# 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 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
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*Attorneys for Complainant*

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

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|---|---|
| In the Matter of the Accusation Against:<br><br>**EDGE PHARMA LLC**<br>**EDGE PHARMACY HOLDINGS LP,**<br>**100% SHAREHOLDER**<br>**WILLIAM MARC CHATOFF,**<br>**PRESIDENT AND MANAGER**<br>**ROGER CHRISTOPHER NADEAU,**<br>**VICE-PRESIDENT AND**<br>**TREASURER/CHIEF FINANCIAL**<br>**OFFICER**<br>**HOWARD SCOTT CHATOFF,**<br>**DIRECTOR**<br>**JULES CHATOFF, DIRECTOR**<br>**856 Hercules Drive**<br>**Colchester, VT 05446**<br><br>**Nonresident Outsourcing Facility Permit**<br>**No. NSF 132**<br><br>Respondent. | Case No. 7047<br><br>OAH No. 2020120528<br><br>**STIPULATED SETTLEMENT AND DISCIPLINARY ORDER** |

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

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## PARTIES

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

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

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

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

## JURISDICTION

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

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

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## ADVISEMENT AND WAIVERS

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

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

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

## CULPABILITY

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

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

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

## CONTINGENCY

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

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

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

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

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

**DISCIPLINARY ORDER**

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

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

1. **Definition: Respondent**

For the purposes of these terms and conditions, "respondent" shall refer to Edge Pharma

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

2. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

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

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

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

3. **Report to the Board**

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

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

4. **Interview with the Board**

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

5. **Cooperate with Board Staff**

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

6. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $85,974.50. Respondent shall make said payments as designated by the board or its designee.

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

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

7. **Probation Monitoring Costs**

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

8. **Status of License**

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

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

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

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

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

10. **Sale or Discontinuance of Business**

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

11. **Notice to Employees**

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

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

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

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

13. **Premises Open for Business**

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

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14. **Posted Notice of Probation**

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

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

15. **Violation of Probation**

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

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

16. **Completion of Probation**

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

17. **Restricted Practice**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

limited to, sanitary garb provided by Respondent to allow the Board inspectors to enter the cleanroom to view production, production steps, and production rooms. Board inspectors will

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take all necessary steps to make the incursion minimal and when necessary with full cooperation between the inspector and Respondent to minimize any effect on production.

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

18. **Remedial Education**

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

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

19. **Ethics Course**

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

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

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

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

21. **Consultant**

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

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

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**ACCEPTANCE**

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

DATED: _____

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

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

DATED: _____

_____
*Attorney for Respondent*

_____
(Print Attorney Name)

**ENDORSEMENT**

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

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

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## ACCEPTANCE

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

DATED: 10/4/21

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

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

DATED: October 5, 2021

*Attorney for Respondent*

Joseph R. LaMagna
(Print Attorney Name)

## ENDORSEMENT

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

DATED: _____

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*

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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*

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# Exhibit A

**Fifth Amended Accusation No. 7047**

ROB BONTA
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*Attorneys for Complainant*

**BEFORE THE**
**BOARD OF PHARMACY**
**DEPARTMENT OF CONSUMER AFFAIRS**
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| In the Matter of the Accusation Against**:**<br><br>**EDGE PHARMA LLC**<br>**EDGE PHARMACY HOLDINGS LP,**<br>**100% SHAREHOLDER**<br>**WILLIAM MARC CHATOFF,**<br>**PRESIDENT AND MANAGER**<br>**ROGER CHRISTOPHER NADEAU,**<br>**VICE-PRESIDENT AND**<br>**TREASURER/CHIEF FINANCIAL**<br>**OFFICER**<br>**HOWARD SCOTT CHATOFF,**<br>**DIRECTOR**<br>**JULES CHATOFF, DIRECTOR**<br>**856 Hercules Drive**<br>**Colchester, VT 05446**<br><br>**Nonresident Outsourcing Facility Permit**<br>**No. NSF 132**<br><br>Respondent. | Case No. 7047<br><br>**FIFTH AMENDED**<br><br>**ACCUSATION** |

## 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.

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

**JURISDICTION**

3. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 4300 of the Code states, in pertinent part:

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

5. Section 4300.1 of the Code states:

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

6. Code section 4307 states:

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

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

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

(b) Manager, administrator, owner, member, officer, director, associate, 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.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability 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.

**BUSINESS AND PROFESSIONS CODE**

7. Section 4022 of the Code states:

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

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

(b) Any device that bears the statement: "Caution: federal law restricts this 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 use of the device.

(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.

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

9. Code section 4129.2 states, in pertinent part:

. . .

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

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

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

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

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

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

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

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

. . .

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

**HEALTH AND SAFETY CODE**

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

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

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

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

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

**REGULATORY PROVISIONS**

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

> (a) The regulations set forth in this part and in parts 211, 225, and 226 of this chapter contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.
>
> (b) The failure to comply with any regulation set forth in this part and in parts 211, 225, and 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action. . . .

