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

In the Matter of the Accusation Against:	Case No. 5282
UNIQUE PHARMACEUTICALS, LTD., DBA UNIQUE PHARMACEUTICALS **5920 S. General Bruce Drive** **Temple, TX 76502** **Non-Resident Pharmacy Permit No. NRP 534** **Non-Resident Sterile Compounding Permit No. NSC 99112** Respondent.	OAH No. 2015090155

DECISION AND ORDER

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

This Decision shall become effective on March 11, 2016.

It is so ORDERED on February 10, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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BEFORE THE
BOARD OF PHARMACY
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STATE OF CALIFORNIA

In the Matter of the Accusation Against: **UNIQUE PHARMACEUTICALS, LTD., DBA UNIQUE PHARMACEUTICALS** **5920 S General Bruce Drive** **Temple, TX 76502** **Non-Resident Pharmacy Permit No. NRP 534** **Non-Resident Sterile Compounding Permit No. NSC 99112** Respondent.	Case No. 5282 OAH No. 2015090155 **STIPULATED SURRENDER OF LICENSE AND ORDER**

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

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Desiree I. Kellogg, Deputy Attorney General.

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2. Unique Pharmaceuticals, Ltd., dba Unique Pharmaceuticals (Respondent) is represented in this proceeding by attorney Joseph R. LaMagna of Hooper, Lundy & Bookman, P.C., whose address is 101 W. Broadway, Suite 1200, San Diego, CA 92101-3890.

3. On or about January 29, 2004, the Board of Pharmacy issued Non-Resident Pharmacy Permit No. NRP 534 to Respondent. The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 5282 and will expire on January 1, 2016, unless renewed.

4. On or about February 2, 2004, the Board of Pharmacy issued Non-Resident Sterile Compounding Permit Number NSC 99112 to Respondent. The Non-Resident Sterile Compounding Permit was suspended on July 21, 2014 and renewed on January 1, 2015. Otherwise, it was, in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2016, unless renewed.

JURISDICTION

5. Accusation No. 5282 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on August 10, 2015. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 5282 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5282. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.

7. 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.

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

CULPABILITY

9. Respondent understands that the charges and allegations in Accusation No. 5282, if proven at a hearing, constitute cause for imposing discipline upon its Non-Resident Pharmacy Permit, as well as for its Non-Resident Sterile Compounding Permit.

10. 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 those charges constitute cause for discipline. Respondent hereby gives up its right to contest that cause for discipline exists based on those charges.

11. Respondent understands that by signing this stipulation, it enables the Board to issue an order accepting the surrender of their Non-Resident Pharmacy Permit and Non-Resident Sterile Compounding Permit without further process.

12. Respondent's right to transfer or sell its assets shall not be affected by this Order, except for its Non-Resident Pharmacy Permit and Non-Resident Sterile Compounding Permit, which are hereby surrendered and its obligation under California law to transfer its inventory of dangerous drugs and patient records to a licensed facility.

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 surrender, 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 Surrender 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 Surrender of License and Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

15. This Stipulated Surrender of License and 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 Surrender of License and 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 Order:

ORDER

IT IS HEREBY ORDERED that Non-Resident Pharmacy Permit No. NRP 534 and Non-Resident Sterile Compounding Permit No. NSC 99112 issued to Respondent Unique Pharmaceuticals, Ltd., dba Unique Pharmaceuticals are surrendered and accepted by the Board of Pharmacy.

1. The surrender of Respondent's Non-Resident Pharmacy Permit and Non-Resident Sterile Compounding Permit and the acceptance of the surrendered license by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board of Pharmacy.

2. Respondent shall lose all rights and privileges as a nonresident pharmacy and non-resident sterile compounder in California as of the effective date of the Board's Decision and Order.

3. Respondent shall cause to be delivered to the Board its Non-Resident Pharmacy Permit and Non-Resident Sterile Compounding Permit pocket license and, if one was issued, its wall certificates on or before the effective date of the Decision and Order.

