From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Wednesday, August 16, 2017 9:17 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Lorazepam Oral Concentrate, USP 2mg/mL by Amneal Pharmaceuticals: Recall - Misprinted Dosing Droppers

ISSUE: Amneal Pharmaceuticals LLC is voluntarily recalling 13 lots of Lorazepam Oral Concentrate, USP 2mg/mL, to the Consumer level due to a defect in the dropper markings. The Lorazepam Oral Concentrate, USP 2mg/mL, product is packaged with a dosing dropper, supplied to Amneal by a third party. In a few instances, the dropper is printed with the dose markings in reverse number order, has no dose markings or has dose markings that are shifted. Amneal learned about the issue from a Consumer's report. To date no adverse events related to these dropper defects have been reported to Amneal. See the press release for product photos and a listing of affected lot numbers.

There is a significant likelihood that the dropper marking errors will result in dispensing either less than, or more than, the prescribed dose. There is a significant probability of a serious health consequence if more than the prescribed dose is dispensed and potential serious adverse events include: drowsiness causing trauma; increased anxiety; increased accidental injury to self or others (e.g., hip fracture, motor vehicle accident); which in the most serious circumstances could result in permanent decreased function or death.

BACKGROUND: The product is indicated for the management of anxiety disorders for the short-term relief of the symptoms of anxiety or anxiety associated with depressive symptoms. It is packaged in an individual carton, identified with the code: NDC 65162-687-84, which contains a 30mL amber glass bottle of liquid produced by Amneal, a package insert with patient information, and a plastic dropper sealed in a clear plastic bag.

The product can be identified by the lot number printed on the bottom-right side of the blue and white label, with the Amneal logo, on the amber bottle supplied with the dropper, in a blue and white carton, with the Amneal logo. The Lorazepam Oral Concentrate, USP 2mg/mL was distributed nationwide to wholesalers.

RECOMMENDATION: Amneal Pharmaceuticals has notified its wholesale customers by a Recall Letter to return all recalled lots. Amneal is notifying pharmacies by providing a Recall Letter and a supply of replacement droppers to all pharmacies that may have received any of the recalled lots. There is no safety issue with the bottled product itself. To avoid any interruption in supply or access to the medication by the patient, pharmacies are instructed to immediately discard the dropper included with the recalled lots and replace it with the dropper included with the Recall Letter. Amneal also is providing the pharmacist with a sticker which the pharmacist is required to place on the box to alert the patient and other pharmacists that the dropper has been replaced. Pharmacists are instructed to notify all Consumers impacted by the recall of the potential defect and the need to exchange a defective dropper. Consumers are instructed to discontinue use of any defective dropper and return it to the place of purchase for a replacement. If Consumers are unsure whether their droppers are defective they are encouraged to confirm with their dispensing pharmacy.

Consumers with questions regarding this recall can contact Amneal Pharmaceuticals at 631.952.0214 x338 or amnealreg@amneal.com on Monday through Friday from 9AM through 5PM Eastern Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the press release, at:

https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm571796.htm