



California State Board of Pharmacy
 2720 Gateway Oaks Drive, Suite 100
 Sacramento, CA 95833
 Phone: (916) 518-3100 Fax: (916) 574-8614
 www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
 Department of Consumer Affairs
 Gavin Newsom, Governor



APPLICATION FOR VOLUNTARY SURRENDER OF PREMISES LICENSE

PLEASE PRINT IN BLACK OR BLUE INK OR TYPE YOUR RESPONSES:

Name: <u>Edge Pharma, LLC</u>	Case No.
Address of Record: <u>856 Hercules Drive</u> <u>Colchester, VT 05443</u>	<u>AC-7047</u>

Pursuant to the terms and conditions of probation against my premises license with the California State Board of Pharmacy (Board) in Case No. 7047, I hereby request to surrender my premises license, License No. NSF 132. 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, the premises will no longer be subject to the terms and conditions of probation. I understand that this surrender constitutes a record of discipline and shall become a part of the premises license history with the Board.

Upon the acceptance of the surrender, I shall relinquish my premises license to the Board within ten (10) days of notification by the Board that the surrender is accepted. I understand that I shall, among other things, submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer. I may not reapply for any new licensure from the board for three (3) years from the effective date of the surrender. I further understand that I shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

PLEASE BE ADVISED THAT YOU ARE NOT RELIEVED OF THE REQUIREMENTS OF YOUR PROBATION UNLESS THE BOARD NOTIFIES YOU THAT YOUR REQUEST TO SURRENDER YOUR LICENSE HAS BEEN ACCEPTED.



Applicant's Signature

7/5/22

Date

William Chaffoff

Applicant's Printed Name

15F-132

Applicant's License Number

Executive Officer's Approval

Date

All items on this application are mandatory in accordance with your probationary order and the Board's Disciplinary Guidelines as authorized by Title 16, California Code of Regulations section 1760. Failure to provide any of the requested information or providing unreadable information will result in the application being rejected as incomplete. The information provided on this form will be used to determine eligibility for surrender. The official responsible for information maintenance is the Executive Officer, telephone (916) 518-3100, 2720 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833. The information you provide may also be disclosed in the following circumstances: (1) in response to a Public Records Act request; (2) to another government agency as required by state or federal law; or, (3) in response to a court or administrative order, a subpoena, or a search warrant. Each individual has the right to review the files or records maintained on them by our agency, unless the records are identified as confidential information and exempted by Section 1798.40 of the Civil Code.

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

In the Matter of the Accusation Against:

**EDGE PHARMA LLC
EDGE PHARMACY HOLDINGS LP**

Nonresident Outsourcing Facility Permit License No. NSF 132,

Respondent.

Agency Case No. 7047

OAH No. 2020120528

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 October 26, 2021.

It is so ORDERED on October 26, 2021.

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 written in a cursive style with a large initial "S" and "O".

Seung W. Oh, Pharm.D.
Board President

1 ROB BONTA
Attorney General of California
2 ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
3 KRISTINA T. JARVIS
Deputy Attorney General
4 State Bar No. 258229
KATELYN E. DOCHERTY
5 Deputy Attorney General
State Bar No. 322028
6 1300 I Street, Suite 125
P.O. Box 944255
7 Sacramento, CA 94244-2550
Telephone: (916) 210-6277
8 Facsimile: (916) 327-8643
Attorneys for Complainant
9

10 **BEFORE THE**
11 **BOARD OF PHARMACY**
12 **DEPARTMENT OF CONSUMER AFFAIRS**
13 **STATE OF CALIFORNIA**

14 In the Matter of the Accusation Against:

15 **EDGE PHARMA LLC**
16 **EDGE PHARMACY HOLDINGS LP,**
17 **100% SHAREHOLDER**
18 **WILLIAM MARC CHATOFF,**
19 **PRESIDENT AND MANAGER**
20 **ROGER CHRISTOPHER NADEAU,**
21 **VICE-PRESIDENT AND**
22 **TREASURER/CHIEF FINANCIAL**
23 **OFFICER**
24 **HOWARD SCOTT CHATOFF,**
25 **DIRECTOR**
26 **JULES CHATOFF, DIRECTOR**
27 **856 Hercules Drive**
28 **Colchester, VT 05446**

Nonresident Outsourcing Facility Permit
No. NSF 132

Respondent.

Case No. 7047

OAH No. 2020120528

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER

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

27 ///

28 ///

1 **PARTIES**

2 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy
3 (Board). She brought this action solely in her official capacity and is represented in this matter by
4 Rob Bonta, Attorney General of the State of California, by Kristina T. Jarvis and Katelyn E.
5 Docherty, Deputy Attorneys General.

6 2. Edge Pharma LLC (Respondent) is represented in this proceeding by attorney Joseph
7 R. LaMagna, whose address is: 101 W. Broadway, Suite 1200, San Diego, CA 92101-3890, and
8 attorney Scott J. Kiepen, whose address is: 101 Montgomery Street, 11th Floor, San Francisco,
9 CA 94104.

10 3. On or about October 25, 2019, the Board of Pharmacy (Board) issued Nonresident
11 Outsourcing Facility Permit number NSF 132 to Edge Pharma LLC (Respondent), Edge
12 Pharmacy Holdings LP, 100 % shareholder, William Marc Chatoff, President and Manager,
13 Roger Christopher Nadeau, Vice-President and Treasurer/Chief Financial Officer, Howard Scott
14 Chatoff, Director, Jules Chatoff, Director. The Nonresident Outsourcing Facility Permit was in
15 full force and effect at all times relevant to the charges brought herein, and will expire on October
16 1, 2021.

17 4. On or about August 31, 2021, the Board denied Respondent’s application to renew
18 Nonresident Outsourcing Facility Permit number NSF 132. On or about September 8, 2021,
19 Respondent appealed the denial.

20 **JURISDICTION**

21 5. Accusation No. 7047 was filed before the Board, and is currently pending against
22 Respondent. The Accusation and all other statutorily required documents were properly served
23 on Respondent on November 13, 2020. Respondent timely filed its Notice of Defense contesting
24 the Accusation. A Fifth Amended Accusation was later filed before the Board and properly
25 served on Respondent.

26 6. A copy of Fifth Amended Accusation No. 7047 is attached as Exhibit A and
27 incorporated by reference.

28 ///

1 **ADVISEMENT AND WAIVERS**

2 7. Respondent has carefully read, fully discussed with counsel, and understands the
3 charges and allegations in Fifth Amended Accusation No. 7047. Respondent has also carefully
4 read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and
5 Disciplinary Order.

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

12 9. Respondent voluntarily, knowingly, and intelligently waives and gives up each and
13 every right set forth above.

14 **CULPABILITY**

15 10. Respondent understands and agrees that the charges and allegations in Fifth Amended
16 Accusation No. 7047, if proven at a hearing, constitute cause for imposing discipline upon its
17 Nonresident Outsourcing Facility Permit.

18 11. For the purpose of resolving the Accusation without the expense and uncertainty of
19 further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual
20 basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest
21 those charges.

22 12. Respondent agrees that its Nonresident Outsourcing Facility Permit is subject to
23 discipline and they agree to be bound by the Board's probationary terms as set forth in the
24 Disciplinary Order below.

25 **CONTINGENCY**

26 13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent
27 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may
28 communicate directly with the Board regarding this stipulation and settlement, without notice to

1 or participation by Respondent or its counsel. By signing the stipulation, Respondent understands
2 and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the
3 time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its
4 Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or
5 effect, except for this paragraph, it shall be inadmissible in any legal action between the parties,
6 and the Board shall not be disqualified from further action by having considered this matter.

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

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

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

19 **DISCIPLINARY ORDER**

20 IT IS HEREBY ORDERED that Nonresident Outsourcing Facility Permit No. NSF 132
21 issued to Respondent Edge Pharma LLC is revoked. However, the revocations are stayed and
22 Respondent is placed on probation for four (4) years on the following terms and conditions:

23 IT IS FURTHER HEREBY ORDERED that the Board will rescind the denial of
24 Nonresident Outsourcing Facility Permit number NSF 132 on the effective date of this Decision
25 and Order and therefore the permit will be renewed, then revoked and the revocation stayed as set
26 forth above

27 1. **Definition: Respondent**

28 For the purposes of these terms and conditions, “respondent” shall refer to Edge Pharma

1 LLC. All terms and conditions states herein shall bind and be applicable to the licensed premises
2 and to all owners, managers, officers, administrators, members, directors, trustees, associates, or
3 partners thereof. For purposes of compliance with any term or condition, and report, submission,
4 filing, payment, or appearance required to be made by respondent to or before the board or its
5 designee shall be made by an owner or executive officer with authority to act on behalf of and
6 legally bind the licensed entity.

7 **2. Obey All Laws**

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

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

- 11 • an arrest or issuance of a criminal complaint for violation of any provision of the
12 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
13 substances laws
- 14 • a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal
15 criminal proceeding to any criminal complaint, information or indictment
- 16 • a conviction of any crime
- 17 • the filing of a disciplinary pleading, issuance of a citation, or initiation of another
18 administrative action filed by any state or federal agency which involves
19 respondent's license or which is related to the practice of pharmacy or the
20 manufacturing, obtaining, handling, distributing, billing, or charging for any drug,
21 device or controlled substance.

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

23 **3. Report to the Board**

24 Respondent shall report to the board quarterly, on a schedule as directed by the board or its
25 designee. The report shall be made either in person or in writing, as directed. Among other
26 requirements, respondent shall state in each report under penalty of perjury whether there has
27 been compliance with all the terms and conditions of probation.

28 ///

1 Failure to submit timely reports in a form as directed shall be considered a violation of
2 probation. Any period(s) of delinquency in submission of reports as directed may be added to the
3 total period of probation. Moreover, if the final probation report is not made as directed,
4 probation shall be automatically extended until such time as the final report is made and accepted
5 by the board.

6 **4. Interview with the Board**

7 Upon receipt of reasonable prior notice, respondent shall appear either in person or
8 virtually, as may be requested by the board, for interviews with the board or its designee, at such
9 intervals and locations as are determined by the board or its designee. Failure to appear for any
10 scheduled interview without prior notification to board staff, or failure to appear for two (2) or
11 more scheduled interviews with the board or its designee during the period of probation, shall be
12 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 its
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 \$85,974.50. Respondent shall
23 make said payments as designated by the board or its designee.

24 There shall be no deviation from any payment schedule set by the board or its designee
25 absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s)
26 as directed shall be considered a violation of probation.

27 ///

28 ///

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

4 **7. Probation Monitoring Costs**

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

10 **8. Status of License**

11 Respondent shall, at all times while on probation, maintain an active, current Nonresident
12 Outsourcing Facility Permit with the board, including any period during which suspension or
13 probation is tolled. Failure to maintain an active, current Nonresident Outsourcing Facility
14 Permit shall be considered a violation of probation.