4. If Respondent ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Accusation No. 5282 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.

5. Respondent shall pay the agency its costs of investigation and enforcement in the amount of $5,148.00 prior to issuance of a new or reinstated license.

6. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation, No. 5282 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

7. Respondent may not apply, reapply, or petition for any licensure or registration of the Board for three (3) years from the effective date of the Decision and Order.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Joseph R. LaMagna. I understand the stipulation and the effect it will have on my Non-Resident Pharmacy Permit, and Non-Resident Sterile Compounding Permit. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 31 DEC 15

UNIQUE PHARMACEUTICALS, LTD., DBA
UNIQUE PHARMACEUTICALS
Respondent

I have read and fully discussed with Respondent Unique Pharmaceuticals, Ltd., dba Unique Pharmaceuticals the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: 1/4/16

JOSEPH R. LAMAGNA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 1/4/16

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General

DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 5282

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Attorneys for Complainant

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

In the Matter of the Accusation Against: **UNIQUE PHARMACEUTICALS, LTD., DBA UNIQUE PHARMACEUTICALS** **5920 S General Bruce Drive** **Temple, TX 76502** **Non-Resident Pharmacy Permit No. NRP 534** **Non-Resident Sterile Compounding Permit No. NSC 99112** Respondent.	Case No. 5282 **ACCUSATION**

Complainant alleges:

PARTIES

1. Virginia Herold (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 January 29, 2004, the Board of Pharmacy issued Non-Resident Pharmacy Permit Number NRP 534 to Unique Pharmaceuticals, Ltd., doing business as Unique Pharmaceuticals (Respondent). The Non-Resident Pharmacy Permit was in full force and effect

at all times relevant to the charges brought herein and will expire on January 1, 2016, unless renewed.

3. On or about February 2, 2004, the Board of Pharmacy issued Non-Resident Sterile Compounding Permit Number NSC 99112 to Respondent. The Non-Resident Sterile Compounding Permit was suspended on July 21, 2014 and renewed on January 1, 2015. Otherwise, it was, in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2016, unless renewed.

JURISDICTION

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

5. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

6. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

7. 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.

8. Section 4303(b) of the Code states:

> The board may deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located.

STATUTORY AND REGULATORY PROVISIONS

9. 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 procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
>
> . . . .
>
> (j) The violation of any of the statues of this state, or of any other state, or of the Untied States regulating controlled substances and dangerous drugs.
>
> . . . .
>
> (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.
>
> . . . .

10. 21 United States Code section 351(a)(2)(B) provides:

> A drug or device shall be deemed to be adulterated…if it is a drug and the methods used in, or the 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 such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess…

11. The Food and Drug Administration's Guidance for Industry, For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act, February 2015, provides that because drugs compounded by outsourcing facilities are not exempt from section 501(a)(2)(B) of the Federal Food and Drug Cosmetic Act, outsourcing facilities are subject to current good manufacturing practice requirements and will be inspected by the Federal Drug Administration on a risk-based schedule.

12. Code of Federal Regulations, title 21, part 211.1(a) provides:

> The regulations in this part contain the minimum current good manufacturing practice for preparation of drug products (excluding positron emission tomography

drugs) for administration to humans or animals.

13. Texas Administrative Code, title 22, Part 15, Chapter 291, Subchapter B, section 291.32(c)(1)(E) provides that all pharmacists on duty at a pharmacy engaged in the compounding of sterile preparations must comply with all state and federal laws or rules governing the practice of pharmacy.

14. Texas Administrative Code, title 22, Part 15, Chapter 291, Subchapter B, section 562.002(3) provides that the Texas Pharmacy Board may discipline a pharmacy license if the Board finds that the an employee of a pharmacy has violated any provision of Texas Pharmacy Law.

