From:	General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To:	PHARM-GENERAL@DCALISTS.CA.GOV
Subject:	Sterile Drug Products by Medaus Pharmacy: FDA Alert - Lack of Sterility Assurance
Date:	Tuesday, April 05, 2016 8:09:38 AM

AUDIENCE: Pharmacy, Nursing, Health Professional

ISSUE: FDA is alerting health care professionals and patients not to use unexpired drug products that are intended to be sterile that were produced by Medaus Pharmacy in Birmingham, Alabama, due to lack of sterility assurance. Medaus' products were distributed nationwide and internationally.

BACKGROUND: During FDA's recent inspection of Medaus' facility, investigators observed insanitary conditions, including poor sterile production practices, which raise concerns about Medaus' ability to assure the sterility of drug products that it produced. Administration of a non-sterile product, intended to be sterile, may result in serious and potentially life-threatening infections or death. The Alabama Board of Pharmacy ordered Medaus to cease sterile compounding operations on March 22, 2016. On March 29, 2016, FDA recommended Medaus recall all unexpired drug products that are intended to be sterile. To date, Medaus has not voluntarily recalled any drug products intended to be sterile. Therefore, FDA alerts health care professionals and patients not to use drug products marketed as sterile from Medaus.

To date, FDA is not aware of any adverse events associated with drug products made by Medaus. Patients who have received drug products produced by Medaus and have concerns should contact their health care professional.

RECOMMENDATION: Health care professionals and patients should immediately check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them.

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

[04/01/2016 - Alert - FDA]

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