



**California State Board of Pharmacy**

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

## ORDER TO CEASE AND DESIST

**Date:** September 16, 2015

**Permit No.:** NSC 99495

**Name as shown on permit:** US Compounding INC

**Address:** 1270 Dons Lane, Conway AR 72032

California Business and Professions Code Section 4127.3 provides whenever the Board has a reasonable belief, based on information obtained during an inspection or investigation, 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.

Specifically on, September 15, 2015, The California State Board of Pharmacy (Board) has received information from US Compounding INC (NSC 99495) of a recall which included all lots of sterile products aseptically compounded and packaged that remain within expiry which was requested by the U.S. Food and Drug Administration (FDA). From 8/10/15 to 8/21/15 FDA investigators conducted inspections of US Compounding INC (NSC 99495) facility and observed unsanitary conditions that resulted in a lack of sterility assurance of purportedly sterile drug products produced by the company, which put patients at risk. The products were shipped nationwide, including California.

The foregoing does or may constitute a violation or violations of California and/or Federal law including but not limited to:

- California Health and Safety Code sections 111255, 111260, 111285, and 111305
- California Business and Professions Code section 4169
- Federal Food, Drug, and Cosmetic Act, 21 U.S.C. sections 351 and 352

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

US Compounding INC (NSC 99495) 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, US Compounding INC (NSC 99495) shall contact **EACH PRESCRIBER, ENTITY, AND PATIENT** in California for whom US Compounding INC (NSC 99495) 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 (if not already done). The product is to be returned to US Compounding INC (NSC 99495).

**SHIPMENT AND PATIENT RECORDS:** Within ten (10) days of today's date (if not already provided), but no later than September 26, 2015, US Compounding INC (NSC 99495) shall provide to the California State Board of Pharmacy the following: (if not already provided)

1. Documentation/records of all compounded sterile injectable products (including drug product name, strength and quantity) shipped into California by US Compounding INC (NSC 99495) 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 US Compounding INC (NSC 99495) compounded sterile injectable products, recalled or otherwise, were shipped, including name, address, phone number 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 September 26, 2015 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: September 16, 2015

Title: Executive Officer

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

By: Eddie Glover

Signed: Eddie Glover

Date: September 17, 2015

Title: Pharmacist-In-Charge, CEO