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

19 **9. License Surrender While on Probation/Suspension**

20 Following the effective date of this decision, should respondent cease practice due to
21 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,
22 respondent may relinquish its license, including any indicia of licensure issued by the board,
23 along with a request to surrender the license. The board or its designee shall have the discretion
24 whether to accept the surrender or take any other action it deems appropriate and reasonable.
25 Upon formal acceptance of the surrender of the license, respondent will no longer be subject to
26 the terms and conditions of probation. This surrender constitutes a record of discipline and shall
27 become a part of the respondent's license history with the board.

28 ///

1 Upon acceptance of the surrender, respondent shall relinquish its pocket and/or wall license,
2 including any indicia of licensure not previously provided to the board within ten (10) days of
3 notification by the board that the surrender is accepted if not already provided. Respondent may
4 not reapply for any license from the board for three (3) years from the effective date of the
5 surrender. Respondent shall meet all requirements applicable to the license sought as of the date
6 the application for that license is submitted to the board, including any outstanding costs.

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

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

16 **11. Notice to Employees**

17 Respondent shall, upon or before the effective date of this decision, ensure that all
18 employees involved in permit operations are made aware of all the terms and conditions of
19 probation, either by posting a notice of the terms and conditions, circulating such notice, or both.
20 If the notice required by the provision is posted, it shall be posted in a prominent place and shall
21 remain posted throughout the probation period. Respondent shall ensure that any employees
22 hired or used after the effective date of this decision are made aware of the terms and conditions
23 of probation by posting a notice, circulating a notice, or both. Additionally, respondent shall
24 submit written notification to the board, within thirty (30) days of the effective date of this
25 decision, that this term has been satisfied. Failure to timely provide such notification to
26 employees, or to timely submit such notification to the board shall be considered a violation of
27 probation.

28 ///

1 “Employees” as used in this provision includes all full-time, part-time, volunteer, temporary
2 and relief employees and independent contractors employed or hired at any time during
3 probation.

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

5 Respondent shall provide, within ninety (90) days after the effective date of this decision,
6 signed and dated statements from its indirect, natural person owners, including any owner or
7 holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and all of
8 its officer, stating under penalty of perjury that said individuals have read and are familiar with
9 state and federal laws and regulations governing the practice of outsourcing. The failure to timely
10 provide said statements under penalty of perjury shall be considered a violation of probation.

11 **13. Premises Open for Business**

12 Respondent shall remain open and engaged in its ordinary business as a nonresident
13 outsourcing facility for a minimum of forty (40) hours per calendar month. Any month during
14 which this minimum is not met shall toll the period of probation, i.e., the period of probation shall
15 be extended by one month for each month during with this minimum is not met. During any such
16 period of tolling of probation, respondent must nonetheless comply with all terms and conditions
17 of probation, unless respondent is informed otherwise in writing by the board or its designee. If
18 respondent is not open and engaged in its ordinary business as a nonresident outsourcing facility
19 for a minimum of forty (40) hours in any calendar month, for any reason (including vacation),
20 respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar
21 month. This notification shall include at minimum all of the following: the date(s) and hours
22 respondent was open; the reason(s) for the interruption or why business was not conducted; and
23 the anticipated date(s) on which respondent will resume business as required. Respondent shall
24 further notify the board in writing with ten (10) days following the next calendar month during
25 which respondent is open and engaged in its ordinary business as a nonresident outsourcing
26 facility for a minimum of forty (40) hours. Any failure to timely provide such notification(s)
27 shall be considered a violation of probation.

28 ///

1 **14. Posted Notice of Probation**

2 Respondent shall prominently post a probation notice in its physical facility in a place
3 conspicuous to and readable by the public, and on its website. The probation notice shall be
4 provided by the board or its designee and must be posted within two (2) business days of receipt.
5 Respondent shall also provide a copy of the notice of probation in all shipments to California.
6 Failure to timely post such notice, or to maintain the posting during the entire period of probation,
7 shall be considered a violation of probation.

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

12 **15. Violation of Probation**

13 If a respondent has not complied with any term or condition of probation, the board shall
14 have continuing jurisdiction over respondent, and probation shall be automatically extended, until
15 all terms and conditions have been satisfied or the board has taken other action as deemed
16 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and
17 to impose the penalty that was stayed.

18 If respondent violates probation in any respect, the board, after giving respondent notice
19 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that
20 was stayed. If a petition to revoke probation or an accusation is filed against respondent during
21 probation, the board shall have continuing jurisdiction and the period of probation shall be
22 automatically extended until the petition to revoke probation or accusation is heard and decided.

23 **16. Completion of Probation**

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

26 **17. Restricted Practice**

27 Respondent's practice as a nonresident outsourcing pharmacy shall be prohibited from
28 compounding diluted allergen sets (i.e., compounding of undiluted allergen extracts will not be

1 prohibited) for shipment into California until appropriate beyond use dates are established and
2 deemed appropriate by the board or its designee. Respondent shall submit proof satisfactory to
3 the board or its designee of compliance with this term of probation. Any failure to timely submit
4 proof, or any shipment of allergen sets in violation of this probation term shall be a violation of
5 probation and respondent's nonresident outsourcing facility permit will automatically be
6 suspended until the board or its designee lifts such suspension in writing or a petition to revoke
7 probation is filed and results in a decision and order, whichever is earlier.

8 Additionally, Respondent shall remediate and demonstrate compliance with the following
9 issues within six (6) months of the effective date of this Decision and Order:

10 A. Respondent shall provide quarterly insect logs setting forth the number and
11 types of insects found within the facility within the previous quarter. Additionally, Respondent
12 shall provide quarterly inspection reports from a licensed pest control company setting forth
13 observations about the amount and type of insects discovered in the facility. Any insects
14 discovered outside of a pest trap of any type must be photographed and the photograph must be
15 provided with the quarterly report.

16 B. The quality control unit must be provided with adequate laboratory facilities for
17 the testing and approval or rejection of components, drug product containers, closures, packaging
18 materials, in-process materials, and drug products. Additionally, the quality control unit must
19 perform proper testing and approval or rejection of components, drug product containers, and
20 closures. Any visual inspection of product shall be either (1) a visual inspection of one (1) item
21 of product at a time, and utilizing the appropriate backgrounds, i.e. light box, removal from box,
22 etc... or (2) through a validated cGMP process.

23 C. No product intended to be sterile may be released for distribution until sterility
24 testing is completed (i.e. sterility testing is not required for non-sterile product unless otherwise
25 required by USP).

26 D. Establish and follow written procedures for cleaning and maintenance of
27 equipment used in the manufacture, processing, packing, or holding of a drug product.
28

1 E. Perform and document line clearance between each batch or type of
2 compounded product at appropriate steps.

3 F. Utilize only containers, container closures, and shipping methods which have
4 documented testing and process validations.

5 G. Utilize an effective environmental monitoring system that includes, but is not
6 limited to continuous non-viable monitoring equipment.

7 H. Ensure all vendors provide a full and complete service report; maintain service
8 reports for a minimum of three (3) years.

9 I. Fully validate all equipment including, but not limited to: refrigerators,
10 dishwashers, autoclave/depyrogenation, glassware washing, cleaner/disinfectant in-use times, and
11 validate or re-validate all pressure gauges and other monitoring equipment.

12 J. Create and implement a quality by design process for the generation, storage,
13 maintenance, sanitization, use, and testing of water used in the preparation of compounded drug.

14 K. Create and implement process for controlling and reconciling all labels used in
15 the production of compounded product.

16 L. Complete validation to demonstrate that cleaning and disinfecting agents are
17 appropriate for use for their intended application. Effectiveness of cleaning and disinfecting
18 agents and processes shall be demonstrated on all surfaces on which they are used.

19 M. Fully validate and complete stability testing on all products to be distributed
20 into California. Concurrent testing is only permitted during the six (6) month period to complete
21 stability testing. Products that have not achieved validated and complete stability testing within
22 six (6) months may not be shipped to California until validation and stability testing is complete.
23 At risk release is not permitted; however, Respondent must provide their SOP for at risk release
24 for review and approval and this prohibition may be reconsidered and removed by the board or its
25 designee after one (1) year of successful completion of probation.

26 N. Respondent shall provide reasonable accommodations for Board inspectors to
27 access all classified areas for inspection during compounding operations. This includes, but is not
28

1 limited to, sanitary garb provided by Respondent to allow the Board inspectors to enter the
2 cleanroom to view production, production steps, and production rooms. Board inspectors will
3 ///
4 take all necessary steps to make the incursion minimal and when necessary with full cooperation
5 between the inspector and Respondent to minimize any effect on production.

6 Respondent shall submit proof satisfactory to the board or its designee of compliance with
7 each item included in this term of probation. Any failure to complete and sustain remediation
8 shall be a violation of probation and respondent's nonresident outsourcing facility permit will
9 automatically be suspended until the board or its designee lifts such suspension in writing or a
10 petition to revoke probation is filed and results in a decision and order, whichever is earlier.

11 18. Remedial Education

12 Within ninety (90) days of the effective date of this decision, respondent shall submit to the
13 board or its designee, for prior approval, an appropriate program of remedial education related to
14 Title 21, or outsourcing facilities, including regulations and guidance for outsourcing facilities.
15 The program of remedial education shall consist of at least ten (10) hours, which shall be
16 completed by William Marc Chatoff and all staff performing compounding duties within twelve
17 (12) months at respondent's own expense. All remedial education shall be in addition to, and
18 shall not be credited toward, any continuing education (CE) courses used for license renewal
19 purposes.

20 Failure to timely submit for approval or complete the approved remedial education shall be
21 considered a violation of probation. The period of probation will be automatically extended until
22 such remedial education is successfully completed and written proof, in a form acceptable to the
23 board, is provided to the board or its designee.

24 19. Ethics Course

25 Within ninety (90) calendar days of the effective date of this decision, each of respondent's
26 owners and officers shall enroll in a course in ethics, at respondent's expense, approved in
27 advance by the board or its designee that complies with Title 16 California Code of Regulations
28 section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days

1 of completion, respondent shall submit a copy of the certificate of completion to the board or its
2 designee. Failure to timely enroll in an approved ethics course, to initiate the course during the
3 first year of probation, to successfully complete it before the end of the second year of probation,
4 or to timely submit proof of completion to the board or its designee, shall be considered a
5 violation of probation.

