

can lead to corneal scarring, which can lead to vision impairment. In extreme cases, corneal ulcer can result in blindness and eye loss. Other risks 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.

FDA believes that these risks cannot be sufficiently controlled unless: (1) The wearer obtains advice from an eye care professional; (2) the lenses are fitted by or under the supervision of such a professional; and (3) the wearer remains under appropriate professional supervision. Eye care professional involvement is legally required (21 CFR 801.109) for contact lenses intended for medical purposes (i.e., prosthetic use or vision correction). These products are regulated by FDA as medical devices under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*).<sup>1</sup> Such control is not available for decorative contact lenses because these products are cosmetics under section 201(i) of the act (21 U.S.C. 321(i)).

Section 201(i) of the act defines "cosmetic" to include "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance \* \* \* " (21 U.S.C. 321(i)(1)). Decorative contact lenses are articles intended to be introduced into the eye, which is a part of the body, to beautify the wearer, promote the attractiveness of the wearer, or alter the wearer's appearance. They are claimed to achieve this cosmetic result by changing the apparent color of the iris; by appearing to add a design to the iris (e.g., a professional sports team insignia); or by imparting a nonhuman or otherwise nonnormal appearance to the eye (e.g., cat's eye). Provided they are not marketed with claims<sup>2</sup> that they effect physical or physiological change, decorative contact lenses are properly regulated as cosmetics under the act (cf. *United States v. An Article* \* \* \* "*Sudden Change*," 409 F.2d 734 (2d Cir. 1969) ("claiming to affect the

structure of the skin in some physiological way" makes a product a "drug"); 21 CFR 700.35 ("sunscreen" claims make a product a drug)).

The fact that contact lenses are "devices" in the colloquial sense does not preclude cosmetic status under the act. FDA has previously determined that section 201(i) of the act applies to appearance-enhancing devices such as wigs, hair brushes, stockings and toothpicks (Refs. 1 through 3).

Moreover, the fact that a product is intended to come into contact with the eye does not make it ineligible for cosmetic regulation (Ref. 4). Indeed, the legislative history accompanying the original 1938 act demonstrates that Congress enacted the cosmetic adulteration provisions to address the risk to users presented by cosmetic products that may cause blindness and other serious injuries (S. Rept. 74-361 at 21 (1935)).

On October 22, 2002, FDA issued Import Alert #86-10, with respect to decorative contact lenses. We are now publishing a revised Import Alert #86-10 in the **Federal Register**. The Import Alert #86-10 does not cover contact lenses that are intended for vision correction or for prosthetic or other medical use.

Section 801(a) of the act (21 U.S.C. 381(a)) authorizes FDA to refuse admission to articles that appear to be adulterated or misbranded. Based on the available evidence, FDA believes that decorative contact lenses presented for importation may appear to be adulterated under section 601(a) of the act (21 U.S.C. 361(a)), in that they contain a deleterious substance that is dangerous to wearers of the lenses when they are put to a labeled, customary, or usual use. The deleterious substance is the matrix in which colorants are embedded. This material can cause the potentially vision-threatening eye conditions discussed previously, particularly if the wearer fails to obtain appropriate professional counseling, fitting, and ongoing supervision; if the wearer trades lenses, fails to use proper disinfection and other care techniques; or if the wearer wears lenses for longer than the recommended period. Consequently, FDA believes that decorative contact lenses appear to be adulterated under section 601(a).

Decorative contact lenses may also be subject to refusal if they appear to contain unsafe color additives (21 U.S.C. 381(a) and 361(e)). FDA understands that certain overseas manufacturers or distributors might have selected color additives for use in decorative contact lenses intended for U.S. distribution based on the fact that

they have been approved by FDA for use in medical devices. To be used lawfully in decorative contact lenses, a color additive must be approved by FDA for use in eye area cosmetics. Not all color additives approved for use in medical devices have been approved for eye area use in cosmetics. Consequently, decorative contact lenses may also appear to be adulterated under section 601(e) of the act.

Finally, decorative contact lenses may be subject to refusal on the ground that they are misbranded under section 602(a) of the act (21 U.S.C. 362(a)) because their labeling is false or misleading "in any particular." Under the act, labeling can be misleading by failing to disclose "facts \* \* \* material with respect to consequences which may result" from use of a product under customary, usual, or labeled conditions (21 U.S.C. 321(n)). As noted previously, decorative contact lenses may cause serious health problems, including (in extreme cases) blindness. FDA believes these risks are material. If they are not disclosed in labeling, then the labeling would be misleading, and the product would appear to be misbranded under section 602(a) of the act and subject to refusal under section 801(a) of the act.

## II. Guidance

FDA's district offices may sample or detain without physical examination decorative contact lenses presented for U.S. importation.

The Import Alert #86-10 applies to contact lenses that are: (1) Intended to change the appearance of the normal eye in decorative fashion; and (2) intended for distribution directly to the wearer, without the involvement of a qualified eye care professional. It does not cover contact lenses that are intended for vision correction or for prosthetic or other medical or therapeutic use and that are, therefore, properly regulated as medical devices under the act.

## III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the sampling or detention without physical examination of decorative contact lenses that appear to be adulterated under section 601(a) and (e) of the act because they contain a deleterious substance that is harmful to users and/or contain an unapproved color additive, or appear to be misbranded under section 602(a) because their labeling is false or misleading. It does not create or confer

<sup>1</sup>There are some lenses currently on the market under cleared 510(k)s covering contact lenses intended for both vision correction use and for solely decorative purposes. The sponsors in these cases voluntarily included a plano lens in the range of corrective powers described in the 510(k) submissions.

<sup>2</sup>*American Health Prods Co. v. Hayes*, 574 F. Supp. 1498, 1505 (S.D.N.Y. 1983), *aff'd on other grounds*, 744 F.2d 912 (2d Cir. 1984) (The courts "have always read the \* \* \* statutory definitions employing the term 'intended' to refer to specific marketing representations.").