

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

PUBLIC SAFETY ALERT – Specialty Compounding LLC ISSUED: August 9, 2013

The California State Board of Pharmacy has been advised that Specialty Compounding LLC of Cedar Park, Texas has initiated a recall of compounded drug products that were shipped nationwide (with the exception of North Carolina), including into California. We write with an urgent response to that notification.

CEASE AND DESIST ORDER: Specialty Compounding LLC (NRP-1021) has furnished adulterated sterile compound preparations into California. Pursuant to Business and Professions Code section 4127.3 Specialty Compounding LLC is ORDERED to CEASE AND DESIST such shipments. The cease and desist order shall remain in effect or 30 days.

Specialty Compounding LLC (NRP-1021) may within 15 days of receipt of this notice, request a hearing before the president of the board to contest the cease and desist order.

SHIPMENT AND PATIENT RECORDS: Within ten (10) days of today's date, by no later than August 19, 2013, provide the California State Board of Pharmacy with the following:

- 1. Documentation/records of all products (including drug product name, strength and quantity) shipped into California by Specialty Compounding LLC in the last three (3) years, and the names and addresses of the individuals or firms to whom such items were shipped.
- 2. A list of all patients, prescribers, or other recipients in California to whom any of Specialty Compounding LLC recalled or otherwise suspect products were shipped, including all name, address, and other contact information you may have. Where drug products were supplied directly to patients, so indicate. Where drug products were supplied to prescribers, so indicate, and provide any information you may have about the patients to whom those products went. 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 patients, prescribers, 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 a 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 August 19, 2013 to the California State Board of Pharmacy, Attn: Supervising Inspector Robert Ratcliff, 1625. North Market Blvd., Suite N219, Sacramento, CA 95834. You may reach Supervising Inspector Ratcliff at (661) 943-4775.

You may find information about becoming licensed in California at www.pharmacy.ca.gov.

We anticipate your prompt response. Thank you for your anticipated cooperation.

Sincerely,