

FOR IMMEDIATE RELEASE
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FDA Warns Consumers Against Using Decorative Contact Lenses Obtained Without a Prescription or Professional Fitting

The Food and Drug Administration (FDA) is warning consumers about serious risks of permanent eye injury, potentially leading to blindness, presented by non-corrective, decorative contact lenses distributed without a prescription and without proper fitting by an eye care professional. FDA has learned that these products are being marketed and distributed directly to consumers through flea markets, convenience stores, and beach shops. Marketing of decorative lenses may increase during the upcoming Halloween season.

Decorative contact lenses present significant risks of blindness and other eye injury if they are distributed without a prescription or without proper fitting by a qualified eye care professional. FDA has received reports of corneal ulcer associated with wear of decorative contact lenses in excess of the recommended period. Corneal ulcer 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 contact lenses include conjunctivitis (an infection of the eye); corneal edema (swelling); allergic reaction; corneal abrasion from poor lens fit; and reduction in visual acuity, contrast sensitivity, and other visual functions, resulting in interference with driving and other activities.

"Consumers should understand that decorative contact lenses, like contact lenses intended for correcting vision, present serious risks to eye health if they are distributed without a valid prescription and proper fitting by a qualified eye care professional," said FDA Deputy Commissioner Dr. Lester M. Crawford. "FDA will aggressively use the full range of its

statutory authorities to prevent the distribution of these potentially dangerous products directly to consumers.”

FDA is issuing an import alert instructing FDA and Customs officials to detain automatically all decorative contact lenses presented at United States ports of entry. FDA will seize decorative contact lenses currently on the market in violation of federal law. FDA is also communicating with the public and with the eye care professional community concerning the dangers of using decorative contact lenses.

Consumers are urged to discontinue immediately use of decorative contact lenses obtained without proper fitting and a prescription and to notify FDA of any complaints or problems associated with these products. FDA requests that consumer reports be submitted to the FDA district office consumer complaint coordinator for your geographic area. Telephone and TTY contact information for FDA's consumer complaint coordinators is available via FDA's web site at <http://www.fda.gov/opacom/backgrounders/complain.html>. You may also report problems or complaints to MedWatch, the FDA's voluntary reporting program, by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane (HF-2), Rockville, MD 20850.

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