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Attorneys for Complainant

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

11 In the Matter of the Investigation of:
12
13 **UNIQUE PHARMACEUTICALS, LTD.**
5920 S General Bruce Drive
Temple, TX 76502

Case No. 5282

**STIPULATED EXTENSION OF CEASE
AND DESIST ORDER**

14
15 **Nonresident Pharmacy License**
No. NRP 534
16 **Nonresident Sterile Compounding License**
No. NSC 99112

17
18 Respondent.

19
20 IT IS HEREBY STIPULATED AND AGREED by and between the parties in this
21 proceeding that the following matters are true:

22 PARTIES

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

27 2. Unique Pharmaceuticals, Ltd. (Respondent) is representing itself in this proceeding
28 and has chosen not to exercise its right to be represented by counsel.

1 ADVISEMENT AND WAIVERS

2 8. Respondent has carefully read, and understands the Cease and Desist Order attached
3 as exhibit A. Respondent has also carefully read, and understands the effects of this Stipulated
4 Extension of Cease and Desist Order.

5 9. Respondent is fully aware of its legal rights in this matter, including its prior right to a
6 hearing before the President of the Board on the July 21, 2014 Cease and Desist Order; the right
7 to be represented by counsel at its own expense; the right to court review of an adverse decision;
8 and all other rights under the California Administrative Procedure Act and other applicable laws.

9 10. Respondent voluntarily, knowingly, and intelligently waives and gives up each and
10 every right set forth above. Specifically, Respondent understands and agrees that it has given up
11 its right to seek a hearing before the President of the Board to contest the July 21, 2014 Cease and
12 Desist Order, as extended by this agreement to be effective until the Board issues a decision
13 following the filing of an accusation and a hearing.

14 11. Respondent agrees that it shall not ship, furnish, transfer, or provide, either directly or
15 indirectly, compounded sterile injectable drug products into or through California, until a decision
16 of the Board of Pharmacy, following the filing of an accusation and a hearing and that any failure
17 to comply with this prohibition shall be deemed unprofessional conduct.

18 EFFECT OF SIGNATURES

19 12. By signing the stipulation, the parties understand and agree that they may not
20 withdraw their agreement or seek to rescind the stipulation.

21 13. The parties understand and agree that facsimile copies of this stipulation, including
22 facsimile signatures thereto, shall have the same force and effect as the originals.

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

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15. The parties agree on the following interim resolution of the matter.

RESOLUTION

16. Until a decision of the Board of Pharmacy following the filing of an accusation and a hearing, Respondent shall not ship, furnish, transfer, or provide, either directly or indirectly, compounded sterile injectable drug products into or through California. In accordance with Business and Professions Code section 4127.3, subdivision (d), any failure by Respondent to comply with this prohibition shall be deemed unprofessional conduct.

17. Until a decision of the Board of Pharmacy following the filing of an accusation and a hearing, Complainant shall not file or serve a petition for interim suspension order against Respondent or Respondent's License(s) with respect to compounded sterile injectable drug products.

ACCEPTANCE

I have carefully read the above Stipulated Extension of Cease and Desist Order. I enter into this Stipulated Extension of Cease and Desist Order on behalf of Unique Pharmaceuticals, Ltd., voluntarily, knowingly, and intelligently, and am bound and bind Unique Pharmaceuticals, Ltd. by its terms.

DATED: 12 Aug 2014 
TRAVIS A. LEEAH, PRESIDENT for
UNIQUE PHARMACEUTICALS, LTD.
Respondent

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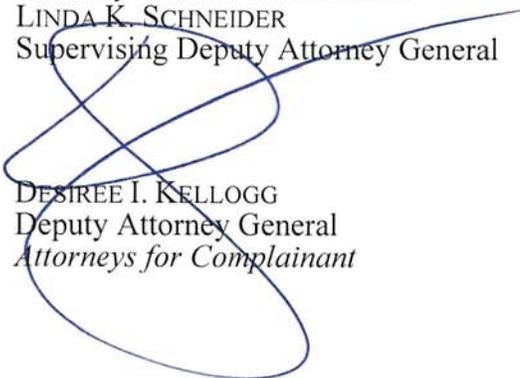
ACCEPTANCE ON BEHALF OF COMPLAINANT

I have discussed the terms and conditions of the above Stipulated Extension of Cease and Desist Order with Complainant and agree to the stipulation on Complainant's behalf.

