit timely reports
3 in a form as directed shall be considered a violation of probation. Any period(s) of delinquency
4 in submission of reports as directed may be added to the total period of probation. Moreover, if
5 the final probation report is not made as directed, probation shall be automatically extended until
6 such time as the final report is made and accepted by the board.

7 **4. Interview with the Board**

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

13 **5. Cooperate with Board Staff**

14 Respondent shall timely cooperate with the board's inspection program and with the board's
15 monitoring and investigation of respondent's compliance with the terms and conditions of the
16 probation, including but not limited to: timely responses to requests for information by board
17 staff; timely compliance with directives from board staff regarding requirements of any term or
18 condition of probation; and timely completion of documentation pertaining to a term or condition
19 of probation. Failure to timely cooperate shall be considered a violation of probation.

20 **6. Reimbursement of Board Costs**

21 As a condition precedent to successful completion of probation, respondent shall pay to the
22 board its costs of investigation and prosecution in the amount of \$33,149. Respondent shall make
23 said payments as specified by the board or its designee in writing, and with full payment to be
24 completed no later than one (1) year prior to the end date of probation. There shall be no
25 deviation from this schedule absent prior written approval by the board or its designee. Failure to
26 pay costs by the deadline(s) as directed shall be considered a violation of probation.

27 ///

28 ///

Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

7. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Probation monitoring costs include travel expenses for an inspector to inspect the facility on a schedule as determined by the board. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

8. Status of License

Respondent shall, at all times while on probation, maintain a current Nonresident Pharmacy Permit and Nonresident Sterile Compounding Pharmacy Permit with the board. Failure to maintain current licensure shall be considered a violation of probation.

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

9. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent wish to discontinue business, respondent may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

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

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

1 **10. Sale or Discontinuance of Business**

2 During the period of probation, should respondent sell, trade or transfer all or part of the
3 ownership of the licensed entity, discontinue doing business under the license issued to
4 respondent, or should practice at that location be assumed by another full or partial owner,
5 person, firm, business, or entity, under the same or a different premises license number, the board
6 or its designee shall have the sole discretion to determine whether to exercise continuing
7 jurisdiction over the licensed location, under the current or new premises license number, and/or
8 carry the remaining period of probation forward to be applicable to the current or new premises
9 license number of the new owner.

10 **11. Notice to Employees**

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

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

24 **12. Owners and Officers: Knowledge of the Law**

25 Respondent shall provide, within thirty (30) days after the effective date of this decision,
26 signed and dated statements from its owners, including any owner or holder of ten percent (10%)
27 or more of the interest in respondent or respondent's stock, and all of its officers, stating under
28 penalty of perjury that said individuals have read and are familiar with state and federal laws and

1 regulations governing the practice of pharmacy. The failure to timely provide said statements
2 under penalty of perjury shall be considered a violation of probation.

3 **13. Premises Open for Business**

4 Respondent shall remain open and engaged in its ordinary business as a pharmacy in
5 California for a minimum of 120 hours per calendar month. Any month during which this
6 minimum is not met shall toll the period of probation, i.e., the period of probation shall be
7 extended by one month for each month during with this minimum is not met. During any such
8 period of tolling of probation, respondent must nonetheless comply with all terms and conditions
9 of probation, unless respondent is informed otherwise in writing by the board or its designee. If
10 respondent is not open and engaged in its ordinary business as a Nonresident Pharmacy and
11 Nonresident Sterile Compounding Pharmacy for a minimum of 120 hours in any calendar month,
12 for any reason (including vacation), respondent shall notify the board in writing within ten (10)
13 days of the conclusion of that calendar month. This notification shall include at minimum all of
14 the following: the date(s) and hours respondent was open; the reason(s) for the interruption or
15 why business was not conducted; and the anticipated date(s) on which respondent will resume
16 business as required. Respondent shall further notify the board in writing with ten (10) days
17 following the next calendar month during which respondent is open and engaged in its ordinary
18 business as a Nonresident Pharmacy and Nonresident Sterile Compounding Pharmacy in
19 California for a minimum of 120 hours. Any failure to timely provide such notification(s) shall
20 be considered a violation of probation.