6 **20. No New Ownership or Management of Licensed Premises**

7 None of respondent's owners or officers shall acquire any new ownership, legal or
8 beneficial interest nor serve as a manager, administrator, member, officer, director, trustee,
9 associate, or partner of any additional business, firm, partnership, or corporation licensed by the
10 board. If respondent currently owns or has any legal or beneficial interest in, or serves as a
11 manager, administrator, member, officer, director, trustee, associate, or partner of any business,
12 firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may
13 continue to serve in such capacity or hold that interest, but only to the extent of that position or
14 interest as of the effective date of this decision. Violation of this restriction shall be considered a
15 violation of probation.

16 **21. Consultant**

17 Within 90 days of the effective date of this Decision and Order, Respondent shall submit to
18 the board the name of an expert in cGMP specific to outsourcing facilities to act as an expert
19 consultant subject to the prior approval of the board or its designee. The consultant shall be
20 responsible for conducting quarterly inspections of the facility for compliance with the provisions
21 of federal law and the terms and conditions of probation. The consultant shall provide the board
22 with an inspection agenda for approval prior to conducting the inspection. Any inspection
23 conducted without prior approval of the inspection agenda shall not be accepted. The consultant
24 shall also provide the board with quarterly reports documenting the inspection. The consultant's
25 quarterly reports shall provide the written reports directly to the board, and receive confirmation
26 of receipt from the board, prior to providing the report to the respondent. Should the board or its
27 designee determine that the consultant is not appropriately assessing the operations of respondent,
28 or providing the appropriate written reports, the board or its designee shall require respondent to

1 obtain a different consultant through the same process outlined above, by submitting a new name
2 of an expert within 60 days of Respondent being notified of the need for a new consultant.

3 ///

4 **ACCEPTANCE**

5 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
6 discussed it with my attorneys, Scott Kiepen and Joseph LaManga. I understand the stipulation
7 and the effect it will have on my Nonresident Outsourcing Facility Permit. I enter into this
8 Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree
9 to be bound by the Decision and Order of the Board of Pharmacy.

10
11 DATED: _____
12 EDGE PHARMA LLC,
13 by WILLIAM MARC CHATOFF, CEO/PRESIDENT
14 Respondent

15 I have read and fully discussed with Respondent Edge Pharma LLC and William Marc
16 Chatoff the terms and conditions and other matters contained in the above Stipulated Settlement
17 and Disciplinary Order. I approve its form and content.

18 DATED: _____
19 Attorney for Respondent
20 _____
21 (Print Attorney Name)

22 **ENDORSEMENT**

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

1 obtain a different consultant through the same process outlined above, by submitting a new name
2 of an expert within 60 days of Respondent being notified of the need for a new consultant.

3 ///

4 **ACCEPTANCE**

5 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
6 discussed it with my attorneys, Scott Kiepen and Joseph LaManga. I understand the stipulation
7 and the effect it will have on my Nonresident Outsourcing Facility Permit. I enter into this
8 Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree
9 to be bound by the Decision and Order of the Board of Pharmacy.


10
11 DATED: 10/4/21



EDGE PHARMA LLC,
by WILLIAM MARC CHATOFF, CEO/PRESIDENT
Respondent

12
13
14 I have read and fully discussed with Respondent Edge Pharma LLC and William Marc
15 Chatoff the terms and conditions and other matters contained in the above Stipulated Settlement
16 and Disciplinary Order. I approve its form and content.

17
18 DATED: October 5, 2021



Attorney for Respondent
Joseph R. LaMagna

(Print Attorney Name)

19
20
21 **ENDORSEMENT**

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

1 DATED: _____
2
3
4

Respectfully submitted,
ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General

5 KRISTINA T. JARVIS
6 Deputy Attorney General
7 KATELYN E. DOCHERTY
8 Deputy Attorney General
9 *Attorneys for Complainant*

10 SA2020303840 / 35418415.docx
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

DATED: 10/5/2021

Respectfully submitted,

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General



KRISTINA T. JARVIS
Deputy Attorney General
KATELYN E. DOCHERTY
Deputy Attorney General
Attorneys for Complainant

SA2020303840 / 35418415.docx

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

Exhibit A

Fifth Amended Accusation No. 7047

1 ROB BONTA
Attorney General of California
2 KAREN R. DENVER
Supervising Deputy Attorney General
3 KRISTINA T. JARVIS
Deputy Attorney General
4 State Bar No. 258229
KATELYN E. DOCHERTY
5 Deputy Attorney General
State Bar No. 322028
6 1300 I Street, Suite 125
P.O. Box 944255
7 Sacramento, CA 94244-2550
Telephone: (916) 210-6088
8 Facsimile: (916) 327-8643
E-mail: Kristina.Jarvis@doj.ca.gov
9 Katelyn.Docherty@doj.ca.gov
Attorneys for Complainant

11 **BEFORE THE**
12 **BOARD OF PHARMACY**
13 **DEPARTMENT OF CONSUMER AFFAIRS**
14 **STATE OF CALIFORNIA**

14 In the Matter of the Accusation Against:

Case No. 7047

15 **EDGE PHARMA LLC**
16 **EDGE PHARMACY HOLDINGS LP,**
17 **100% SHAREHOLDER**
18 **WILLIAM MARC CHATOFF,**
19 **PRESIDENT AND MANAGER**
20 **ROGER CHRISTOPHER NADEAU,**
21 **VICE-PRESIDENT AND**
22 **TREASURER/CHIEF FINANCIAL**
23 **OFFICER**
24 **HOWARD SCOTT CHATOFF,**
25 **DIRECTOR**
26 **JULES CHATOFF, DIRECTOR**
27 **856 Hercules Drive**
28 **Colchester, VT 05446**

FIFTH AMENDED
ACCUSATION

Nonresident Outsourcing Facility Permit
No. NSF 132

Respondent.

PARTIES

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

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

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

5 (b) Manager, administrator, owner, member, officer, director, associate,
6 partner, or any other person with management or control of a license as used in this
section and Section 4308, may refer to a pharmacist or to any other person who
serves in such capacity in or for a licensee.

7 (c) The provisions of subdivision (a) may be alleged in any pleading filed
8 pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of
9 the Government Code. However, no order may be issued in that case except as to a
10 person who is named in the caption, as to whom the pleading alleges the applicability
11 of this section, and where the person has been given notice of the proceeding as
required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of
the Government Code. The authority to proceed as provided by this subdivision shall
be in addition to the board's authority to proceed under Section 4339 or any other
provision of law.

12 **BUSINESS AND PROFESSIONS CODE**

13 7. Section 4022 of the Code states:

14 "Dangerous drug" or "dangerous device" means any drug or device unsafe for
15 self-use in humans or animals, and includes the following:

16 (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing
without prescription," "Rx only," or words of similar import.

17 (b) Any device that bears the statement: "Caution: federal law restricts this
18 device to sale by or on the order of a , " "Rx only," or words of similar import, the
blank to be filled in with the designation of the practitioner licensed to use or order
19 use of the device.

20 (c) Any other drug or device that by federal or state law can be lawfully
dispensed only on prescription or furnished pursuant to Section 4006.

21 8. Code section 4129, subdivision (e), states, "An outsourcing facility licensed by the
22 board shall not perform the duties of a pharmacy, such as filling individual prescriptions for
23 individual patients."

24 9. Code section 4129.2 states, in pertinent part:

25 . . .

26 (e) A nonresident outsourcing facility licensed pursuant to this section shall
27 provide the board with all of the following:

28 (1) A copy of any disciplinary or other action taken by another state or the FDA
within 10 days of the action.

1 (2) Notice within 24 hours of any recall notice issued by the nonresident
2 outsourcing facility.

3 (3) A copy of any complaint it receives involving an outsourcing facility's
4 compounded products from or involving any provider, pharmacy, or patient in
5 California within 72 hours of receipt.

6 (4) Notice within 24 hours after learning of adverse effects reported or
7 potentially attributable to a nonresident outsourcing facility's products.

8 10. Code section 4129.2, subdivision (b), states, "A nonresident outsourcing facility shall
9 compound all sterile products and nonsterile products to be distributed or used in this state in
10 compliance with regulations of the board and with federal current good manufacturing practices
11 applicable to outsourcing facilities."

12 11. Section 4301 of the Code states, in pertinent part:

13 The board shall take action against any holder of a license who is guilty of
14 unprofessional conduct or whose license has been issued by mistake. Unprofessional
15 conduct includes, but is not limited to, any of the following:

16 . . .

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

22 **HEALTH AND SAFETY CODE**

23 12. Health and Safety Code section 111260 states, "Any drug or device is adulterated if
24 the methods, facilities, or controls used for its manufacture, processing, packing, or holding do
25 not conform to, or are not operated or administered in conformity with current good
26 manufacturing practice to assure that the drug or device meets the requirements of this part as to
27 safety and has the identity and strength, and meets the quality and purity characteristics that it
28 purports or is represented to possess."

13 13. Health and Safety Code section 111295 states, "It is unlawful for any person to
14 manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

15 14. Health and Safety Code section 111330 states, "Any drug or device is misbranded if
16 its labeling is false or misleading in any particular."

1 15. Health and Safety Code section 111440 states, “It is unlawful for any person to
2 manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.”

3 16. Health and Safety Code section 111445 states, “It is unlawful for any person to
4 misbrand any drug or device.”

5 **REGULATORY PROVISIONS**

6 17. Code of Federal Regulations, title 21 (Regulation), section 210.1, states in pertinent
7 part:

8 (a) The regulations set forth in this part and in parts 211, 225, and 226 of this
9 chapter contain the minimum current good manufacturing practice for methods to be
10 used in, and the facilities or controls to be used for, the manufacture, processing,
11 packing, or holding of a drug to assure that such drug meets the requirements of the
12 act as to safety, and has the identity and strength and meets the quality and purity
13 characteristics that it purports or is represented to possess.

14 (b) The failure to comply with any regulation set forth in this part and in parts
15 211, 225, and 226 of this chapter in the manufacture, processing, packing, or holding
16 of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the
17 act and such drug, as well as the person who is responsible for the failure to comply,
18 shall be subject to regulatory action. . . .

19 18. Regulation section 211.22, states, in pertinent part:

20 (a) There shall be a quality control unit that shall have the responsibility and
21 authority to approve or reject all components, drug product containers, closures, in-
22 process materials, packaging material, labeling, and drug products, and the authority
23 to review production records to assure that no errors have occurred or, if errors have
24 occurred, that they have been fully investigated. The quality control unit shall be
25 responsible for approving or rejecting drug products manufactured, processed,
26 packed, or held under contract by another company.

27 (b) Adequate laboratory facilities for the testing and approval (or rejection) of
28 components, drug product containers, closures, packaging materials, in-process
materials, and drug products shall be available to the quality control unit. . . .

(c) The quality control unit shall have the responsibility for approving or
rejecting all procedures or specifications impacting on the identity, strength,
quality, and purity of the drug product.