DATED: August 12, 2014

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
LINDA K. SCHNEIDER
Supervising Deputy Attorney General



DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Cease and Desist Order



California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

ORDER TO CEASE and DESIST

Date: 7/21/14

Permit No. NSC-99112

Name as Shown on Permit: Unique Pharmaceuticals LTD.

Address: 5920 S. General Bruce Dr. City: Temple, TX 76502

California Business and Professions Code Section 4127.3 provides that whenever the Board has a reasonable belief that a pharmacy compounding injectable sterile drug products poses an immediate threat to the public health or safety, the Board may issue an order to the pharmacy to immediately cease and desist from compounding injectable sterile drug products, which order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

The California State Board of Pharmacy (Board) has received information from the U.S. Food and Drug Administration (FDA) that FDA investigators conducted two recent inspections of the Unique Pharmaceuticals (NSC-99112) facility and observed unsanitary conditions that resulted in a lack of sterility assurance of purportedly sterile drug products produced by the company, which puts patients at risk. The products were shipped nationwide, including California.

The foregoing does or may constitute a violation or violations of California law pursuant to California Health and Safety Code sections 111255, 111260, and/or 111285 (definitions of adulterated drug, and/or Health and Safety Code sections 111295, 111300, and/or 111305 (making it unlawful to manufacture, sell, deliver, hold, or offer for sale an adulterated drug, to adulterate any drug, to receive in commerce any drug that is adulterated, or to deliver or proffer for delivery any adulterated drug).

On the basis of the foregoing, the Board has a reasonable belief that Unique Pharmaceuticals sterile injectable compounding practices pose an immediate threat to the public health or safety in California, and therefore **ORDERS:**

Unique Pharmaceuticals LTD shall immediately **CEASE AND DESIST** from compounding sterile injectable products for shipment into California. This cease and desist order shall remain in effect for 30 days or until the date of a hearing seeking an interim suspension order, whichever is earlier. Pursuant to Business and Professions Code section 4127.3, subdivision (c), within 15 days of the receipt of this notice you may request a hearing before the president of the board to contest the cease and desist order.

Additionally, Unique Pharmaceuticals LTD shall contact **EACH PRESCRIBER, ENTITY, AND PATIENT** in California for whom Unique Pharmaceuticals LTD has prepared sterile injectable medications to determine if the prescriber, entity, or patient has any such preparation in his/her possession. Any such preparation in the possession of prescribers/entities/patients shall be recalled. The product is to be returned to Unique Pharmaceuticals LTD.

SHIPMENT AND PATIENT RECORDS: Within ten (10) days of today's date, but no later than July 31, 2014, Unique Pharmaceuticals LTD shall provide to the California State Board of Pharmacy the following:

1. Documentation/records of all compounded sterile injectable products (including drug product name, strength and quantity) shipped into California by Unique Pharmaceuticals LTD within the last six (6) months, including the names and address of the individuals or firms to whom such products were shipped.
2. A list of all prescribers, patients, and/or entities to whom any Unique Pharmaceuticals LTD compounded sterile injectable products, recalled or otherwise, were shipped, including name, address, and other contact information you may have. Where compounded sterile injectable products were furnished directly to patients, so indicate, and provide any information you may have about the patients to whom those products sent. Where compounded sterile injectable products were furnished to prescribers, so indicate. If any other recipients are included on the list, describe their function or role in patient care.
3. Documentation/records of all contacts made with physicians, patients, or other recipients in California to whom recalled or otherwise suspect products were shipped, including any written materials that were shared and the substance of oral communications. Where contact was made directly with a patient, so indicate. Where contact was made with the prescriber in lieu of direct patient contact, so indicate. If any other contacts were made, describe with whom.
4. Any and all information you have about the health of any California patients.

The above-listed materials shall be provided by July 31, 2014 to the California State Board of Pharmacy, Attn: Supervising Inspector Christine Acosta, 1625 North Market Blvd., Suite N-219, Sacramento, CA 95834. You may reach Supervising Inspector Acosta at 619-818-7255.

California State Board of Pharmacy

By: Virginia Herold

Signed: Virginia Herold

Date: 7/21/2014

Title: Executive Officer

Any additional information (for example – corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent to the Board's attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with you information submitted.

I hereby acknowledge receipt of the above cease and desist order and notice.

By: Travis A. Leach

Signed: Travis A. Leach

Date: 7/23/14

Title: President