21 **14. Consultant Review of Pharmacy Operations**

22 Respondent shall retain, at its own expense, an independent consultant who shall review the
23 operations of the facility, during the period of probation, on a quarterly basis for compliance of
24 the facility with state and federal laws and regulations governing the practice of pharmacy, and
25 compliance by respondent. The consultant shall provide the board with an inspection agenda for
26 approval prior to conducting the inspection. Any inspection conducted without prior approval of
27 the inspection agenda shall not be accepted. The consultant shall also provide the board with
28 reports documenting the inspection. The reports shall be provided directly to the board, and

1 receive confirmation of receipt from the board, prior to providing to the respondent. Should the
2 board determine that the consultant is not appropriately assessing the operations of respondent, or
3 providing the appropriate written reports, the board shall require respondent to obtain a different
4 consultant through the same process outlined above, by submitting a new name of an expert
5 within sixty (60) days of respondent being notified of the need for a new consultant. During the
6 period of probation, the board shall retain discretion to reduce the frequency of the consultant's
7 review.

8 Respondent shall submit the name of the proposed consultant for approval within thirty (30)
9 days of the effective date of this decision. The consultant shall be a pharmacist licensed by and
10 not on probation with the board or other professional as appropriate and not on probation with the
11 board, who has been approved by the board to serve in this position. The consultant shall have
12 sufficient education, training, and professional experience to be able to provide guidance to
13 respondent related to the causes for discipline in Case No. 7212. Assumption of any unauthorized
14 supervision responsibilities shall be considered a violation of probation.

15 Failure to timely seek approval for, timely retain, or ensure timely reporting by the
16 consultant shall be considered a violation of probation.

17 **15. Posted Notice of Probation**

18 Respondent shall prominently post a probation notice provided by the board or its designee
19 in a place conspicuous to and readable by the public within two (2) days of receipt thereof from
20 the board or its designee. Failure to timely post such notice, or to maintain the posting during the
21 entire period of probation, shall be considered a violation of probation.

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

26 **16. Violation of Probation**

27 If a respondent has not complied with any term or condition of probation, the board shall
28 have continuing jurisdiction over respondent, and probation shall be automatically extended, until

1 all terms and conditions have been satisfied or the board has taken other action as deemed
2 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and
3 to impose the penalty that was stayed.

4 If respondent violates probation in any respect, the board, after giving respondent notice
5 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that
6 was stayed. If a petition to revoke probation or an accusation is filed against respondent during
7 probation, the board shall have continuing jurisdiction and the period of probation shall be
8 automatically extended until the petition to revoke probation or accusation is heard and decided
9 and the charges and allegations in First Amended Accusation No. 7212 shall be deemed true and
10 correct .

11 **17. Completion of Probation**

12 Upon written notice by the board or its designee indicating successful completion of
13 probation, respondent's license will be fully restored.

14 **18. No Additional Ownership or Management of Licensed Premises**

15 Respondent shall not acquire any additional ownership, legal or beneficial interest in, nor
16 serve as a manager, administrator, member, officer, director, associate, partner or any business,
17 firm, partnership, or corporation currently or hereinafter licensed by the board except as approved
18 by the board or its designee. Violations of this restriction shall be considered a violation of
19 probation.

20 **19. Labeling Claims**

21 Respondent will not use the terms "BioRelease", or "LA"/"Long Acting" or similar term, in
22 its labels, literature, website or marketing materials that are intended for sent into California. A
23 violation of this term shall be considered a violation of probation.

24 **20. Beyond Use Date Testing**

25 Respondent agrees to set Beyond Use Dates in conformance with Cal. Code of Regulations,
26 tit. 16 section 1735.2(i), for any preparations intended for or sent into California. A violation of
27 this term shall be considered a violation of probation.

