

Certain Compounded Drugs from Franck's: FDA Issues Second Warning to Physicians(2)

U.S. Food & Drug Administration

[UPDATED 05/04/2012] The Centers for Disease Control and Prevention (CDC) has advised healthcare personnel to avoid use of compounded products labeled as sterile from Franck's during the ongoing investigation. Franck's Lab has recalled one additional lot of triamcinolone acetonide P.F. 80mg/ml. The recall involved four physicians and five prescriptions.

AUDIENCE: Eye Care, Family Practice, Pharmacy

ISSUE: FDA has received additional reports of fungal endophthalmitis (eye infections) in patients who were given Brilliant Blue G (BBG) during eye surgery since the FDA Warning to Physicians was posted on March 19, 2012. The agency has also recently received reports of eye infections in patients who were given injections of drug products containing triamcinolone during eye surgery.

BACKGROUND: Clinicians in several states reported the adverse events. FDA, CDC, and local and state public health agencies are actively investigating these incidents.

These drugs were supplied by Franck's Pharmacy in Ocala, Florida. Brilliant Blue G is not an approved drug in the United States. Franck's has recalled all lots of BBG and one lot of Triamcinolone Acetonide P.F

RECOMMENDATION: The Centers for Disease Control and Prevention (CDC) has advised healthcare personnel to stop use of all sterile triamcinolone-containing products purchased from Franck's until further information regarding the safety of these products is available.

FDA requests that practitioners report to FDA any cases of suspected fungal or bacterial infections, which have occurred within the last six months, associated with drugs labeled as sterile from Franck's Pharmacy:

- 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

[05/04/2012 - [MMWR Weekly Report](#) [3] - CDC]

[05/04/2012 - [Press Release](#) [4] - FDA]

[04/20/2012 - [Updated Warning](#) [5] - FDA]

[03/31/2012 - [Press Release](#) [6] - Franck's Compounding Lab]

Previous MedWatch Safety Alert

[[03/19/2012](#) [7]]

[SOURCE](#) [8]

Source URL (retrieved on 03/07/2015 - 12:37am):

http://www.mdtmag.com/news/2012/05/certain-compounded-drugs-francks-fda-issues-second-warning-physicians2?qt-video_of_the_day=0

Links:

[1] <http://www.fda.gov/MedWatch/report.htm>

[2] <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>

[3] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6117a5.htm?s_cid=mm6117a5_w

[4] <http://wcms.fda.gov/FDAgov/Safety/Recalls/ucm302899.htm>

[5] <http://www.fda.gov/Drugs/DrugSafety/ucm301027.htm>

[6] <http://www.fda.gov/Safety/Recalls/ucm300712.htm>

[7] <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm296383.htm>

[8] <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm301137.htm>