...

19. Regulation section 211.42 states, in pertinent part:

...

(c) Operations shall be performed within specifically defined areas of adequate
size. There shall be separate or defined areas or such other control systems for the
firm’s operations as are necessary to prevent contamination or mixups during the
course of the following procedures:

1 (1) Receipt, identification, storage, and withholding from use of
2 components, drug product containers, closures, and labeling, pending the
3 appropriate sampling, testing, or examination by the quality control unit before
4 release for manufacturing or packaging;

5 (2) Holding rejected components, drug product containers, closures, and
6 labeling before disposition;

7 (3) Storage of released components, drug product containers, closures,
8 and labeling;

9 (4) Storage of in-process materials;

10 (5) Manufacturing and processing operations;

11 (6) Packaging and labeling operations;

12 (7) Quarantine storage before release of drug products;

13 (8) Storage of drug products after release;

14 (9) Control and laboratory operations;

15 (10) Aseptic processing, which includes as appropriate:

16 (i) Floors, walls, and ceilings of smooth, hard surfaces that are
17 easily cleanable;

18 (ii) Temperature and humidity controls;

19 (iii) An air supply filtered through high-efficiency particulate air
20 filters under positive pressure, regardless of whether flow is laminar or
21 nonlaminar;

22 (iv) A system for monitoring environmental conditions;

23 (v) A system for cleaning and disinfecting the room and
24 equipment to produce aseptic conditions;

25 (vi) A system for maintaining any equipment used to control the
26 aseptic conditions. . . .

27 20. Regulation section 211.46, subdivision (b) states:

28 Equipment for adequate control over air pressure, micro-organisms, dust,
humidity, and temperature shall be provided when appropriate for the manufacture,
processing, packing, or holding of a drug product.

29 21. Regulation section 211.56, subdivision (c) states:

30 There shall be written procedures for use of suitable rodenticides, insecticides,
31 fungicides, fumigating agents, and cleaning and sanitizing agents. Such written
32 procedures shall be designed to prevent the contamination of equipment, components,
33 drug product containers, closures, packaging, labeling materials, or drug products and

1 shall be followed. Rodenticides, insecticides, and fungicides shall not be used unless
2 registered and used in accordance with the Federal Insecticide, Fungicide, and
3 Rodenticide Act (7 U.S.C. 135).

4 22. Regulation section 211.67 states:

5 (a) Equipment and utensils shall be cleaned, maintained, and, as appropriate for
6 the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent
7 malfunctions or contamination that would alter the safety, identity, strength, quality,
8 or purity of the drug product beyond the official or other established requirements.

9 (b) Written procedures shall be established and followed for cleaning and
10 maintenance of equipment, including utensils, used in the manufacture, processing,
11 packing, or holding of a drug product. These procedures shall include, but are not
12 necessarily limited to, the following:

13 (1) Assignment of responsibility for cleaning and maintaining equipment;

14 (2) Maintenance and cleaning schedules, including, where appropriate,
15 sanitizing schedules;

16 (3) A description in sufficient detail of the methods, equipment, and
17 materials used in cleaning and maintenance operations, and the methods of
18 disassembling and reassembling equipment as necessary to assure proper
19 cleaning and maintenance;

20 (4) Removal or obliteration of previous batch identification;

21 (5) Protection of clean equipment from contamination prior to use;

22 (6) Inspection of equipment for cleanliness immediately before use.

23 (c) Records shall be kept of maintenance, cleaning, sanitizing, and inspection as
24 specified in §§ 211.180 and 211.182.

25 23. Regulation section 211.84 states, in pertinent part:

26 (a) Each lot of components, drug product containers, and closures shall be
27 withheld from use until the lot has been sampled, tested, or examined, as appropriate,
28 and released for use by the quality control unit.

...

(d) Samples shall be examined and tested as follows:

(1) At least one test shall be conducted to verify the identity of each
component of a drug product. Specific identity tests, if they exist, shall be used.

(2) Each component shall be tested for conformity with all appropriate
written specifications for purity, strength, and quality. In lieu of such testing by
the manufacturer, a report of analysis may be accepted from the supplier of a
component, provided that at least one specific identity test is conducted on such

1 component by the manufacturer, and provided that the manufacturer establishes
2 the reliability of the supplier's analyses through appropriate validation of the
supplier's test results at appropriate intervals.

3 (3) Containers and closures shall be tested for conformity with all
4 appropriate written specifications. In lieu of such testing by the manufacturer, a
5 certificate of testing may be accepted from the supplier, provided that at least a
6 visual identification is conducted on such containers/closures by the
manufacturer and provided that the manufacturer establishes the reliability of
the supplier's test results through appropriate validation of the supplier's test
results at appropriate intervals.

7 (4) When appropriate, components shall be microscopically examined.

8 (5) Each lot of a component, drug product container, or closure that is
9 liable to contamination with filth, insect infestation, or other extraneous
adulterant shall be examined against established specifications for such
contamination.

10 (6) Each lot of a component, drug product container, or closure with
11 potential for microbiological contamination that is objectionable in view of its
intended use shall be subjected to microbiological tests before use. . . .

12 24. Regulation section 211.100 states:

13 (a) There shall be written procedures for production and process control
14 designed to assure that the drug products have the identity, strength, quality, and
15 purity they purport or are represented to possess. Such procedures shall include all
16 requirements in this subpart. These written procedures, including any changes, shall
be drafted, reviewed, and approved by the appropriate organizational units and
reviewed and approved by the quality control unit.

17 (b) Written production and process control procedures shall be followed in the
18 execution of the various production and process control functions and shall be
documented at the time of performance. Any deviation from the written procedures
shall be recorded and justified.

19 25. Regulation section 211.113, subdivision (b) states:

20 Appropriate written procedures, designed to prevent microbiological
21 contamination of drug products purporting to be sterile, shall be established and
22 followed. Such procedures shall include validation of all aseptic and sterilization
processes.

23 26. Regulation section 211.122 states:

24 (a) There shall be written procedures describing in sufficient detail the receipt,
25 identification, storage, handling, sampling, examination, and/or testing of labeling
26 and packaging materials; such written procedures shall be followed. Labeling and
packaging materials shall be representatively sampled, and examined or tested upon
receipt and before use in packaging or labeling of a drug product.

27 ///

28 ///

1 (b) Any labeling or packaging materials meeting appropriate written
2 specifications may be approved and released for use. Any labeling or packaging
3 materials that do not meet such specifications shall be rejected to prevent their use in
4 operations for which they are unsuitable.

5 27. Regulation section 211.130 states:

6 There shall be written procedures designed to assure that correct labels,
7 labeling, and packaging materials are used for drug products; such written procedures
8 shall be followed. These procedures shall incorporate the following features:

9 (a) Prevention of mixups and cross-contamination by physical or spatial
10 separation from operations on other drug products.

11 (b) Identification and handling of filled drug product containers that are set
12 aside and held in unlabeled condition for future labeling operations to preclude
13 mislabeling of individual containers, lots, or portions of lots. Identification need not
14 be applied to each individual container but shall be sufficient to determine name,
15 strength, quantity of contents, and lot or control number of each container.

16 (c) Identification of the drug product with a lot or control number that permits
17 determination of the history of the manufacture and control of the batch.

18 (d) Examination of packaging and labeling materials for suitability and
19 correctness before packaging operations, and documentation of such examination in
20 the batch production record.

21 (e) Inspection of the packaging and labeling facilities immediately before use to
22 assure that all drug products have been removed from previous operations. Inspection
23 shall also be made to assure that packaging and labeling materials not suitable for
24 subsequent operations have been removed. Results of inspection shall be documented
25 in the batch production records.

26 28. Regulation section 211.137 states:

27 (a) To assure that a drug product meets applicable standards of identity,
28 strength, quality, and purity at the time of use, it shall bear an expiration date
determined by appropriate stability testing described in § 211.166.

(b) Expiration dates shall be related to any storage conditions stated on the
labeling, as determined by stability studies described in § 211.166.

(c) If the drug product is to be reconstituted at the time of dispensing, its
labeling shall bear expiration information for both the reconstituted and
unreconstituted drug products.

(d) Expiration dates shall appear on labeling in accordance with the
requirements of § 201.17 of this chapter.

(e) Homeopathic drug products shall be exempt from the requirements of this
section.

(f) Allergenic extracts that are labeled “No U.S. Standard of Potency” are
exempt from the requirements of this section.

1 (g) New drug products for investigational use are exempt from the requirements
2 of this section, provided that they meet appropriate standards or specifications as
3 demonstrated by stability studies during their use in clinical investigations. Where
4 new drug products for investigational use are to be reconstituted at the time of
dispensing, their labeling shall bear expiration information for the reconstituted drug
product.

5 (h) Pending consideration of a proposed exemption, published in the Federal
6 Register of September 29, 1978, the requirements in this section shall not be enforced
for human OTC drug products if their labeling does not bear dosage limitations and
they are stable for at least 3 years as supported by appropriate stability data.

7 29. Regulation section 211.160 states:

8 (a) The establishment of any specifications, standards, sampling plans, test
9 procedures, or other laboratory control mechanisms required by this subpart,
including any change in such specifications, standards, sampling plans, test
10 procedures, or other laboratory control mechanisms, shall be drafted by the
appropriate organizational unit and reviewed and approved by the quality control unit.
11 The requirements in this subpart shall be followed and shall be documented at the
time of performance. Any deviation from the written specifications, standards,
12 sampling plans, test procedures, or other laboratory control mechanisms shall be
recorded and justified.

13 (b) Laboratory controls shall include the establishment of scientifically sound
14 and appropriate specifications, standards, sampling plans, and test procedures
designed to assure that components, drug product containers, closures, in-process
15 materials, labeling, and drug products conform to appropriate standards of identity,
strength, quality, and purity. Laboratory controls shall include:

16 (1) Determination of conformity to applicable written specifications for
17 the acceptance of each lot within each shipment of components, drug product
containers, closures, and labeling used in the manufacture, processing, packing,
18 or holding of drug products. The specifications shall include a description of the
sampling and testing procedures used. Samples shall be representative and
adequately identified. Such procedures shall also require appropriate retesting
19 of any component, drug product container, or closure that is subject to
deterioration.

20 (2) Determination of conformance to written specifications and a
21 description of sampling and testing procedures for in-process materials. Such
samples shall be representative and properly identified.

22 (3) Determination of conformance to written descriptions of sampling
23 procedures and appropriate specifications for drug products. Such samples shall
be representative and properly identified.

24 (4) The calibration of instruments, apparatus, gauges, and recording
25 devices at suitable intervals in accordance with an established written program
containing specific directions, schedules, limits for accuracy and precision, and
26 provisions for remedial action in the event accuracy and/or precision limits are
not met. Instruments, apparatus, gauges, and recording devices not meeting
27 established specifications shall not be used.