COST RECOVERY

15. Section 125.3 of the Code provides, 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.

FACTUAL ALLEGATIONS

16. On or about November 17, 2014, Respondent was initially registered as a human drug outsourcing facility under 21 United States Code 503B of the Federal Food and Drug Cosmetic Act.

17. From approximately January 15, 2014 through July 15, 2014, Respondent compounded sterile injectable drug products at its compounding facility in Texas and furnished certain of those drug products to patients in California.

18. On or about March 17 through April 2, 2014, the Federal Drug Administration (FDA) conducted an inspection of Respondent and issued a Form FDA-483, finding that Respondent had not complied with current good manufacturing practice requirements. Namely, the FDA made the following observations: "(1) procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed; (2) testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to

release; (3) production errors are not fully investigated; (4) clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform; (5) aseptic processing areas are deficient regarding the system for monitoring environmental conditions; (6) the separate or defined areas necessary to prevent contamination or mix-ups are deficient; (7) container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product; (8) aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions; (9) each batch of drug products purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements; and (10) the labels of your firm's drug products observed by FDA do not contain information required by section 503(b)(a)(10) of the Act."

19. On or about June 9 through 20, 2014, the FDA conducted an investigation of Respondent and issued another Form FDA-483, finding again that Respondent had not complied with current good manufacturing practice requirements. Namely, the FDA made the following observations: "(1) there is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed; (2) production errors are not fully investigated; (3) procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed; (4) the separate or defined areas necessary to prevent contamination or mix-ups are deficient; and (5) aseptic processing areas are deficient regarding the system for monitoring environmental conditions."

20. In July 2014, the FDA issued a MedWatch advising health professionals not to use drugs marketed as sterile produced by Respondent as they may be contaminated. On or about July 11, 2014, the FDA requested Respondent to recall all sterile drug products within expiry.

21. On July 21, 2014, the Board issued a Cease and Desist Order, directing Respondent not to ship, furnish, transfer, or provide, either directly or indirectly compounded sterile injectable drugs into or through California. On or about August 12, 2014, Respondent entered into a Stipulated Extension of that Cease and Desist Order, until a decision of the Board of Pharmacy following the filing of an accusation and a hearing.

22. In or about March 2015, the FDA informed Respondent that it did not object to it resuming the production and distribution of compounded sterile drugs but noted that although [Respondent has] "attributed a particular lot of syringes and the process used to fill those syringes as the apparent cause of the leaks most recently identified, [the FDA] remain[s] concerned that [Respondent's] investigation into leaking syringes did not evaluate the ability of the syringes to maintain sterility through the expiry period. [Respondent has] a continuing trend of leaking syringes in sterile drug production batches. Leaking syringes indicated a potential breach of container-closure integrity and may affect the ability of the container-closure to prevent the ingress of microbial contamination."

FIRST CAUSE FOR DISCIPLINE

(Failure to Comply with Current Good Manufacturing Practice Requirements)

23. Respondent is subject to disciplinary action under Code sections 4301(j) and (o), for violating 21 United States Code section 351(a)(2)(B) and 21 Code of Federal Regulations Part 211, in that it failed to comply with current good manufacturing practice requirements, as set forth in paragraphs 16 through 22, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

24. Respondent is subject to disciplinary action under Code section 4301 for unprofessional conduct in that it engaged in the activities described in paragraphs 16 through 22 above, which are incorporated herein by reference.

PRAYER

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

1. Revoking or suspending Non-Resident Pharmacy Permit Number NRP 534, issued to Unique Pharmaceuticals, Ltd., doing business as Unique Pharmaceuticals;

2. Revoking or suspending Non-Resident Sterile Compounding Permit Number NSC 99112, issued to Unique Pharmaceuticals, Ltd., doing business as Unique Pharmaceuticals;

3. Ordering Unique Pharmaceuticals, Ltd., doing business as Unique Pharmaceuticals to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

DATED: 8/10/15

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

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