



HEALTH ALERT

APRIL 16, 2012

TO HEALTHCARE PROVIDERS, HOSPITALS LABORATORIES, CLINICAL LABORATORIES, AND PHARMACISTS

Fungal endophthalmitis following use of products from Franck's Compounding Pharmacy

The Los Angeles County Department of Public Health (LAC DPH) has identified 2 outbreaks of fungal endophthalmitis infections following intraocular use of products from Franck's Compounding Pharmacy in Ocala, Florida. An investigation to determine the source and extent of the contamination is ongoing with the California Department of Public Health (CDPH), Centers for Disease Control and Prevention (CDC), Florida Department of Health, and the federal Food and Drug Administration (FDA). Outbreaks of fungal endophthalmitis have been identified in six other states. Healthcare personnel should be advised to cease using Brilliant Blue G (BBG) dye and triamcinolone-containing products from Franck's while the investigation is ongoing.

Fungal endophthalmitis cases have been reported following the use of BBG during retinal surgery and several cases have been associated with growth of the mold *Fusarium*. Franck's recalled their BBG products on March 9, 2012. Fungal endophthalmitis cases have also been reported after intraocular injection of triamcinolone, prepared either alone or compounded with another medication, and several have been linked to growth of the mold *Bipolaris*.

Healthcare providers should be aware that the extent of contamination among Franck's products is unknown and should consider fungal or bacterial infections in patients who may have been given sterile compounded products from Franck's Compounding Pharmacy since 8/24/11 to the present.

Currently, we advise healthcare providers to immediately report to LAC DPH the following in any patient(s) that was given sterile compounded products from Franck's Compounding Pharmacy since 8/24/11:

- a) A single case of fungal endophthalmitis
- b) A single case of fungal or bacterial infection
- c) Clusters of infections (occurring in more than 1 patient), bacterial or fungal

Report these suspected cases immediately to the Los Angeles County Acute Communicable Disease Control Program (ACDC) at (213) 240-7941. Do NOT wait for laboratory confirmation before reporting a suspected case.

Prompt reporting is critical to expedite laboratory specimen collection/transport/identification at the LAC DPH Laboratory, coordination for molecular typing by the CDC, and possible testing of unused medication. Unused sterile triamcinolone-containing products from Franck's should be retained and notifications sent to ACDC for further testing by FDA and CDC.

Patients with possible fungal infections can present with an inflammatory reaction that may be initially attributed to an allergic/sensitivity reaction; patients may also present with persistent symptoms despite empiric treatment for a bacterial infection. We recommend that healthcare providers obtain specimens for bacterial and fungal cultures BEFORE treatment with antifungal or antibacterial medications. Notify your clinical laboratory to use Sabouraud dextrose media for fungal culture. Please contact ACDC regarding questions about laboratory testing.

For patients with suspected fungal endophthalmitis who require surgery, sending the vitreous cassette for fungal culture may have a higher yield for organisms.

The scope and root cause of this outbreak are still under active investigation; as such, healthcare personnel are advised to stop use of all sterile BBG dye and triamcinolone-containing products purchased from Franck's until further information regarding the safety of these products is available.

We ask that all clinical laboratories immediately notify ACDC at (213) 240-7941 of any cultures positive for fungus from eye vitreous fluid from 8/24/11 to the present.

We ask that pharmacists check their stock for sterile compounded products from Franck's Compounding Pharmacy and notify healthcare providers using these products of this health alert.

Medical specialties that may use sterile compounded products include but are not limited to: anti-aging, bio-identical hormones, dental preparations, dermatology, endocrinology, gastroenterology, oncology, ophthalmology, pain management, pediatrics, podiatry, rheumatology, radiology, and urology. Sterile formulations include products administered by injection (IV, IM, SQ, ID, intrathecal, epidural) or inhalation, intranasal or ophthalmic routes of administration (e.g. intravitreal).

For cases among residents of the Cities of Long Beach or Pasadena, call the Long Beach City Health Department (562-570-4302) or the Pasadena City Health Department (626-744-6000).