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

30. Regulation section 211.165 states, in pertinent part:

(a) For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release. Where sterility and/or pyrogen testing are conducted on specific batches of shortlived radiopharmaceuticals, such batches may be released prior to completion of sterility and/or pyrogen testing, provided such testing is completed as soon as possible.

(b) There shall be appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms. . . .

31. Regulation section 211.166 states, in pertinent part:

(a) There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates. The written program shall be followed and shall include:

(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability;

(2) Storage conditions for samples retained for testing;

(3) Reliable, meaningful, and specific test methods;

(4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed;

(5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted. . . .

32. Regulation section 211.186 states, in pertinent part:

(a) To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed. . . .

33. Regulation section 211.188 states:

Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include:

(a) An accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed;

(b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including:

- 1 (1) Dates;
- 2 (2) Identity of individual major equipment and lines used;
- 3 (3) Specific identification of each batch of component or in-process
4 material used;
- 5 (4) Weights and measures of components used in the course of
6 processing;
- 7 (5) In-process and laboratory control results;
- 8 (6) Inspection of the packaging and labeling area before and after
9 use;
- 10 (7) A statement of the actual yield and a statement of the percentage
11 of theoretical yield at appropriate phases of processing;
- 12 (8) Complete labeling control records, including specimens or copies
13 of all labeling used;
- 14 (9) Description of drug product containers and closures;
- 15 (10) Any sampling performed;
- 16 (11) Identification of the persons performing and directly supervising
17 or checking each significant step in the operation, or if a significant step in
18 the operation is performed by automated equipment under § 211.68, the
19 identification of the person checking the significant step performed by the
20 automated equipment.
- 21 (12) Any investigation made according to § 211.192.
- 22 (13) Results of examinations made in accordance with § 211.134. . . .

23 34. Regulation section 211.192 states:

24 All drug product production and control records, including those for
25 packaging and labeling, shall be reviewed and approved by the quality control unit to
26 determine compliance with all established, approved written procedures before a batch
27 is released or distributed. Any unexplained discrepancy (including a percentage of
28 theoretical yield exceeding the maximum or minimum percentages established in
master production and control records) of the failure of a batch or any of its
components to meet any of its specifications shall be thoroughly investigated, whether
or not the batch has already been distributed. The investigation shall extend to other
batches of the same drug product and other drug products that may have been
associated with the specific failure or discrepancy. A written record of the
investigation shall be made and shall include the conclusions and followup.

COST RECOVERY

35. Section 125.3 of the Code states, in pertinent part, that the Board may request the
administrative law judge to direct a licentiate found to have committed a violation or violations of

1 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
2 enforcement of the case.

3 **CONTROLLED SUBSTANCES/DANGEROUS DRUGS**

4 36. *Methotrexate* is a prescription medication used to treat cancer, rheumatoid arthritis,
5 ectopic pregnancy, and other medical conditions that are very severe and cannot be treated with
6 other medications. It is a dangerous drug pursuant to Code section 4022.

7 37. *Ceftazidime* is a prescription antibiotic used for the treatment of a number of bacterial
8 infections. It is a dangerous drug pursuant to Code section 4022.

9 38. *Allergen Testing Sets*: Injectable allergen extracts are used for both diagnosis and
10 treatment and are sterile liquids that are manufactured from natural substances (such as molds,
11 pollens, insects, insect venoms, and animal hair) known to elicit allergic reactions in susceptible
12 individuals. Injectable allergen extracts for food allergies are used only for diagnostic purposes.
13 Among the injectable allergen extracts, some are standardized; for these products there is an
14 established method to determine the potency (or strength) of the product on a lot-by-lot basis. For
15 the other injectable allergen extracts there is no measure of potency, and these are called "non-
16 standardized." An allergen treatment set is a dangerous drug pursuant to Code section 4022.

17 39. *Methacholine Challenge 5-syringe test kits, Sterile Inhalation Solution*: A
18 methacholine challenge test (also known as a bronchoprovocation test) is performed to evaluate
19 how "reactive" or "responsive" an individual's lungs are to things in the environment. It can help
20 a doctor evaluate symptoms suggestive of asthma, such as cough, chest tightness, and shortness of
21 breath, and help diagnose whether or not an individual has asthma. During the test, the patient is
22 asked to inhale doses of methacholine, a drug that can cause narrowing of the airways, similar to
23 those seen in asthma. A breathing test will be repeated after each dose of methacholine to
24 measure the degree of narrowing or constriction of the airways. Methacholine is a dangerous
25 drug pursuant to Code section 4022.

26 40. *Betadine (Providone-Iodine) 5% syringe*: A Betadine 5% syringe is a disinfectant and
27 antiseptic agent used for preoperative preparation of the skin and mucous membranes, as well as

28 ///

1 for the treatment of contaminated wounds. Betadine 5% is a dangerous drug pursuant to Code
2 section 4022.

3 **JULY 31, 2020 INVESTIGATION**

4 41. On or about March 19, 2020, the Board received notification from Respondent of a
5 voluntary drug recall on two compounded drug products: (1) methotrexate 125mg/5ml (25
6 mg/ml) 5cc syringe, shipped between February 20 and March 10, 2020, lot #01-2020-28@10; and
7 (2) ceftazidime 11.25mg/0.5ml 1cc syringe, shipped between February 24 and March 16, 2020,
8 lot #02-2020-04@4. The recall notice stated, “in review of batch records, it was realized that one
9 of two lots of media¹ used for sterility testing for this lot had reached its expiration date just prior
10 to being used for testing this lot.”

11 42. On or about July 8, 2020, Respondent provided a Board inspector with the results of
12 Respondent’s investigation into the issue of the expired culture media that was used for testing
13 the lots of methotrexate and ceftazidime. The investigation revealed that the most probable root
14 cause was insufficient processes for inventory control for sterility testing media. The areas
15 affected included the cleanroom staff responsible for performing sterility testing media and the
16 quality staff responsible for processing and analyzing test results. Respondent’s Quality
17 Assurance desk and Quality Control Microbiology Department were responsible for filling out
18 sterility media lots and expirations. This meant that if expired sterility media were used, it could
19 only be detected after the issue had already occurred. Additionally, there were no written
20 procedures outlining that sterility media expirations must be checked to ensure they were still
21 within the expiration date once incubation had finished. Thus, Respondent had no written
22 procedures or laboratory controls to ensure that testing with only non-expired sterility media
23 occurred before distributing methotrexate and ceftazidime to consumers.

24 ///

25 ///

26 _____
27 ¹ A microbiological culture medium is a substance that encourages the growth, support,
28 and survival of microorganisms. Culture media contains nutrients, growth promoting factors,
energy sources, buffer salts, minerals, metals, and gelling agents. Some culture media types used
are used for the growth of bacteria (aerobic and anaerobic) as part of the sterility test.

1 **FIRST CAUSE FOR DISCIPLINE**

2 (Unprofessional Conduct—No Written Procedures or Sufficient Laboratory Controls)

3 43. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
4 on the grounds of unprofessional conduct, by and through Regulation sections 211.100,
5 subdivision (b), and 211.160, subdivision (b)(1), in that for a lot of methotrexate and a lot of
6 ceftazidime, Respondent had no written procedures or sufficient laboratory controls to ensure that
7 these lots were tested with non-expired sterility media before distributing to consumers. The facts
8 and circumstances are described with more particularity in paragraphs 41-42, above.

9 **SECOND CAUSE FOR DISCIPLINE**

10 (Unprofessional Conduct—Lacking Sterility Assurance—Adulterated and/or Misbranded)

11 44. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
12 on the grounds of unprofessional conduct, by and through Health and Safety Code sections
13 111260 and 111295, in that a lot of methotrexate and a lot of ceftazidime, Respondent failed to
14 properly perform sterility testing before distributing to consumers. The facts and circumstances
15 are described with more particularity in paragraphs 41-42, above.

16 **AUGUST 28, 2020 INVESTIGATION**

17 45. On or about April 6, 2020, the Board received notification from Respondent of a
18 voluntary drug recall on allergen sets² dispensed between March 25 and April 2, 2020. The
19 voluntary recall was initiated due to environmental monitoring excursions³ detected within
20 Respondent’s cleanroom during the days of processing.

21 46. On or about April 10, 2020, Respondent informed the Board of 32 affected
22 clients/customers in California.

23 47. On or about April 16, 2020, Respondent provided a Board inspector with the Health
24 Risk Assessment it had sent to the Federal Drug Administration (FDA) regarding the allergen

25 _____
26 ² A set of allergenic dilutions from an extract of an allergen, such as weed, grass, or tree
27 pollen, molds, house dust, or animal dander, used for diagnostic skin testing or for
28 immunotherapy for allergy.

³ Environmental monitoring results that exceed established alert or actions for the
presence of microbiological contamination in aseptic processing areas.

1 recall issue. The Health Risk Assessment stated that allergy extract lots produced from March 25
2 through April 2, 2020, were recalled due to microbial growth on media plates⁴ above acceptable
3 levels (out-of-specification). The Health Risk Assessment also revealed that the media plates
4 were sent out for identification and the bacterial sequence was identified as *Bacillus altitudinis*.⁵

5 48. The Health Risk Assessment further disclosed that Respondent determined the
6 primary root cause of the bacterial growth was a leaking media fill bag that was handled
7 incorrectly, causing contamination of several items throughout the facility, including items that
8 were passed into the cleanroom. The media fill bag was transferred to several departments
9 without proper biocontamination control. In addition, Respondent's investigation identified a
10 contributing cause to the microbial excursion was improper wiping technique used by staff to
11 wipe all items going into the cleanroom (resulting from cross-contamination of the contaminated
12 media fill bag transferred through the facility).

13 **THIRD CAUSE FOR DISCIPLINE**

14 (Unprofessional Conduct—Failure to Have Equipment and Utensils Cleaned)

15 49. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
16 on the grounds of unprofessional conduct, by and through Code section 4129.2, subdivision (b),
17 and Regulation section 211.67, subdivision (a), in that for allergen extracts dispensed between
18 March 25 and April 2, 2020, Respondent failed to have its equipment and utensils cleaned,
19 maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at
20 appropriate intervals to prevent malfunctions or contamination that would alter the safety,
21 identity, strength, quality, or purity of the drug product beyond the official or other established
22 requirements. The facts and circumstances are described with more particularity in paragraphs
23 45-48, above.

24 ///

25 ///

26 _____
27 ⁴ A petri dish that contains culture media which acts as a growth medium for
28 microorganisms. It is commonly used in pharmaceutical companies to assess the level of
microorganisms in their cleanrooms in order to maintain a clean environment.