28 ///

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28

- 2
- 3
- 4

5

6
7
8
9
10

12

13
14
15

17

19
20
21
22

24

25

26

27
28


21. **Cease Deslorelin Distribution into California**

Respondent agrees to cease distribution of their Deslorelin preparation and any similar preparation under any other name, in any form, into California.. A violation of this term 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, Douglas R. Ottenwess. I understand the stipulation and the effect it will have on my Nonresident Pharmacy Permit, and Nonresident Sterile Compounding Permit. 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: 4/18/23


BET PHARM LLC, GREEN WORLD PHARMACY,
LLC, SOLE OWNER WITH ROBERT H. DOUGLAS
AS MANAGER/MEMBER OF GREEN WORLD
PHARMACY, LLC
Respondent

By: Robert H Douglas, Manager
(Print Name and Title)

I have read and fully discussed with Respondent to BET Pharm LLC, with Green World Pharmacy, LLC, as the sole owner and Robert H. Douglas as Manager/Member of Green World Pharmacy, LLC, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: April 18, 2023


DOUGLAS R. OTTENWESS,
QUARLES & BRADY, LLP
Attorney for Respondent

ENDORSEMENT

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

3 DATED: _____

Respectfully submitted,

4 ROB BONTA
5 Attorney General of California
6 ANDREW M. STEINHEIMER
7 Supervising Deputy Attorney General

8 ANAHITA S. CRAWFORD
9 Deputy Attorney General
10 *Attorneys for Complainant*

11
12
13 SA2021304982
14 36980413.docx
15
16
17
18
19
20
21
22
23
24
25
26
27
28

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

3 DATED: 04/20/2023
4 _____

Respectfully submitted,

5 ROB BONTA
6 Attorney General of California
7 ANDREW M. STEINHEIMER
8 Supervising Deputy Attorney General



9 ANAHITA S. CRAWFORD
10 Deputy Attorney General
11 *Attorneys for Complainant*

12
13 SA2021304982
14 36980413.docx
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Exhibit A

Amended Accusation No. 7212

1 ROB BONTA
Attorney General of California
2 ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
3 ANAHITA S. CRAWFORD
Deputy Attorney General
4 State Bar No. 209545
1300 I Street, Suite 125
5 P.O. Box 944255
Sacramento, CA 94244-2550
6 Telephone: (916) 210-6099
Facsimile: (916) 327-8643
7 *Attorneys for Complainant*

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

12 In the Matter of the Amended Accusation
Against:

Case No. 7212

13
14 **BET Pharm LLC**
Green World Pharmacy, LLC, Sole Owner
15 Robert H. Douglas, Member/Manager of Green
World Pharmacy, LLC.
16 **1501 Bull Lea Rd., Ste 102B**
Lexington, Ky 40511

AMENDED ACCUSATION

17
18 Nonresident Pharmacy Permit No. NRP 1759

19 Nonresident Sterile Compounding Permit
20 Number NSC 100946

21 Respondent.

22
23 **PARTIES**

24 1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity
25 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

26 2. On or about June 22, 2016, the Board of Pharmacy issued Nonresident Pharmacy
27 Permit Number NRP 1759 to BET Pharm LLC, with Green World Pharmacy, LLC, as the sole
28 owner and Robert H. Douglas as Manager/Member of Green World Pharmacy, LLC

1 (Respondent). The Nonresident Pharmacy Permit was in full force and effect at all times relevant
2 to the charges brought herein and will expire on June 1, 2022, unless renewed.

3 3. On or about June 22, 2016, the Board of Pharmacy issued Nonresident Sterile
4 Compounding Permit Number NSC 100946 to BET Pharm LLC, with Green World Pharmacy,
5 LLC, as the sole owner and Robert H. Douglas as Manager/Member of Green World Pharmacy,
6 LLC, (Respondent). The Nonresident Sterile Compounding Permit was in full force and effect at
7 all times relevant to the charges brought herein and will expire on June 1, 2022, unless renewed.

8 JURISDICTION

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

12 5. Code section 4300 states, in pertinent part:

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

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

16 (1) Suspending judgment.

