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From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@DCALISTS.CA.GOV>
on behalf of Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, December 10, 2015 2:51 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: Product Recall - Taizhou Xinyou Pharmaceutical and Chemical - FDA Warns of Potential Contamination

Baclofen Active Pharmaceutical Ingredient from Taizhou Xinyou Pharmaceutical and Chemical: FDA Statement - FDA Warns of Potential Contamination

AUDIENCE: Health Professional, Anesthesiology, Pain Management, Neurology, Pharmacy

ISSUE: FDA is alerting drug compounders that certain lots of baclofen active pharmaceutical ingredient (API) manufactured by Taizhou Xinyou Pharmaceutical & Chemical Co., Limited (Taizhou) Taizhou City, Zhejiang Province, China, may be at risk for contamination with particulates and should not be used to compound sterile injectable drugs.

BACKGROUND: Taizhou manufactures APIs for repackagers and distributors, some of which sell these products to compounding facilities in the United States. FDA contacted Taizhou through its US agent, and the company confirmed that, due to the level of controls in the manufacturing process, the baclofen API it manufactures is not suitable for use in injectable drugs. Based on available information, the affected API may potentially pose serious safety risks for U.S. patients who use or receive injectable drug products compounded with the affected baclofen, especially when administered directly into the spinal column. For example, use of baclofen API contaminated with particulate matter can result in serious injury if injected directly into the spinal column and may also clog pumps used to administer the medication. There is also a potential risk that the baclofen API may be contaminated by endotoxin or microorganisms. FDA is continuing to investigate this incident.

RECOMMENDATION: FDA recommends that no baclofen API from Taizhou be used to manufacture or compound any injectable drugs.

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 FDA Statement, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm476514.htm>

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.

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