



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: 12/23/13

Permit No. NSC-99466

Name as shown on Permit: Abrams Royal Pharmacy

Address: 8220 Abrams Rd.

City: Dallas, TX 75231

California Business and Professions Code Section 4127.3 provides that whenever the Board has a reasonable belief, based on information obtained during an inspection or investigation, 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 been notified by the California Department of Public Health of an adverse reaction experienced by a California patient being infused with "Mineral IV" at a physician's office. The patient was subsequently transported to a nearby hospital and admitted for treatment. The patient had a positive blood culture for *Stenotrophomonas*, a gram negative rod bacteria. The "Mineral IV" solution was compounded by Abrams Royal Pharmacy located in Dallas, TX. Subsequent investigation determined that the "Mineral IV" infusion was contaminated with *Sphingomonas paucimobilis*, a gram negative rod bacteria.

Specifically, on or about November 14, 2013, Abrams Royal Pharmacy compounded Mineral IV, a sterile solution for intravenous administration, Rx #6170364, for patient TM. On or about December 5, 2013, the Mineral IV was administered to TM in her physician's office. TM developed fever, chills, and vomiting while being infused. TM was transported to a nearby hospital where she developed shock and was admitted. TM had a positive blood culture for *Stenotrophomonas*. Subsequent investigation determined the Mineral IV was contaminated with *Sphingomonas paucimobilis*, and that the contamination occurred within the premises at Abrams Royal Pharmacy.

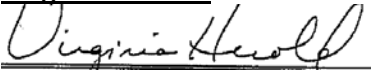
The foregoing does or may constitute a violation or violations of California law pursuant to California Health and Safety Code sections 111255, 111260, and/or 111285 (definitions of adulterated drug), and/or Health and Safety Code sections 111295, 111300, and/or 111305 (making it unlawful to manufacture, 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 Abrams Royal Pharmacy's sterile injectable compounding practices pose an immediate threat to the public health or safety in California, and therefore **ORDERS**:

Abrams Royal Pharmacy 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 Abrams Royal Pharmacy shall contact **EACH PRESCRIBER AND PATIENT** in California for whom Abrams Royal Pharmacy has prepared sterile injectable medications to determine if the patient or prescriber has any such preparation in his/her possession. Any such preparation in the possession of prescribers/patients shall be recalled. The product is to be returned to Abrams Royal Pharmacy.

California State Board of Pharmacy

By: Virginia Herold
Signed: 
Date: December 23, 2013
Title: Executive Officer

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

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

By: _____
Signed: _____
Date: _____
Title: _____