⁵ A type of bacteria mostly commonly found in soil which can cause wet rot.

1 **FOURTH CAUSE FOR DISCIPLINE**

2 (Unprofessional Conduct—Lacking Sterility Assurance—Adulterated and/or Misbranded)

3 50. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
4 on the grounds of unprofessional conduct, by and through Health and Safety Code sections
5 111260 and 111295, in that for allergen extracts dispensed between March 25 and April 2, 2020,
6 Respondent failed to ensure sterility assurance of the extracts before distributing to consumers.
7 The facts and circumstances are described with more particularity in paragraphs 45-48, above.

8 **SEPTEMBER 28, 2020 INVESTIGATION**

9 51. On or about July 22, 2020, the Board received notification from Respondent that it
10 initiated a voluntary recall for one Allergen Extract Vial/Allergen Testing Set that was dispensed
11 on July 21, 2020, because Respondent mislabeled it. The single allergen set was sent directly to a
12 patient in San Diego, California.

13 52. On or about September 17, 2020, Respondent provided a Board inspector with a
14 document describing the recall to the FDA. Respondent reported to the FDA that 1) it failed to
15 follow its own Standard Operating Procedures (SOP) for reporting a recall to the FDA (the report
16 was five days late); 2) it did not follow its own policy on the labeling of materials for the allergen
17 sets; and 3) its procedure was determined by its quality staff to be inadequate.

18 **FIFTH CAUSE FOR DISCIPLINE**

19 (Unprofessional Conduct—Mislabeling of Allergen Extract)

20 53. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
21 on the grounds of unprofessional conduct, by and through Code section 4129.2, subdivision (b),
22 and Regulation section 211.100, subdivisions (a) and (b), in that Respondent dispensed an
23 Allergen Extract Vial on July 21, 2020, because it was mislabeled, which was caused by
24 Respondent failing to maintain proper written procedures for production and process control
25 designed to assure the drug products have the identity, strength, quality, and purity they purport
26 or are represented to possess, and Respondent failed to follow its written procedures. The facts
27 and circumstances are described with more particularity in paragraphs 51-52, above.

28 ///

1 **SIXTH CAUSE FOR DISCIPLINE**

2 (Unprofessional Conduct—Adulterated and/or Misbranded)

3 54. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
4 on the grounds of unprofessional conduct, by and through Health and Safety Code section
5 111295, in that Respondent dispensed an Allergen Extract Vial on July 21, 2020, because it was
6 mislabeled, which was caused by Respondent failing to maintain proper written procedures for
7 production and process control designed to assure the drug products have the identity, strength,
8 quality, and purity they purport or are represented to possess. The facts and circumstances are
9 described with more particularity in paragraphs 51-52, above.

10 **SEVENTH CAUSE FOR DISCIPLINE**

11 (Unprofessional Conduct—Dispensing of Allergen Extract Directly to Patient)

12 55. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
13 on the grounds of unprofessional conduct, by and through Code section 4129, subdivision (e), in
14 that on July 21, 2020, Respondent dispensed an allergen extract set directly to a patient. The facts
15 and circumstances are described with more particularity in paragraph 51, above.

16 **NOVEMBER 5, 2020 INVESTIGATION**

17 56. On or about September 3, 2020, the Board conducted a remote inspection of
18 Respondent’s facility as part of an annual inspection for Respondent’s outsourcing license. This
19 inspection revealed that between January 1, 2019 and August 27, 2020, Respondent shipped over
20 24,089 prescription, patient-specific, allergen sets into California.

21 57. The information Respondent provided to a Board inspector regarding the allergen sets
22 revealed that Respondent assigned a one-year Beyond Use Date (BUD)⁶ to all prescription sets
23 provided to California consumers.

24 ///

25 ///

26 _____
27 ⁶ Under title 16 of the California Code of Regulations, section 1735.1(b), "BUD means the
28 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)."

1
2 58. Respondent provided a Board inspector with invoices for its purchase of the raw
3 materials used in the allergen sets, which revealed that Respondent purchased the raw materials
4 from Stallergenes Greer (Greer). Greer’s prescribing and use information stated:

5 a. “Dilutions of concentrated extract result in a glycerin content of less than 50% which
6 results in reduced stability of the extracts. 1:100 dilutions should be kept no longer than a month,
7 and more dilute solutions no more than a week.”

8 59. A review of Respondent’s prescription sets revealed that many had dilutions greater
9 than 1:100 and were given a one-year BUD. Thus, there was no assurance of the stability of the
10 product leading to the possibility or likelihood of decomposed or expired components in the
11 product. Moreover, these products were mislabeled with a one-year BUD.

12 60. During the course of the inspection, Respondent failed to produce: 1) a master batch
13 record, 2) executed Current Good Manufacturing Practices (cGMP)⁷ compliant batch records, 3)
14 cGMP compliant labels, 4) cGMP label reconciliation, 5) line clearance, 6) second signature for
15 charge in of components, or 7) any other evidence of the prescription sets being cGMP compliant.

16 61. The inspection also revealed that the following information was missing from
17 Respondent’s prescription set labels, making them noncompliant with cGMP and Respondent's
18 own SOP:

- 19 a. Not for resale
20 b. This prescription set was prepared by Edge Pharma LLC
21 c. The address and phone number of Edge Pharma LLC
22 d. Identity of each allergenic extract in the AIT and the quantity of each
23 e. Lot number or batch number
24 f. The day it was manufactured
25 g. Storage and handling instructions

26
27 ⁷ Defined by the FDA as systems to assure proper design, monitoring, and control over
28 manufacturing processes and facilities in pharma and other FDA-regulated industries. These
systems are designed to help organizations assure drug products are the correct identity, strength,
purity, and quality.

1 greater. The facts and circumstances are described with more particularity in paragraphs 56-67,
2 above.

3 **NINTH CAUSE FOR DISCIPLINE**

4 (Unprofessional Conduct—Mislabeling Allergen Extracts)

5 69. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
6 on the grounds of unprofessional conduct, by and through Health and Safety Code sections
7 111330, 111440, and 111445, in that by assigning a BUD of one year to all allergen sets,
8 Respondent mislabeled its allergen extracts. The facts and circumstances are described with more
9 particularity in paragraphs 56-67, above.

10 **TENTH CAUSE FOR DISCIPLINE**

11 (Unprofessional Conduct—Violation of Applicable Federal Laws and Regulations Governing
12 Pharmacy)

13 70. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
14 on the grounds of unprofessional conduct, by and through Code section 4129.2, subdivision (b),
15 in that Respondent failed to comply with specific Regulation sections as follows:

16 a. Regulation section 210.1, subdivision (b), in that Respondent's labeling for allergen
17 sets should have listed a BUD of one month or one week, not one year, for all of Respondent's
18 dilutions 1:100 or greater.

19 b. Regulation section 211.22, subdivision (a), in that Respondent's labeling for allergen
20 sets should have listed a BUD of one month or one week, not one year for all of Respondent's
21 dilutions 1:100 or greater.

22 c. Regulation sections 211.22, subdivision (b), and 211.84, subdivision (d)(3), in that
23 Respondent failed to make available to the quality control unit adequate laboratory facilities for
24 the testing and approval (or rejection) of components, drug product containers, closures,
25 packaging materials, in-process materials, and drug products, and failed to conduct proper testing
26 and approval or rejection of components, drug product containers, and closures.

27 d. Regulation section 211.42, subdivision (c)(10)(v), in that Respondent had no cleaning
28 validation.

1 e. Regulation section 210.122, subdivision (b), in that Respondent's prescription set
2 labels were missing information required by cGMP and Respondent's own SOP.

3 f. Regulation section 211.165, subdivision (b), in that Respondent released allergen sets
4 for distribution prior to sterility testing being completed.

5 g. Regulation section 211.166, subdivision (a)(3), in that Respondent failed to
6 implement a written testing program designed to assess the stability characteristics of drug
7 products and Respondent's test method for Formula ID 1566 Gemcitabine 1 gm in 50mL syringe
8 did not consider the firm specific matrix of the product.

9 h. Regulation section 211.67, subdivision (b), in that Respondent failed to establish and
10 follow written procedures for cleaning and maintenance of equipment, including utensils, used in
11 the manufacture, processing, packing, or holding of a drug product.

12 i. Regulation section 211.186, subdivision (a), in that Respondent failed to provide
13 complete master production records during the Board's inspection.

14 j. Regulation section 211.188, subdivisions (a) and (b), in that Respondent maintained
15 inadequate batch production and control records.

16 k. Regulation section 211.188, subdivisions (a) and (b), Respondent's batch records
17 lacked documentation of each significant step in the manufacture of the product and a second
18 signature for charge in of components.

19 l. The facts and circumstances are described with more particularity in paragraphs 56-
20 67, above.

21 **JANUARY 26, 2021 INVESTIGATION**

22 71. On or about September 4, 2020, Respondent e-mailed the Board a complaint it
23 received from Palo Alto Medical Foundation (PAMF) allergy department, located in San Carlos,
24 CA, regarding mislabeled vials for allergen sets, RX #938529, that Respondent provided to
25 PAMF. Respondent received the complaint from PAMF on or about August 28, 2020.

26 72. PAMF's complaint included photographs of the allergen sets for RX #938529, which
27 showed a 1:10 V/V Set B Tree Mix (Yellow) label switched with the 1:100 V/V Set B Tree Mix
28 (Blue) label.

1 73. In response to Respondent's September 4, 2020 e-mail, the Board conducted an
2 investigation.

3 74. As part of the Board's investigation, a Board inspector obtained the final label of the
4 allergen prescription set RX #938529 from Respondent, which identified a BUD of one year. The
5 Board inspector compared the final label with the FDA approved labeling of allergenic extracts
6 for the manufacturer of the dilutions used in RX #938529, Greer, which requires dilutions of
7 1:100 be kept no longer than one month and more dilute solutions no more than one week.

8 75. The Board inspector obtained allergen prescription sets from respondent. At least RX
9 #946973, 946935, and 946627 were made on August 28, 2020 by Respondent, and all had
10 dilutions of at least 1:100,000 or greater. Respondent assigned BUD's to these allergen sets of
11 one year. The Board inspector compared the final labels for these prescription sets with the FDA
12 approved labeling of allergenic extracts for the manufacturer of the dilutions used, Greer, which
13 requires dilutions of 1:100 or higher be kept no longer than one month and more dilute solutions
14 no more than one week.

15 76. As part of the Board's investigation, Respondent provided the Board with information
16 regarding its production process for allergen sets. For allergen sets to be safe for consumers, they
17 must contain an adequate amount of a preservative to inhibit microbial growth. The allergen sets
18 produced by Respondent require an effective preservative system to inhibit microbial growth. As
19 demonstrated by the manufacturer Greer, preservative effectiveness has been demonstrated at
20 levels of 0.28% or greater. The Board inspector's analysis of RX # 924783, 933387, 937913, and
21 932002, all produced by Respondent, revealed that they were all made on a single production day
22 and contained phenol in a concentration of 0.24% or less.