17 (2) Placing him or her upon probation.

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

20 (4) Revoking his or her license.

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

22 6. Code section 4300.1 states:

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

27 ///

28 ///

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

REGULATORY PROVISIONS

9. California Code of Regulations (Regulation), title 16, section 1735 states, in pertinent part:

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

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

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a compounded drug preparation from chemicals or bulk drug substances

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

10. Regulation section 1735.1 states, in pertinent part:

...

(b) “Beyond use date” means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

...

(ae) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

11. Regulation section 1735.2, states, in pertinent part:

...

(d) No pharmacy or pharmacist shall compound a drug preparation that:

...

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short

supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

...

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

...

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

12. Regulation section 1751 states, in pertinent part:

(a) Any pharmacy engaged in compounding sterile drug preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile compounding.

HEALTH AND SAFETY CODE PROVISION

13. Health and Safety Code section 111330 states: "Any drug or device is misbranded if its labeling is false or misleading in any particular."

COST RECOVERY

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

FACTUAL ALLEGATIONS

15. On or about March 25, 2021, Board Inspector LF conducted a sterile compounding remote renewal inspection of Respondent pharmacy located at 1501 Bull Lea Road, Suite 102B, Lexington, KY 40511. On or about April 1, 2021, Pharmacist-In-Charge (PIC) MC provided

1 Inspector LF with reports of sterile compounded products that Respondent compounded,
2 dispensed, and shipped into California from 3/24/20 to 3/24/21. The compounded products in the
3 report contained the words “BioRelease” and “LA” in the drug names. According to the
4 pharmacy, “BioRelease” refers to a group of proprietary diluent and vehicles that enable the
5 veterinary practitioner to deliver drugs in a precise release pattern following intramuscular (IM)
6 injection. The term “LA” refers to long acting. Respondent did not have any documentation for
7 FDA approval for the BioRelease drug delivery system or clinical studies to support the LA
8 claim.

9 **FIRST CAUSE FOR DISCIPLINE**

10 **(Misbranded Drug)**

11 16. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
12 section 4301, subd. (j) for violating statutes regulating controlled substances and dangerous drugs
13 as they relate to misbranded drugs described in Health and Safety Code section 111330, in that in
14 and between 3/24/20 to 3/24/21 Respondent was labeling their compounded products as
15 BioRelease and/or LA, as further indicated in paragraph 16, above. This is a labeled claim and
16 there is no FDA approval for this drug delivery system.

17 **SECOND CAUSE FOR DISCIPLINE**

18 **(Failure to Provide Documentation to Support Extension of Beyond Use Date
19 for Sterile Drug Preparation)**

20 17. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
21 Business and Professions Code section 4301, subd. (o) for violating pharmacy regulations
22 described in Regulation section 1735.2, subsection (i)(3), as follows:

23 a. In and between 12/17/19 to 7/1/20, Respondent compounded:

- 24 1) at least 1,080 mls of Histrelin in BioRelease (LD) 50mcg/ml injectable,
25 2) at least 6,000 mls of Deslorelin + HCG 1.5mg/2,500IU/ml injectable, and
26 3) at least 3,500 mls of BioRelease Estradiol Cypionate 10mg/ml injectable.

27 Respondent assigned extended BUDs without method suitability test, container closure integrity
28 test, and stability studies to support the extension.

b. In and between 1/21/21 and 3/29/21, Respondent compounded and shipped at least 210 mls (7x30ml vials) of Histrelin in BioRelease (LD) 50mcg/ml injectable into California.

c. In and between 5/13/20 and 3/15/21, Respondent compounded at least 6,000 mls of Deslorelin in BioRelease 2mg/ml and assigned an extended BUD without method suitability test, container closure integrity test, and stability studies to support the extension.

d. In and between 6/9/20 and 3/29/21, Respondent compounded and shipped at least 450mls (45 x 10ml vials) of the Deslorelin in BioRelease 2mg/ml referenced in sub-paragraph (c) above, into California.

