Franck’s Compounding Pharmacy Sterile Preparations: Reports of Fungal Endophthalmitis, Expanded Recall

U.S. Food & Drug Administration

AUDIENCE: Ophthalmology, Urology, Primary Care, Pharmacy

ISSUE: FDA is notifying all physicians and medical care organizations who have ordered any compounded product sold as a sterile preparation by Franck's Compounding Pharmacy of Ocala, Florida, of the recall of all sterile products sold by Franck's since November 2011 due to the possibility of lack of sterility.

BACKGROUND: The recall is being carried out to the user physician. An active investigation of this matter by the CDC and FDA is ongoing at this time. In March 2012, FDA received reports of fungal endophthalmitis (eye infections) in patients who were given Brilliant Blue G (BBG), supplied by Franck's Pharmacy, during eye surgeries. Clinicians in several states reported the adverse events. In April 2012, FDA received reports of eye infections in patients who were given injections of Franck’s drug products containing triamcinolone during eye surgery.

RECOMMENDATIONS: FDA advises that any product received from Franck's since November 2011 not be used and customer/physicians follow the instructions provided by Franck’s. FDA also recommends that any adverse events suspected to be associated with use of the products be reported to FDA:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] 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

[05/24/2012 - Press Release [3] - Franck's Compounding Pharmacy]
[05/04/2012 - MMWR Weekly Report [4] - CDC]

Previous MedWatch Alerts:

[03/19/2012 - Brilliant Blue G Recall [5]]

SOURCE [6]

Source URL (retrieved on *01/28/2015 - 5:20pm*):

http://www.mdtmag.com/news/2012/05/franck%E2%80%99s-compounding-pharmacy-sterile-preparations-reports-fungal-endophthalmitis-expanded-recall

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Safety/Recalls/ucm305509.htm
[4] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6117a5.htm?s_cid=mm6117a5_w.
[5] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm296383.htm
[6] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm305592.htm