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

> (a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.
>
> (b) Adequate laboratory facilities for the testing and approval (or rejection) of 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) Receipt, identification, storage, and withholding from use of components, drug product containers, closures, and labeling, pending the appropriate sampling, testing, or examination by the quality control unit before release for manufacturing or packaging;

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

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

(4) Storage of in-process materials;

(5) Manufacturing and processing operations;

(6) Packaging and labeling operations;

(7) Quarantine storage before release of drug products;

(8) Storage of drug products after release;

(9) Control and laboratory operations;

(10) Aseptic processing, which includes as appropriate:

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

(ii) Temperature and humidity controls;

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

(iv) A system for monitoring environmental conditions;

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

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

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

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.

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

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

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

22. Regulation section 211.67 states:

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

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

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

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

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

(4) Removal or obliteration of previous batch identification;

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

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

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

23. Regulation section 211.84 states, in pertinent part:

(a) Each lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, 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

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

(3) Containers and closures shall be tested for conformity with all appropriate written specifications. In lieu of such testing by the manufacturer, a certificate of testing may be accepted from the supplier, provided that at least a 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.

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

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

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

24. Regulation section 211.100 states:

(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all 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.

(b) Written production and process control procedures shall be followed in the 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.

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

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

26. Regulation section 211.122 states:

(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling 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.

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

27. Regulation section 211.130 states:

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

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

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

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

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

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

28. Regulation section 211.137 states:

(a) To assure that a drug product meets applicable standards of identity, 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.

(g) New drug products for investigational use are exempt from the requirements of this section, provided that they meet appropriate standards or specifications as demonstrated by stability studies during their use in clinical investigations. Where 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.

(h) Pending consideration of a proposed exemption, published in the Federal 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.

29. Regulation section 211.160 states:

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

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

(1) Determination of conformity to applicable written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and labeling used in the manufacture, processing, packing, 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 of any component, drug product container, or closure that is subject to deterioration.

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

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

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

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) Dates;

(2) Identity of individual major equipment and lines used;

(3) Specific identification of each batch of component or in-process material used;

(4) Weights and measures of components used in the course of processing;

(5) In-process and laboratory control results;

(6) Inspection of the packaging and labeling area before and after use;

(7) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;

(8) Complete labeling control records, including specimens or copies of all labeling used;

(9) Description of drug product containers and closures;

(10) Any sampling performed;

(11) Identification of the persons performing and directly supervising or checking each significant step in the operation, or if a significant step in the operation is performed by automated equipment under § 211.68, the identification of the person checking the significant step performed by the automated equipment.

(12) Any investigation made according to § 211.192.

(13) Results of examinations made in accordance with § 211.134. . . .

34. Regulation section 211.192 states:

All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of 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

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

**CONTROLLED SUBSTANCES/DANGEROUS DRUGS**

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

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

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

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

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

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

**JULY 31, 2020 INVESTIGATION**

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

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

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[1] A microbiological culture medium is a substance that encourages the growth, support, 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.

**FIRST CAUSE FOR DISCIPLINE**

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

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

**SECOND CAUSE FOR DISCIPLINE**

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

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

**AUGUST 28, 2020 INVESTIGATION**

45. On or about April 6, 2020, the Board received notification from Respondent of a voluntary drug recall on allergen sets[2] dispensed between March 25 and April 2, 2020. The voluntary recall was initiated due to environmental monitoring excursions[3] detected within Respondent's cleanroom during the days of processing.

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

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

[2] A set of allergenic dilutions from a extract of an allergen, such as weed, grass, or tree pollen, molds, house dust, or animal dander, used for diagnostic skin testing or for immunotherapy for allergy.

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

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

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

**THIRD CAUSE FOR DISCIPLINE**

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

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

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[4] A petri dish that contains culture media which acts as a growth medium for 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.

**FOURTH CAUSE FOR DISCIPLINE**

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

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

**SEPTEMBER 28, 2020 INVESTIGATION**

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

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

**FIFTH CAUSE FOR DISCIPLINE**

(Unprofessional Conduct—Mislabeling of Allergen Extract)

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

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**SIXTH CAUSE FOR DISCIPLINE**

(Unprofessional Conduct—Adulterated and/or Misbranded)

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

**SEVENTH CAUSE FOR DISCIPLINE**

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

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

**NOVEMBER 5, 2020 INVESTIGATION**

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

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

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[6] Under title 16 of the California Code of Regulations, section 1735.1(b), "BUD means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes)."

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

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

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

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

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

a. Not for resale

b. This prescription set was prepared by Edge Pharma LLC

c. The address and phone number of Edge Pharma LLC

d. Identity of each allergenic extract in the AIT and the quantity of each

e. Lot number or batch number

f. The day it was manufactured

g. Storage and handling instructions

[7] Defined by the FDA as systems to assure proper design, monitoring, and control over 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.

62. Respondent allowed the noncompliant prescription labels to be used even though they did not match specifications.

63. The inspection further revealed that Respondent released allergen sets for distribution prior to sterility testing[8] being completed. Respondent's practice allowed the prescription sets to be distributed after sterility testing was initiated but not completed. This caused at least one recall for product sent to a California consumer.