THIRD CAUSE FOR DISCIPLINE

(Compounding a Drug Preparation that is Commercially Available)

18. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Business and Professions Code section 4301, subd. (o) for violating pharmacy regulations described in Regulation section 1735.2, subsection (d)(3), in that in and between 5/13/20 and 3/25/21, at least 45 vials of Deslorelin in BioRelease 2mg/ml injectable 10ml were compounded and shipped into California, even though a commercially available product, SucroMate Equine, was available. Respondent did not establish a documented medical need to justify the preparation for each individual equine patient and admitted the need for the compounded product was for ease of use for the veterinarians.

OTHER MATTERS

19. Pursuant to Business and Professions Code section 4307 of the Code, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 1759 issued to Bet Pharm LLC, then it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a California licensee for 1) a period not to exceed five (5) years if Nonresident Pharmacy Permit Number NRP 1759 is placed on probation; or, 2) if the pharmacy permit is revoked, the prohibition shall continue until the pharmacy permit is reinstated.

20. Pursuant to section 4307 of the Code, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 1759 issued to Bet Pharm LLC, then Nonresident Sterile Compounding Permit Number NSC 100946 issued to Bet Pharm LLC shall be prohibited from

1 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
2 California licensee for 1) a period not to exceed five (5) years if Nonresident Pharmacy Permit
3 Number NRP 1759 is placed on probation; or, 2) if Nonresident Pharmacy Permit Number NRP
4 1759 is revoked, the prohibition shall continue until the pharmacy permit is reinstated.

5 21. Pursuant to section 4307 of the Code, if discipline is imposed on Nonresident
6 Pharmacy Permit Number NRP 1759 issued to Bet Pharm LLC, then Robert H. Douglas,
7 Manager/Member of Green World Pharmacy, LLC, which is the owner of BET Pharm LLC, shall
8 be prohibited from serving as a manager, administrator, owner, member, officer, director,
9 associate, or partner of a California licensee for 1) a period not to exceed five (5) years if
10 Nonresident Pharmacy Permit Number NRP 1759 is placed on probation; or, 2) if Nonresident
11 Pharmacy Permit Number NRP 1759 is revoked, the prohibition shall continue until the pharmacy
12 permit is reinstated.

13 **PRAYER**

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

16 1. Revoking or suspending Nonresident Pharmacy Permit Number NRP 1759, issued to
17 BET Pharm LLC;

18 2. Revoking or suspending Nonresident Sterile Compounding Permit Number NSC
19 100946, issued to BET Pharm LLC;

20 3. Prohibiting Nonresident Pharmacy Permit Number NRP 1759, issued to Bet Pharm
21 LLC, from serving as a manager, administrator, owner, member, officer, director, associate,
22 partner, or in any other position with management or control of any California Pharmacy licensee;

23 4. Prohibiting Nonresident Sterile Compounding Permit Number NSC 100946, issued to
24 Bet Pharm LLC, from serving as a manager, administrator, owner, member, officer, director,
25 associate, partner, or in any other position with management or control of any California
26 Pharmacy licensee;

27 5. Prohibiting Robert H. Douglas, Manager/Member of Green World Pharmacy, LLC,
28 which is the sole owner of BET Pharm LLC, from serving as a manager, administrator, owner,

1 member, officer, director, associate, partner, or in any other position with management or control
2 of any California Pharmacy licensee;

3 6. Ordering BET Pharm LLC, with Green World Pharmacy, LLC, as the sole owner,
4 and Robert H. Douglas as Manager/Member of Green World Pharmacy, LLC, to pay the Board of
5 Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to
6 Business and Professions Code section 125.3; and,

7 7. Taking such other and further action as deemed necessary and proper.
8
9

10 DATED: 3/15/2023

Sodergren,
Anne@DCA

Digitally signed by
Sodergren, Anne@DCA
Date: 2023.03.15 07:54:48
-07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

15
16 SA2021304982
36967627.docx
17
18
19
20
21
22
23
24
25
26
27
28