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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

June 4, 2003

E. EDWARD KAVANAUGH
PRESIDENT

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Guidance on Decorative Contact Lenses
FDA Docket No. 03D-0118

In accordance with the Notice published in 68 Fed. Reg. 16520 (April 4, 2003), the Cosmetic, Toiletry, and Fragrance Association ("CTFA") hereby submits the following comments with respect to the Guidance for FDA Staff on Sampling or Detention without Physical Examination of Decorative Contact Lenses ("Guidance"). The Notice states that, because these products are "intended solely to change the normal appearance of the eye in decorative fashion," they are properly regulated as cosmetics rather than as medical devices.

CTFA represents the cosmetic, toiletry, and fragrance industry and does not represent the contact lens industry.[1] Accordingly, CTFA takes no position specifically on the contact lens

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[1] CTFA is the national trade association representing the cosmetic, toiletry and fragrance industry. The products manufactured by CTFA members include products such as color cosmetics, skin care products, sunscreens, oral care products, antiperspirants, deodorants and fragrances. CTFA has not represented, nor has it been asked to represent, the contact lens industry, and that industry will presumably file its own comments addressing the proper regulatory classification of those products. Founded in 1894, CTFA has almost 600 members, approximately one-half of which manufacture or distribute such products throughout the United States. Other CTFA members supply goods and services to those manufacturers and distributors.

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aspects of the Guidance.[2] CTFA does, however, agree with the Agency's position that proper classification of a product under the Federal Food, Drug, and Cosmetic Act (FD&C Act) depends upon the intended use of the product and not upon the composition or safety of the product. The FD&C Act provides FDA with adequate legal authority to assure the safety of every product subject to its jurisdiction, regardless whether it is classified as a food, a drug, a medical device, or a cosmetic. We concur that FDA must assert that authority when necessary to protect the safety of the consumer.

The definition of a "drug" in Sections 201(g)(1)(B) and (C) of the FD&C Act, the definition of a "device" in Sections 201(h)(2) and (3) of the FD&C Act, and the definition of a "cosmetic" in Section 201(i)(1) of the FD&C Act, all depend on the "intended" use of a product. The 1935 Senate Report on the legislation that ultimately became the FD&C Act explained the central importance of the "intent" element of these definitions as follows:

> "The use to which the product is to be put will determine the category into which it will fall. *** The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put."[3]

That legislative history remains the definitive statement of congressional mandate with respect to the difference between a food, a drug, a medical device, and a cosmetic.

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[2] The 1935 Senate Report on the legislation that ultimately became the Federal Food, Drug, and Cosmetic Act states that "the definition of the term cosmetic does not include devices." S. Rep. No. 361, 74th Cong., 1st Sess. 3 (1935).

[3] S. Rep. No. 361, 74th Cong. 1st Sess. 4 (1935).

The courts have consistently followed this congressional mandate. As the United States Court of Appeals for the Fourth Circuit recognized in the 1998 tobacco litigation, no court has ever found that a product is intended for a drug use "absent manufacturer claims as to that product's use."[4] For example, the United States Court of Appeals for the Second Circuit on two occasions overruled FDA regulations purporting to classify high doses of vitamins A and D as drugs, based solely upon the level of those nutrients in a product.[5] The court ruled that, when labeled as dietary supplements to maintain optimal health, high levels of these vitamins are properly classified as foods rather than as drugs unless FDA can demonstrate that they are taken "almost exclusively" for therapeutic purposes.

As FDA Chief Counsel Daniel E. Troy recently stated in a letter determining that an implanted identification device that has no medical purpose is not a medical device under the FD&C Act:

> "It is well settled that intended use is determined with reference to marketing claims.
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[4] Brown & Williamson Tobacco Corporation v. Food & Drug Administration, 153 F.3d 155, 163 (4th Cir. 1998), quoting from Coyne Beahm, Inc. v. United States Food & Drug Administration, 966 F. Supp. 1374, 1390 (M.D.N.C. 1997), affirmed on other grounds, Food and Drug Administration v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

[5] National Nutritional Foods Association v. Weinberger, 512 F.2d 688 (2d Cir. 1975); National Nutritional Foods Association v. Mathews, 557 F.2d 325 (2d Cir. 1977).

> . . . a foreseeable effect on the structure or function of the body does not establish an intended use.
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> * * *
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> Foreseeability by the manufacturer does not suffice to establish intended use. Rather, there must be 'objective intent' in the form of marketing claims."[6]

CTFA agrees that this is an accurate interpretation of the "intended use" component of the product definitions in the FD&C Act.

A product that is marketed with labeling and advertising that represents the product for uses to beautify, promote attractiveness, and alter the appearance of consumers is clearly intended for cosmetic use and therefore is properly classified as a cosmetic under Section 201(i)(1) of the FD&C Act. If a product which the Agency determines to be a cosmetic product is determined to be unsafe for consumers under customary or usual conditions of use, the appropriate regulatory response is for FDA to declare that the product is an adulterated cosmetic in violation of Section 601(a) of the FD&C Act rather than attempt erroneously to reclassify it as a drug or device. As the Second Circuit explicitly held in the cases involving vitamins A and D, toxicity is not a relevant criterion for classifying products under the FD&C Act.

Accordingly, CTFA agrees with the Agency that the proper inquiry for FDA, in classifying under the FD&C Act a product that is labeled and advertised for traditional cosmetic uses, is to determine whether the representations made for the product involved demonstrate an

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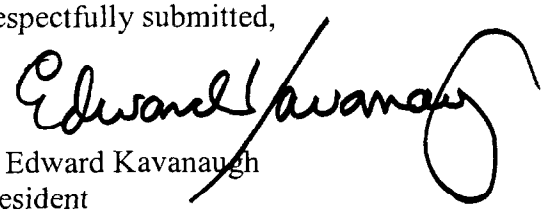
[6] Letter from FDA Chief Counsel Daniel E. Troy to Jeffrey N. Gibbs (October 17, 2002).

intent that the product be used to prevent or treat disease or to affect the structure or function of the human body. Absent such a demonstrable intent, the product is appropriately classified as a cosmetic rather than as a drug or device.

Respectfully submitted,



E. Edward Kavanaugh
President

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