23 77. The Board inspector reviewed allergen sets RX # 931628, 923235, 938693, and
24 940835, all of which were produced by Respondent. These allergen sets contain mixtures of
25 ingredients that have been demonstrated to have an expected loss of potency, necessitating that
26 they be used by a consumer relatively soon after their production (certainly sooner than one year
27 from their production). In response to the Board inspector's requests, Respondent failed to

28 ///

1 produce any validated stability studies to support their assigned one-year BUD for these allergen
2 sets.

3 78. The Board inspector also reviewed Respondent’s documentation for 22 different lots
4 of allergen prescription sets produced on August 7, 2020. The inspector discovered that line
5 clearance⁹ was only noted prior to cleaning and after cleaning prior to production. There was no
6 line clearance between each lot of allergen prescription set production. Respondent only notated
7 the start and end time of production of multiple lots of allergen prescription sets that occurred
8 between 0721 to 1400 hours.

9 **ELEVENTH CAUSE FOR DISCIPLINE**

10 (Unprofessional Conduct—Failure to Provide Board With a Copy of a Clinically Related
11 Complaint Within 72 Hours of Receipt)

12 79. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
13 on the grounds of unprofessional conduct, by and through Code section 4129.2, subdivision
14 (e)(3), in that Respondent failed to provide the Board with a copy of a clinically related complaint
15 it received involving Respondent’s compounded products from or involving any provider,
16 pharmacy, or patient in California within 72 hours of receipt. The facts and circumstances are
17 described with more particularity in paragraph 71, above.

18 **TWELFTH CAUSE FOR DISCIPLINE**

19 (Unprofessional Conduct—Mislabeling of Allergen Extract)

20 80. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
21 on the grounds of unprofessional conduct, by and through Code section 4129.2, subdivision (b),
22 and Regulation section 211.130, subdivision (b), in that allergen prescription set RX #938529,
23 which was produced and sold by Respondent to a consumer in California, was mislabeled and did
24 not accurately state the contents of the vial. The facts and circumstances are described with more
25 particularity in paragraphs 71-72, above.

26 ///

27 _____
28 ⁹ Line clearance is a process which provides a high degree of confidence or assurance that
the said line or area is free from any unwanted residue or left over of previous processing before
proceeding for next process.

1 **THIRTEENTH CAUSE FOR DISCIPLINE**

2 (Unprofessional Conduct—Violation of Applicable Federal Laws and Regulations Governing
3 Pharmacy)

4 81. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
5 on the grounds of unprofessional conduct, by and through Code section 4129.2, subdivision (b),
6 in that Respondent failed to comply with the following Regulations:

7 a. Regulation section 211.22, subdivision (a), in that Respondent assigned a one-year
8 BUD to at least allergen prescription set RX #938529, which exceeded the manufacturer "Storage
9 and Handling" requirements.

10 b. Regulation section 211.22, subdivision (a), in that Respondent distributed allergen
11 prescription set vials as multi-dose vials without adequate data to support indefinite use of the
12 product through expiration.

13 c. Regulation section 211.137, subdivision (a), in that Respondent does not have any
14 process controls when combining different allergenic extracts. Specifically, RX #931628,
15 923235, 938693, and 940835 contain mixtures of ingredients that have been demonstrated to have
16 an expected significant loss of potency, however Respondent has not completed any validated
17 stability studies to support their one-year BUD.

18 d. Regulation section 211.188, subdivision (b), in that on August 7, 2020, line clearance
19 prior to production was documented only once by Respondent for the production of 22 different
20 lots of allergen prescription sets. Line clearance was only noted prior to cleaning and after
21 cleaning prior to production. Respondent only notated the start and end time of production of
22 multiple lots of allergen prescription sets that occurred between 0721 to 1400 hours.

23 e. The facts and circumstances are described with more particularity in paragraphs 71-
24 78, above.

25 **MARCH 23, 2021 INVESTIGATION**

26 82. On or about February 18, 2021, Respondent e-mailed the Board, providing
27 notification of a voluntary recall for Methacholine Challenge 5-syringe test kits, Sterile Inhalation
28 Solution, NDC: 05446-1600-05, Lot Numbers #12-2020-16@10 (expiration March 30, 2021) and

1 #11-2020-18@11 (expiration March 2, 2021). According to Respondent, the external packaging
2 of the product had the incorrect storage conditions listed. The label listed the storage conditions
3 as room temperature instead of the intended requirement of refrigeration. Respondent notified the
4 FDA on February 17, 2021, and all customers were sent a recall notice on February 17 and 18,
5 2021.

6 83. In response to Respondent's February 18, 2021 e-mail, the Board conducted an
7 investigation.

8 84. As part of the Board's investigation, a Board inspector obtained additional
9 information from Respondent regarding the recall. Specifically, on or about March 17, 2021,
10 Respondent provided the Board with the following information regarding the recall and its
11 suspected root cause:

12 a. Per Respondent's Standard Operating Procedures (SOP), the fulfillment team was
13 permitted to print box/external packaging labels while fulfilling sales orders without Quality
14 Assurance (QA) involvement.

15 b. The labeling error was caused by an Order Fulfillment Specialist (Non-Quality
16 Assurance).

17 c. Respondent's procedure for labeling allowed for the issuance, printing, and adhesion
18 of batch labels by the sales department (Non-Quality Assurance).

19 **FOURTEENTH CAUSE FOR DISCIPLINE**

20 (Unprofessional Conduct—Violation of Applicable Federal Laws and Regulations Governing
21 Pharmacy)

22 85. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
23 on the grounds of unprofessional conduct, by and through Code section 4129.2, subdivision (b),
24 in that Respondent failed to comply with the following Regulations:

25 a. Regulation section 211.22, subdivision (a), in that the packaging procedure approved
26 by Respondent's SOP failed to establish a procedure to provide a reliable method for approval or
27 rejection of all packaging material and labeling. Specifically, violative batch labels were issued,

28 ///

1 printed, and used for packaging and distribution of Methacholine Challenge 5-syringe test kits,
2 NDC: 05446-1600-05, Lot Numbers #12-2020-16@10 and #11-2020-18@11.

3 b. Regulation section 211.130, subdivision (d), in that Methacholine Challenge 5-
4 syringe test kits, NDC: 05446-1600-05, Lot Numbers #12-2020-16@10 and #11-2020-18@11
5 were labeled incorrectly and distributed to customers. The product was misbranded and did not
6 accurately state the required storage conditions.

7 c. The facts and circumstances are described with more particularity in paragraphs 82-
8 84, above.

9 **MAY 25, 2021 INVESTIGATION**

10 86. On or about April 13, 2021, Respondent e-mailed the Board, providing notification of
11 a voluntary recall for Betadine (Providone-Iodine) 5% syringes, Sterile Ophthalmic, Preservative
12 Free, NDC: 05446-0574-01, Lot Number #02-2021-16@4 (expiration May 31, 2021). According
13 to Respondent, the reason for the recall was that the drug contents were able to migrate past the
14 plunger seal of the syringe. Respondent notified the FDA on April 12, 2021, and all customers
15 were sent a recall notice on April 12, 2021.

16 87. In response to Respondent's April 13, 2021 e-mail, the Board conducted an
17 investigation.

18 88. Respondent provided the Board with the following information regarding the recall
19 and its suspected root cause:

20 a. Respondent had recently transitioned from using syringes which contained silicone to
21 a silicone-free syringe.

22 b. Following production of a recent batch of Betadine syringes (Lot # 03-2021-31@1), it
23 was noted that a significant number of syringes failed visual inspection. Respondent continued to
24 visually inspect this lot of Betadine syringes and discovered significant additional leakage. The
25 product was disposed of and was not released for distribution.

26 c. Respondent then went back and inspected a previously distributed lot of Betadine
27 syringes, the lot at issue herein (Lot # 02-2021-16@4), and observed the same failure where drug
28 contents migrated past the syringe plunger.

1 89. Lot # 02-2021-16@4 had been actively distributed from March 3, 2021 to April 8,
2 2021, with one thousand, six hundred, and thirty-one (1631) syringes still within expiration at the
3 time the recall was instigated.

4 **FIFTEENTH CAUSE FOR DISCIPLINE**

5 (Unprofessional Conduct—Violation of Applicable Federal Laws and Regulations Governing
6 Pharmacy)

7 90. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
8 on the grounds of unprofessional conduct, by and through Code section 4129.2, subdivision (b),
9 in that Respondent failed to comply with the following Regulations:

10 a. Regulation section 211.22, subdivision (c), in that the quality control unit shall have
11 the responsibility for approving or rejecting all procedures or specifications impacting on the
12 identity, strength, quality, and purity of the drug product. However, the quality unit allowed a
13 visual inspection process and subsequent acceptable quality limit process which allowed defective
14 product to be released for sale.

15 b. Regulation section 211.100, subdivision (a), in that there shall be written procedures
16 for production and process control designed to assure that the drug products have the identity,
17 strength, quality, and purity they purport or are represented to possess. However, Respondent
18 failed to have or to follow the appropriate written procedures which allowed a defective product
19 to be released for sale.

20 c. The facts and circumstances are described with more particularity in paragraphs 86-
21 89, above.

22 **JULY 1, 2021 INVESTIGATION**

23 91. On or about April 19, 2021, Respondent notified the Board of a customer complaint
24 from Sutter Santa Rosa Regional Hospital, regarding a syringe of methotrexate, which had leaked
25 at the junction of the syringe and the leur-lock¹⁰ connection. Respondent did not conduct a recall
26 relating to this customer complaint.

27 _____
28 ¹⁰ A leur-lock connection is a standardized system of small-scale fluid fittings used for
making leak-free connections between a tapered fitting on medical and laboratory instruments.

1 92. In response to Respondent’s April 19, 2021 notification, the Board conducted an
2 investigation.

3 93. During the investigation, the following was discovered:

4 a. Respondent had received two prior consumer complaints about similar failures of the
5 leur-lock system, and had failed to fully investigate and determine the root cause of the failures.

6 b. On February 1, 2021, a consumer complaint from a non-California consumer was
7 received by Respondent. Respondent failed to test retained samples, failed to determine a root
8 cause, and had never performed process qualification with the product to ensure it would not leak
9 during shipment or prior to use.

