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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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