

Guidance for FDA Staff

SAMPLING AND DETENTION WITHOUT PHYSICAL EXAMINATION OF DECORATIVE CONTACT LENSES

Comments and suggestions regarding this document should be submitted by [date] to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 10-61, Rockville, MD 20852.

After [date], submit comments to Thaddeus J. Poplawski, Division of Import Operations and Policy (HFC-170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Comments should be identified with the docket number [03D-0118].

For questions regarding this document contact Thaddeus J. Poplawski at 301-443-6553.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
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03D-0118

GDL 1

IMPORT ALERT# 86-10, 4/1/03, "SAMPLING OR DETENTION WITHOUT PHYSICAL EXAMINATION OF DECORATIVE CONTACT LENSES"

TYPE OF
ALERT: Increased Coverage
Detention without Physical Examination (DWPE)

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

PRODUCT: Decorative contact lenses that are (1) intended to change the appearance of the eye in decorative fashion and (2) intended for distribution directly to the wearer, without the involvement of a qualified eye care professional. The alert does not cover contact lenses that are intended for vision correction, prosthetic, or other medical use.

PRODUCT
CODE: 86H[] []PX
86H[] []JK
86H[] []QD
86M[] []UW
86M[] []VN
86M[] []WL
86N[] []CZ
86N[] []IC
86L[] []PL
86L[] []PM

PROBLEM: FDA believes these products present substantial risks to ocular health, including corneal scarring and blindness, when dispensed without the involvement of a qualified eye care practitioner. In legal terms, they appear to be adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act.

PAF: HAZ - Hazardous Conditions
AAP - Approvals

PAC FOR
COLLECTION: 82008

COUNTRY: All (ZZ)

MANUFACTURER/
SHIPPER
FEI: See Attachment

CHARGE: "The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a poisonous or deleterious substance which may render it injurious to users under the conditions prescribed in the labeling or under

such conditions of use as are customary or usual. [Adulteration, Section 601(a)]."

or

"The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it is not a hair dye and appears to bear or contain a color additive which is unsafe within the meaning of Section 721(a). [Adulteration, Section 601(e)]."

or

"The article is subject to refusal of admission pursuant to Section 801(a)(3) in that its labeling appears to be false or misleading within the meaning of Section 201(n). [MISBRANDING, Section 602(a)]."

OASIS CHARGE

CODE: POISONOUS
COSM COLOR
COSM MISB

RECOMMENDING

OFFICE: Office of the Chief Counsel (GCF-1)

REASON FOR

ALERT: This alert was initiated in response to information indicating a risk of permanent eye damage, including corneal infections resulting in scarring and (potentially) blindness, resulting from product use and particularly wear beyond the recommended period, lens sharing between individuals, improper fit.

GUIDANCE: Review all entries of contact lenses to determine their PMA/510(k) status. If a PMA/510(k) is not on file and the product is not listed on the Attachment, the product may be sampled and/or detained without physical examination as follows:

* If the product is labeled solely to change the appearance of the eye in decorative fashion, districts may sample and/or detain the shipment using the charges cited in this alert. For guidance, contact James F. Saviola, O.D., F.A.A.O., CDRH, Office of Device Evaluation (HFZ-460) (FAX 301-480-4201).

* If the product is labeled for vision correction or prosthetic use, districts may detain the shipment using the appropriate charge as referenced in Import Alert# 89-08.

Appropriate OASIS screening criteria has been set.

PRIORITIZATION

GUIDANCE: N/A

FOI: No purging required

KEYWORDS: Decorative Contact Lenses, Noncorrective Contact Lenses, Cosmetic Contact Lenses, Novelty Contact Lenses, Plano Contact Lenses

PREPARED

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DATE LOADED

INTO FIARS: April 1, 2003

ATTACHMENT FOR IMPORT ALERT# 89-10

Manufacturers/Shippers of Decorative Contact Lenses not recommended for DWPE

FIRM

PRODUCT DESCRIPTION

At the time of publication in the Federal Register, there were no firms identified.