10 c. On April 5, 2021, a consumer complaint from a non-California consumer was
11 received by Respondent. Respondent failed to test retained samples, failed to alter their
12 instructions or offer suggestions to their customers for preventing leakage. The consumer
13 believed that the root cause of the failure was that leur-lock connections could become loose
14 during transit or had not been completely tightened at Respondent’s facility. Respondent decided
15 from this information that the root cause of the leakage was becoming loose during transit.

16 94. Respondent failed to investigate the consumer complaint from Sutter Santa Rosa
17 Regional Hospital, instead simply referring to the investigation from the April 5, 2021 consumer
18 complaint and stating “...the root cause of the leakage was determined to be movement of the kit
19 during shipment...”

20 **SIXTEENTH CAUSE FOR DISCIPLINE**

21 (Unprofessional Conduct—Violation of Applicable Federal Laws and Regulations Governing
22 Pharmacy)

23 95. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
24 on the grounds of unprofessional conduct, by and through Code section 4129.2, subdivision (b),
25 in that Respondent failed to comply with the following Regulations:

26 a. Regulation section 211.22, subdivision (c), in that the quality control unit shall have
27 the responsibility for approving or rejecting all procedures or specifications impacting on the
28 identity, strength, quality, and purity of the drug product. However, the quality unit allowed a

1 product to be released for sale which did not have an adequate container closure process
2 qualification to ensure there was no leaking of the product contained in it.

3 b. Regulation section 211.192, in that Respondent failed to properly investigate the leu-
4 lock failures reported by three separate consumers. A possible fix for the problem was developed
5 by one of the consumers, but previous and current customers were not notified of the problem or
6 the possible fix.

7 c. The facts and circumstances are described with more particularity in paragraphs 91-
8 94, above.

9 **AUGUST 30, 2021 INVESTIGATION**

10 96. On or about August 3-5, 2021, Board inspectors conducted an onsite inspection at
11 Respondent's facilities. This is a standard annual inspection required for renewal of the
12 nonresident outsourcing permit. Prior to August 3-5, 2021, Board inspectors requested and
13 received documentation from Respondent relevant to the inspection. Board inspectors focused
14 mainly on issues that had arisen in the inspection conducted in the prior year, 2020.

15 97. After the inspection, Board inspectors issued nine (9) written notices to Respondent
16 regarding violations of pharmacy law.

17 98. During the inspection, the following was discovered:

18 a. Respondent continues to ship product with an inappropriate BUD as set forth in
19 paragraphs 74-77, above.

20 b. Respondent failed to have adequate shipping and packing validation procedures
21 supported by studies. For example, a 25L payload box was tested with a max load of 108 vials of
22 10 mL (1080 mL total, or 1.08L), so the 25L box would have significantly more product during
23 an actual shipment. Frozen products are also shipped without a validated pack out to confirm that
24 the product stays frozen throughout the shipping process.

25 c. Respondent failed to conduct USP <788/789> testing of all required drug products.
26 This was addressed with Respondent in the 2020 inspection, and Respondent informed the Board
27 in an inspection update for the 2020 inspection that all products requiring USP <788/789> testing
28 were now being tested.

1 d. Respondent has not fully implemented continuous non-viable monitoring. This was
2 addressed with Respondent during the 2020 inspection. For the 2021 inspection, Respondent's
3 pre-inspection statement was that the equipment had been purchased and installed, leaving the
4 implication that the equipment was being used. However, the equipment is not currently in use.

5 e. Numerous live and dead insects were in the facility. Some in traps, many outside of
6 traps.

7 f. Respondent failed to adequately monitor pressure differentials and failed to have
8 gauges certified accurate. For example, on May 26, 2021, cleanrooms 200, 201, and 202 showed
9 that the pressure differential between rooms 201 and 202 did not have the required pressure
10 differential of >0.02 inches of water column (WC). Pressure was observed by a third party
11 contractor to be 0.006 WC, while Respondent's gauge showed 0.025 WC. Respondent failed to
12 conduct any investigation as to the duration of the pressure loss event or whether batches of drugs
13 were compromised. Additionally there was observed to be a red/dark stain on the HEPA filter
14 supplying to workstation 1C, which was stated by Respondent's employee to have been there "for
15 a while."

16 g. Respondent has failed to fully validate all drug products. This was a repeat issue
17 from the 2020 inspection. Respondent has fully validated some products, but 26 validations are
18 still under development or review. This means that many products do not have adequate stability
19 indication to determine whether it is safe to be used for each product's intended use.

20 h. Respondent has failed to perform adequate cleaning validation for disinfectants.
21 Disinfectants have been tested on stainless steel and plastic, but during the inspection these
22 disinfectants were being used on other substrates including aluminum, vinyl, epoxy, paper, and
23 glass.

24 i. Respondent has not validated all equipment, including two refrigerators, and three
25 dishwashers.

26 ///

27 ///

28 ///

1 **SIXTEENTH CAUSE FOR DISCIPLINE**

2 (Unprofessional Conduct—Violation of Applicable Federal Laws and Regulations Governing
3 Pharmacy)

4 99. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
5 on the grounds of unprofessional conduct, by and through Code section 4129.2, subdivision (b),
6 in that Respondent failed to comply with the following Regulations:

7 a. Regulation section 211.22, subdivision (c), in that the quality control unit shall have
8 the responsibility for approving or rejecting all procedures or specifications impacting on the
9 identity, strength, quality, and purity of the drug product. However, the quality control unit
10 allowed allergan extract sets to be released for sale which did not have the appropriate BUD, as
11 set forth in paragraphs 74-77 and 98, subdivision (a), above.

12 b. Regulation section 211.22, subdivision (c), in that the quality control unit failed to
13 ensure that shipping validations and procedures were adequate prior to shipping the drug product,
14 as set forth in paragraph 98, subdivision (b), above.

15 c. Regulation section 211.160, subdivision (b), in that Respondent failed to conduct
16 USP <788/789> testing prior to the release of all drugs requiring such testing, as set forth in
17 paragraph 98, subdivision (c), above.

18 d. Regulation section 211.113, subdivision (b), in that Respondent has failed to
19 implement continuous no-viable monitoring, as set forth in paragraph 98, subdivision (d), above.

20 e. Regulation section 211.56, subdivision (c), in that Respondent has failed to
21 adequately control pests, as set forth in paragraph 98, subdivision (e), above.

22 f. Regulation section 211.46, subdivision (b), in that Respondent has failed to have
23 equipment for adequate control over air pressure, micro-organisms, dust, humidity, and
24 temperature by failing to have adequate working gauges and continuing to use a HEPA filter with
25 a red/dark stain on it, as set forth in paragraph 98, subdivision (f), above.

26 g. Regulation section 211.166, subdivision (a)(3), in that Respondent has failed to
27 conduct testing utilizing stability indicating test methods, many of Respondent's drug products
28 are not fully verified, as set forth in paragraph 98, subdivision (g), above.

1 h. Regulation section 211.42, subdivision (c)(10), in that Respondent failed to perform
2 appropriate cleaning validation on all substrates on which the cleaning compound would be used,
3 as set forth in paragraph 98, subdivision (h), above.

4 i. Regulation section 211.67, subdivision (b), in that Respondent failed to validate all
5 equipment needing validation, as set forth in paragraph 98, subdivision (i), above.

6 **OTHER MATTERS**

7 100. Pursuant to Code section 4307, if discipline is imposed on Nonresident Outsourcing
8 Facility Permit Number NSF 132 issued to Edge Pharmacy Holdings LP, 100 % shareholder to do
9 business as Edge Pharma LLC, Edge Pharmacy Holdings LP, Edge Pharma LLC, William Marc
10 Chatoff, Roger Christopher Nadeau, Howard Scott Chatoff, and Jules Chatoff shall be prohibited
11 from serving as a manager, administrator, owner, member, officer, director, associate, or partner
12 of a licensee for five years if Nonresident Outsourcing Facility Permit Number NSF 132 is placed
13 on probation or until Nonresident Outsourcing Facility Permit Number NSF 132 is reinstated if it
14 is revoked.

15 **DISCIPLINE CONSIDERATIONS**

16 101. To determine the degree of discipline, if any, to be imposed on Respondent,
17 Complainant alleges that on or about June 18, 2020, in a prior action, the Board issued Citation
18 Number CI 2019 86855 based upon Respondent's violation of Business and Professions Code
19 section 4129.2, subdivision (e)(2) (failure to provide the Board within 24 hours of any recall
20 notice issued by the nonresident outsourcing facility), when on or about August 14, 2019,
21 Respondent failed to notify the Board of a drug recall (or market withdrawal) of a compounded
22 drug product, mitomycin C 0.2mg/ml, lot #06-2019-26@7. That Citation is now final and is
23 incorporated by reference as if fully set forth.

24 102. To determine the degree of discipline, if any, to be imposed on Respondent,
25 Complainant alleges that on or about February 4, 2021, in a prior action, the Board issued
26 Citation Number CI 2019 86897 based upon Respondent's violation of Business and Professions
27 Code section 4129.2, subdivisions (e)(3) (failure to provide the Board a copy of any complaint
28 received involving an outsourcing facility's compounded products from or involving any

1 provider, pharmacy, or patient in California within 72 hours of receipt) and (e)(4) (failure to
2 provide the Board with notice within 24 hours after learning of adverse effects reported or
3 potentially attributable to a nonresident outsourcing facility's products). That Citation is now
4 final and is incorporated by reference as if fully set forth.

5 103. To determine the degree of discipline, if any, to be imposed on Respondent,
6 Complainant alleges that on or about August 6, 2021, the Executive Officer of the Board issued a
7 cease and desist against Respondent due to the issues set forth above relating to the August 30,
8 2021, investigation report. On or about August 24, 2021, a cease and desist hearing was held
9 before the Board President pursuant to Bus. & Prof. Code section 4129.4, subdivision (c). On or
10 about August 28, 2021, the Board President issued a written decision upholding the cease and
11 desist order.

12 **PRAYER**

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

- 15 1. Revoking or suspending Nonresident Outsourcing Facility Permit Number NSF 132,
16 issued to Edge Pharma LLC;
- 17 2. Prohibiting Edge Pharma LLC, Edge Pharmacy Holdings LP, William Marc Chatoff,
18 Roger Christopher Nadeau, Howard Scott Chatoff, and Jules Chatoff from serving as a manager,
19 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
20 Nonresident Outsourcing Facility Permit Number NSF 132 is placed on probation or until
21 Nonresident Outsourcing Facility Permit Number NSF 132 is reinstated if Nonresident
22 Outsourcing Facility Permit Number NSF 132 issued to Edge Pharmacy holdings LP, 100%
23 shareholder to do business as Edge Pharma LLC is revoked;
- 24 3. Ordering Edge Pharma LLC, to pay the Board the reasonable costs of investigation
25 and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

26 ///

27 ///

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

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

DATED: 9/29/2021

Signature on File _____

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

SA2020303840