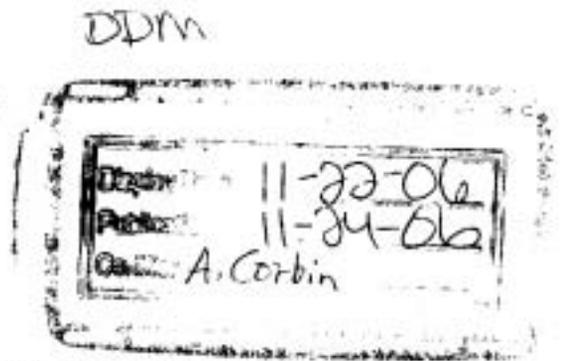


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0451]



Guidance for Industry, Food and Drug Administration Staff, Eye Care Professionals, and Consumers; Decorative, Non-Corrective Contact Lenses; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Guidance for Industry, FDA Staff, Eye Care Professionals, and Consumers: Decorative, Non-Corrective Contact Lenses." This guidance document explains recently enacted legislation under which all contact lenses are deemed devices within the meaning of the Federal Food, Drug, and Cosmetic Act (the act). All contact lenses, including decorative, non-corrective contact lenses, require premarket approval or clearance by FDA and may be dispensed only upon a lawful prescription order by an eye care professional. Although this guidance document is being immediately implemented, the agency welcomes comments at any time in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Guidance for Industry, FDA Staff, Eye Care Professionals, and Consumers: Decorative, Non-Corrective Contact Lenses" to the Division of
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Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ernest N. Smith, Center for Devices and Radiological Health (HFZ-331), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240-276-0115.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance outlines FDA's current thinking on the application of device requirements to decorative, non-corrective contact lenses under the act. Decorative, non-corrective contact lenses are intended to change the normal appearance of the eye, such as to make brown eyes appear green. Although some of these products are covered by premarket notifications (510(k)s) filed under section 510(k) of the act (21 U.S.C. 360(k)) or premarket approval applications (PMAs) filed under section 515 of the act (21 U.S.C. 360e), other products have been sold without FDA premarket review and have been labeled for distribution without a prescription, proper fitting by a qualified eye care professional, and ongoing professional supervision.

Decorative, non-corrective contact lenses, like all other contact lenses, can cause a variety of eye injuries or conditions. For example, lens wear has been associated with corneal ulcers, conjunctivitis, and allergic reactions. Because of these risks, contact lenses, including decorative, non-corrective contact lenses, are not safe for use except under the supervision of a qualified eye care professional licensed by law to direct the use of such devices.

President Bush signed Public Law No. 109–96 into law on November 9, 2005. The legislation provides that “[a]ll contact lenses shall be deemed to be devices under section 201(h) [of the act].” The Senate report that accompanied the bill that became Public Law No. 109–96 explains the basis for this legislation. “Some non-corrective, decorative contact lenses have not been approved by FDA and are sold without a prescription. Previously, FDA regulated these non-corrective contact lenses under its cosmetic authority in chapter VI of the [act]. These contact lenses present a public health threat. S. Rep. 109–110, at 2 (2005).”

As a result of this legislation, decorative contact lenses that are not the subject of an approved PMA, cleared 510(k), or exemption for investigational use are in violation of federal law. Specifically, such devices are adulterated under section 501(f)(1)(B) of the act (21 U.S.C. 351(f)(1)(B)) and misbranded under section 502(o) of the act (21 U.S.C. 352(o)). Adulterated and misbranded devices are subject to enforcement action under the act, including seizure, injunction, and civil money penalties. Manufacturers, distributors, and importers of non-corrective contact lenses that are not currently approved or cleared by FDA should cease distribution of the devices and submit the appropriate application or submission to FDA for approval or clearance if they wish to distribute non-corrective contact lenses. Guidance for 510(k)

submissions and PMA applications for contact lenses is available at <http://www.fda.gov/cdrh/devadvice/3122.html>. Non-corrective contact lenses are also subject to general controls, including the Quality System regulation (QS regulation, part 820 (21 CFR part 820)).

FDA is implementing this guidance document immediately because prior public participation is not feasible or appropriate due to the need to provide guidance to implement Public Law 109-96, which was effective upon enactment on November 9, 2005.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGP regulation (21 CFR 10.115). The guidance represents the agency's current thinking on decorative, non-corrective contact lenses regulated as devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive "Decorative, Non-Corrective Contact Lenses" you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1613 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and

manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 820 have been approved under OMB control number 0910–0073, the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807 have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this

document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/15/06
November 15, 2006.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

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