On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

Guidance for Industry, FDA Staff, Eye Care Professionals, and Consumers

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Decorative, Non-corrective Contact Lenses

Document Issued on: November 24, 2006

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Ophthalmic Devices Branch
Division of Enforcement A
Office of Compliance

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. Please identify your comments with the docket number listed in the notice of availability that publishes in the *Federal Register* announcing the availability of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/comp/guidance/1613.pdf. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance 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.

Guidance for Industry, FDA Staff, Eye Care Professionals, and Consumers

Decorative, Non-corrective Contact Lenses

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

On November 9, 2005, section 520(n) was added to the Federal Food, Drug, and Cosmetic Act (the Act) by Public Law 109-96 to establish that all contact lenses are devices under section 201(h) of the Act. Because all contact lenses are now regulated as devices, including decorative, non-corrective contact lenses intended only to change the normal appearance of the eye, all contact lenses must be the subject of a cleared premarket notification (510(k)) or an approved premarket approval application (PMA) before they may be legally marketed. Additional device authorities, such as the requirement that lenses be dispensed only upon a prescription order, also apply. This guidance explains how section 520(n) affects FDA's regulation of non-corrective contact lenses intended to change the appearance or color of a normal eye for decorative use.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those

requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

I. Background

FDA is aware of the distribution and use of non-corrective contact lenses that are used to change the normal appearance of the eye in a decorative fashion, such as with colors or designs (decorative contact lenses). Decorative contact lenses that do not have FDA premarket authorization have been marketed directly to consumers. Consumers have used such lenses without the benefit of a valid prescription.

Without a valid prescription, fitting, supervision, or regular check-ups by a qualified eye care professional, decorative contact lenses, like all contact lenses, can cause a variety of serious injuries or conditions. For example, lens wear has been associated with corneal ulcer, which can lead rapidly to internal ocular infection if left untreated. Uncontrolled infection can cause corneal scarring, which can lead to vision impairment, and in extreme cases, blindness or the loss of an eye. Other risks include conjunctivitis; corneal edema (swelling); allergic reaction; abrasion from poor lens fit; reduction in visual acuity, contrast sensitivity, and other visual complications that can interfere with driving and other activities.

Because of these risks, contact lenses, including decorative contact lenses that are non-corrective, are not safe for use except under the supervision of a practitioner licensed by law to direct the use of such devices. The Agency believes that these risks cannot be sufficiently controlled unless the wearer does the following under professional supervision:

- Obtains advice about using contact lenses;
- Has a valid prescription;
- Has the lenses fitted properly; and
- Remains under appropriate professional care for contact lens use.

II. How does recent legislation affect FDA's regulation of contact lenses?

FDA has reviewed premarket notification submissions (510(k)s) under section 510(k) of the Act (21 U.S.C. 360(k)) and premarket approval applications (PMAs) under section 515 of the Act (21 U.S.C. 360(e)) for most corrective and non-corrective contact lenses marketed in the United States, including certain decorative contact lenses intended to

change the appearance of a normal eye. All currently approved or cleared decorative contact lenses are legally marketed only as prescription devices (21 CFR 801.109). However, some non-corrective, decorative contact lenses have not been reviewed by FDA and are sold without a prescription. Although FDA had taken the position that contact lenses intended solely for decorative use may be regulated as cosmetics under section 201(i) of the Act, enactment of section 520(n) requires that all contact lenses be regulated as devices.

Thus, all contact lenses in commercial distribution, including decorative contact lenses that are non-corrective, require either a cleared 510(k), an approved PMA, or an exemption for investigational use (IDE). Without such premarket authorization by FDA, decorative contact lenses 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)).

III. Can manufacturers, importers, distributors, or retailers market decorative contact lenses as over-the-counter products?

No. Decorative contact lenses should not be marketed or made available to consumers by manufacturers, importers, distributors, or retailers as an over-the counter item. Manufacturers or initial importers should cease distribution of the devices and submit to FDA an appropriate premarket notification for clearance or application for approval if they intend to distribute any type of non-corrective contact lenses, including decorative lenses used to change the appearance of a normal eye. Guidance for 510(k) submissions for contact lenses is located at http://www.fda.gov/cdrh/ode/conta.html. Contact lenses, including decorative, non-corrective contact lenses, are also subject to general controls of the Act, including the Quality System regulation (21 Code of Federal Regulations (CFR) Part 820), and other applicable device regulations and statutory requirements, including conformance with labeling requirements such as 21 CFR 801.109.

IV. Are manufacturers, importers, distributors, or retailers subject to inspection by FDA?

Yes. FDA has inspected several firms distributing decorative contact lenses and warned firms that selling decorative contact lenses without a valid prescription or proper labeling that includes information about the risks and proper instructions for safe use violates federal law. FDA has also alerted mass marketing firms and operators of on-line sites about the risks associated with decorative contact lenses distributed without appropriate eye care professional involvement.

V. How are imported lenses affected by FDA's law?

As devices, imported decorative contact lenses that do not comply with applicable premarket device requirements are subject to detention without physical examination under the procedures described in FDA's Import Alert #89-08, "Detention without Physical Examination of Devices without Approved PMA's or IDE's and Other Devices not Equivalent or no 510(k)" (see also section 801 of the act, 21 U.S.C. 381). The import alert instructs FDA personnel and officials of the United States Customs Service to detain automatically all devices presented at the United States ports of entry that are in violation of federal law. Import Alert #89-08, can be accessed on the Internet at: http://www.fda.gov/ora/fiars/ora_import_ia8908.html.

VI. Can consumers still buy contact lenses used for decorative purposes only?

Yes, if there is a valid prescription. As when buying all contact lens, consumers should be seen by an eye care professional and obtain proper fitting and instructions for using a contact lens. These devices present significant risks of eye injuries, including blindness, if distributed without a valid prescription and the involvement of a qualified eye care professional and appropriate follow-up care.

More information for consumers on the use of decorative lenses can be found on FDA's web site http://www.fda.gov/bbs/topics/NEWS/2003/NEW00955.html.