CDC links eye infections to troubled Fla. pharmacy

May 3 2012, By KELLI KENNEDY , Associated Press

(AP) -- Federal health officials confirmed 33 cases of a rare fungal eye infection across seven states on Thursday, stemming from products mixed in a Florida pharmacy that also mixed supplements that killed 21 elite polo horses in 2009.

The patients had all undergone some type of eye procedure, including surgery or injections. Twenty-three suffered some degree of vision loss and 24 patients had to undergo another eye surgery, according to a report from the Centers for Disease Control and Prevention.

Health officials traced many of the cases to a dye and an injection including triamcinolone and other products from Franck's Compounding Lab in Ocala. The Food and Drug Administration tested unopened bottles and unused syringes of the dye collected, finding multiple bacterial and fungal species.

California health officials first alerted the CDC after nine patients developed the eye infection in March. Franck's recalled dye lots that same month. A single lot of triamcinolone was recalled on Mar. 31.

CDC officials said the investigation to identify the root cause is ongoing and warned doctors and patients to stay away from "compounded products labeled as sterile from Franck's," according to the report.

The pharmacy has not recalled or halted production of other sterile compounded products, which chemotherapy and other injectables.

Pharmacy officials said in a statement they have conducted a thorough investigation and traced the cause of the contamination to a dye used in eye injections of triamcinolone and formulas containing that drug.

The pharmacy says it has made several changes, including hiring a new pharmacist to oversee quality assurance. It says it has cooperated with federal health officials "in an effort to isolate the source of contamination and prevent future occurrences."

Compounding is a process in which pharmacists mix drugs using bulk ingredients. Patients - both human and animal - usually turn to compounders when they are allergic to inactive ingredients in FDA-approved medicines. They are also used when a patient needs a different dose or a different form of delivery - such as a cream, powder or injectable liquid - than what is commercially available.

State health officials said they can't confirm whether they are investigating Franck's or any pharmacy until 10 days after the alleged investigation and only if probable cause is found. If they do determine a pharmacy poses an immediate threat, the agency can immediately suspend the facility's license.

Franck's came under intense scrutiny in 2009 after 21 polo horses died before a championship match near West Palm Beach. The horses from the Venezuelan-owned Lechuza Caracas team had just been given a cocktail of vitamins and minerals compounded by the pharmacy on order from the team's veterinarian.

Franck's later acknowledged using too much selenium in the mix. Florida's top veterinarian blamed the deaths on an overdose of the mineral often used to help horses recover from fatigue.

The horses' owners have since filed a lawsuit against the pharmacy.

Following the horse deaths, the FDA accused Franck's of illegally creating copies of similar drugs. The agency also says the pharmacy is mixing brews outside of federal guidelines and is compounding animal products from drugs that have not been approved for use in the U.S. Officials warned pharmacies can circumvent the statutory drug approval process by manufacturing drugs under the guise of pharmacy compounding.

The FDA says Franck's was also warned in 2005, four years before the horses' deaths, that it was compounding animal drugs illegally. The agency warned the pharmacy again in December 2009, according to the complaint. Franck's first promised to "comply immediately and completely with any and all FDA and other legal requirements," but later said it disagreed with the FDA's interpretation of the law.

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