

# **FDA Public Health Web Notification: Non-Corrective Decorative Contact Lenses Dispensed Without a Prescription**

October 23, 2002

**(You are encouraged to copy and distribute this Notification.)**

## **Purpose of This Notification**

The Food and Drug Administration (FDA) continues to receive reports that non-corrective, decorative/cosmetic contact lenses are being distributed directly to consumers without a prescription or proper fitting by an eye care professional. These products present significant risks of blindness and other eye injury if distributed without the involvement of a qualified eye care professional. Because of these safety concerns, FDA has cautioned consumers against using decorative contact lenses that have not been prescribed and fitted by a qualified eye care professional. (<http://www.fda.gov/bbs/topics/NEWS/2002/NEW00846.html>)

**FDA is requesting that healthcare professionals report adverse events resulting from the use of decorative/cosmetic lenses distributed to consumers without appropriate professional involvement.**

## **Background**

FDA is aware of injuries related to the use of contact lenses distributed directly to consumers and intended solely to change the appearance of the eye. These products can cause corneal ulcers, which can progress rapidly, leading to internal ocular infection if left untreated. Uncontrolled infection can lead to corneal scarring and vision impairment. In extreme cases, this condition can result in blindness and eye loss. Other risks associated with use of decorative/cosmetic contact lenses include conjunctivitis; corneal edema; allergic reaction; abrasion from poor lens fit; and reduction in visual acuity, contrast sensitivity, and other visual functions, resulting in interference with driving and other activities.

Because of the safety concerns these products present, FDA is taking a number of actions. In addition to communicating with the public and with the healthcare community concerning the dangers of using decorative/cosmetic contact lenses, FDA has issued an import alert instructing FDA personnel and officials of the United States Customs Service to detain automatically all decorative contact lenses presented at United States ports of entry. FDA will also seize decorative contact lenses currently on the market in violation of federal law. FDA is responding separately to those eye care professionals who have individually contacted the agency expressing interest in the regulation of these products. In addition, in order to fully assess the extent of the problem associated with these products, this notification is requesting that all healthcare

professionals continue to report adverse events associated with decorative/cosmetic lenses sold without a prescription.

### **Reporting Injuries and Complaints**

If you become aware of a problem associated with these decorative/cosmetic contact lenses, please contact MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch one of four ways: online at <http://www.accessdata.fda.gov/scripts/medwatch/>; by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

### **Getting More Information**

If you have questions about this Notification, please contact James F. Saviola, O.D., F.A.A.O., CDRH, Office of Device Evaluation, HFZ-460, 9200 Corporate Blvd., Rockville, MD 20850 or FAX 301-480-4201. Additionally, a voice mail message may be left at 301-594-0650 and your call will be returned as soon as possible.