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From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Friday, February 12, 2016 1:52 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Syrspend SF and Syrspend SF Grape Suspending Agents by Fagron: FDA Alert - Microbial Contamination with Yeast

AUDIENCE: Pharmacy, Risk Manager, Health Professional, Pediatrics

ISSUE: The U.S. Food and Drug Administration is alerting compounding pharmacies of the voluntary recall of certain lots of SyrSpend SF and SyrSpend SF Grape suspending agents used in compounding of various oral liquid drug products, due to the presence of yeast (Candida galli).

The SyrSpend SF lots are:

- 15I21-U01-026920
- 15J26-U05-027457
- 15J26-U05-027473
- 15I21-U01-027370
- 15J19-U05-027406

The SyrSpend SF Grape lots are:

- 15G29-U03-025975
- 15A05-U03-022765
- 15A05-U06-023277

BACKGROUND: If an immunocompromised patient or a child with an immature immune system ingests the contaminated product, there is a potential the patient will get an infection for which systemic antimicrobial therapy would be necessary. FDA is not aware of adverse events reports with patients who may have used the suspending agents.

RECOMMENDATION: FDA recommends that compounders not use the referenced lots of contaminated Syrspend SF and Syrspend SF Grape in compounding drug products for patients. Compounding pharmacieswho have received the referenced lots of Syrspend SF and Syrspend SF Grape flavor should immediately discontinue use, quarantine the products, and return the products to Fagron, Inc.

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.

[02/10/2016 - CDER Alert - FDA]