64. The inspection also revealed that all the allergen extracts produced at Respondent's facility are provided in vials. The vials are labeled with a one-year BUD. There were no instructions on the vial to discard after 28 days once punctured. Respondent did not provide requested data to show their container was able to inhibit growth 28 plus days after first puncture. Their vials were not complaint with cGMP and United States Pharmacopeia (USP) standards.

65. During the inspection, the Board inspector discovered that Respondent compounded Formula ID 1566 Gemcitabine 1 gm in 50mL syringe. The test methods Respondent utilized for establishment of stability of this product were not specific in that they are indicated by contract lab ARL to be for "non-cGMP analysis" and "Product specific method validation is not available for this sample ..." This test method did not consider the firm-specific matrix of the product.

66. The inspection also revealed that Respondent had no cleaning validation and incomplete vendor qualifications. The vendors who supplied container closures did not have the reliability of their methods established at appropriate intervals by Respondent.

67. The inspection also revealed that Respondent had several gaps in the process for maintaining and validation of equipment.

**EIGHTH CAUSE FOR DISCIPLINE**

(Unprofessional Conduct—Mislabeling Allergen Extracts With Incorrect BUD)

68. Respondent is subject to disciplinary action under Code section 4301, subdivision (o), on the grounds of unprofessional conduct, by and through Health and Safety Code sections 111260 and 111295, in that Respondent mislabeled all allergen sets with a BUD of one year, rather than one month or one week, as specified by the manufacturer for dilutions of 1:100 or

[8] Testing to determine the likelihood that a product is sterile.

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

**NINTH CAUSE FOR DISCIPLINE**

(Unprofessional Conduct—Mislabeling Allergen Extracts)

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

**TENTH CAUSE FOR DISCIPLINE**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**JANUARY 26, 2021 INVESTIGATION**

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

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

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

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

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

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

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

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

78. The Board inspector also reviewed Respondent's documentation for 22 different lots of allergen prescription sets produced on August 7, 2020. The inspector discovered that line clearance[9] was only noted prior to cleaning and after cleaning prior to production. There was no line clearance between each lot of allergen prescription set production. Respondent only notated the start and end time of production of multiple lots of allergen prescription sets that occurred between 0721 to 1400 hours.

**ELEVENTH CAUSE FOR DISCIPLINE**

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

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

**TWELFTH CAUSE FOR DISCIPLINE**

(Unprofessional Conduct—Mislabeling of Allergen Extract)

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

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[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.

**THIRTEENTH CAUSE FOR DISCIPLINE**

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

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

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

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

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

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

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

**MARCH 23, 2021 INVESTIGATION**

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

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

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

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

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

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

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

**FOURTEENTH CAUSE FOR DISCIPLINE**

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

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

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

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

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

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

**MAY 25, 2021 INVESTIGATION**

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

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

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

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

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

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

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

**FIFTEENTH CAUSE FOR DISCIPLINE**

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

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

a. Regulation section 211.22, subdivision (c), in that 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. However, the quality unit allowed a visual inspection process and subsequent acceptable quality limit process which allowed defective product to be released for sale.

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

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

**JULY 1, 2021 INVESTIGATION**

91. On or about April 19, 2021, Respondent notified the Board of a customer complaint from Sutter Santa Rosa Regional Hospital, regarding a syringe of methotrexate, which had leaked at the junction of the syringe and the leur-lock[10] connection. Respondent did not conduct a recall relating to this customer complaint.

[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.

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

93. During the investigation, the following was discovered:

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

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

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

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

**SIXTEENTH CAUSE FOR DISCIPLINE**

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

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

a. Regulation section 211.22, subdivision (c), in that 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. However, the quality unit allowed a

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

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

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

**AUGUST 30, 2021 INVESTIGATION**

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

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

98. During the inspection, the following was discovered:

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

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

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

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

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

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

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

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

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

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## SIXTEENTH CAUSE FOR DISCIPLINE

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

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

a. Regulation section 211.22, subdivision (c), in that 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. However, the quality control unit allowed allergan extract sets to be released for sale which did not have the appropriate BUD, as set forth in paragraphs 74-77 and 98, subdivision (a), above.

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

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

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

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

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

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

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

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

**OTHER MATTERS**

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

**DISCIPLINE CONSIDERATIONS**

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

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

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

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

**PRAYER**

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

1. Revoking or suspending Nonresident Outsourcing Facility Permit Number NSF 132, issued to Edge Pharma LLC;

2. Prohibiting Edge Pharma LLC, Edge Pharmacy Holdings LP, William Marc Chatoff, Roger Christopher Nadeau, Howard Scott Chatoff, and Jules Chatoff from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Outsourcing Facility Permit Number NSF 132 is placed on probation or until Nonresident Outsourcing Facility Permit Number NSF 132 is reinstated if Nonresident Outsourcing Facility Permit Number NSF 132 issued to Edge Pharmacy holdings LP, 100% shareholder to do business as Edge Pharma LLC is revoked;

3. Ordering Edge Pharma LLC, to pay the Board the reasonable costs of investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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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