Federal Register: Guidance for Industry and Food and Drug Administration Staff; Impact-Resistant Lenses: Questions and Answers; Availability.

U.S. Food & Drug Administration

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---------- DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration [Docket No. FDA-2007-D-0367] Guidance for Industry and Food and Drug Administration Staff; Impact-Resistant Lenses: Questions and Answers; Availability AGENCY: Food and Drug Administration, HHS. ACTION: Notice. ---------- SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ``Impact-Resistant Lenses: Questions and Answers.'' This guidance document answers manufacturer, importer, and consumer questions on impact-resistant lenses, including questions on test procedures, lens testing apparatus, record maintenance, and exemptions to testing. DATES: Submit either electronic or written 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 ``Impact-Resistant Lenses: Questions and Answers'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66. rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847- 8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit electronic comments on the guidance to http://www.regulations.gov [1]. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document. FOR FURTHER INFORMATION CONTACT: John Stigi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4622, Silver Spring, MD 20993-0002, 301-796-5848. SUPPLEMENTARY INFORMATION: I. Background To reduce the number of eye injuries, eyeglasses and sunglasses must be fitted with impact-resistant lenses capable of withstanding the impact test described under 21 CFR 801.410(d)(2). This guidance answers questions for manufacturers, importers, and testing laboratories on such topics as test procedures, lens testing apparatus, record maintenance, and exemptions to testing. This document also contains more detailed and updated discussions of (1) lens blanks, (2) semi- finished, finished, and plano lenses, and (3) import entry inspections. The draft version of this document was announced in the Federal Register of October 26, 2007 (72 FR 60862). Interested persons were invited to comment by January 24, 2008. FDA received numerous comments from laboratories, trade associations, retail establishments,

and consumers surrounding three main issues. FDA further clarified the definition of ``manufacturer'' according to the Quality System regulation (21 CFR 820.3(o)). Additionally, based on data provided in the comments, FDA eliminated a question regarding the salability of plastic prescription lenses tested as part of a statistical sample. FDA also modified several questions which had indicated that the testing of all lenses had to be done after edging to clarify that all plastic prescription lenses and glass over-the-counter lenses could be tested in either ``un-cut finished'' or ``finished'' form. This guidance supersedes ``Impact-Resistant Lenses: Questions and Answers'' (FDA 87-4002), issued September 1987. II. Significance of Guidance This 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 impact-resistant lenses. 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 ``Impact-Resistant Lenses: Questions and Answers,'' you may either send an e-mail request to dsmica@fda.hhs.gov [2] to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (23) to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at http://www.fda.gov/ MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ default.htm [3]. Guidance documents are also available at http:// www.regulations.gov [1]. 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 21 CFR 801.109 have been approved under OMB Control No. 0910-0485; the collections of information in 21 CFR 807.87 have been approved under OMB Control No. 0910-0120; and the collections of information in 21 CFR Part 820 have been approved under OMB Control No. 0910-0073. V. Comments Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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: August 27, 2010. Nancy K. Stade, Deputy Director for Policy, Center for Devices and Radiological Health. [FR Doc. 2010-21908 Filed 9-1-10; 8:45 am] BILLING CODE 4160-01-S

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