Drugs

FDA Alerts Health Care Professionals of Infection Risk from Repackaged Avastin Intravitreal Injections

The U.S. Food and Drug Administration (FDA) is alerting health care professionals that repackaged intravitreal injections of Avastin (bevacizumab) have caused a cluster of serious eye infections in the Miami, Florida area.

The Florida Department of Health (DOH) notified FDA of a cluster of *Streptococcus endophthalmitis* infections in three clinics following intravitreal injection of repackaged Avastin. Investigators traced the tainted injections to a single pharmacy located in Hollywood, Florida. The pharmacy repackaged the Avastin from sterile injectable 100 mg/4 mL, single-use, preservative-free vials into individual 1 mL single-use syringes.

The pharmacy then distributed the Avastin to multiple eye clinics for use in treating patients. To date, FDA is aware of at least twelve patients in at least three of these clinics who had eye infection. While all of these patients had visual deficits prior to their injections witl Avastin, some of these patients lost all remaining vision in that eye due to the endophthalmitis.

The agency and Florida health officials continue to investigate the cause of the infection. While the investigation is not yet complete, th common link for the infections is the pharmacy that repackaged the Avastin and the single lot of Avastin used in the re-packaging.

Health care professionals should be aware that repackaging sterile drugs without proper aseptic technique can compromise product sterility, potentially putting the patient at risk for microbial infections. Health care professionals should ensure that drug products are obtained from appropriate, reliable sources and properly administered.

Avastin solution for intravenous infusion is approved for the treatment of various types of cancers. Some physicians also prescribe Avastin off-label for the treatment of wet age-related macular degeneration, although Avastin is not currently approved for this indication. Lucentis (ranibizumab injection) has been approved by the FDA for wet age-related macular degeneration.

Health care professionals and patients are encouraged to report any adverse events, side effects, or product quality problems related with the use of repackaged intravitreal injections of Avastin to the FDA's MedWatch Safety Information and Adverse Event Reporting program:

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

Links on this page:

1. http://www.fda.gov/MedWatch/report.htm