FOR FURTHER INFORMATION CONTACT: Danielle Williams, U.S. Department of Health and Human Services, Office of Community Services, Administration for Children and Families, 370 L’Enfant Promenade, SW., Washington, DC 20047, Telephone: (202) 205–4717, E-mail: Danielle.Williams@acf.hhs.gov.
Dated: August 26, 2010.
Yolanda J. Butler, Acting Director, Office of Community Services.

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(f)). 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.


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
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0435]

Guidance for Industry: Small Entities Compliance Guide—The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a Level 2 guidance for industry #201 entitled “Small Entities Compliance Guide—The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.” This small entities compliance guide aids industry in complying with the requirements of the final rule that published in the Federal Register of December 6, 2007. This regulation establishes administrative procedures and criteria for index listing a new animal drug for use in a minor species as provided by the Minor Use and Minor Species Animal Health Act of 2004 (MUMS).

DATES: Submit either electronic or written comments on Agency guidelines at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joan Gotthardt, Center for Veterinary Medicine (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., MPN2, rm. N371, Rockville, MD 20855, 240–276–9090, email: joan.gotthardt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a Level 2 guidance for industry #201 entitled “Small Entities Compliance Guide—The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.” This guidance aids industry in complying with the requirements of the final rule published in the Federal Register of December 6, 2007 (72 FR 69108) (the indexing regulation).

FDA has prepared this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121). This document is intended to provide guidance to small businesses on the requirements of section 572 of the MUMS act. Congress, in enacting MUMS, sought to encourage the development of animal drugs that are currently unavailable to minor species (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats) in the United States or to major species afflicted with uncommon diseases or conditions (minor uses). The indexing regulation establishes procedures and criteria for index listing a new animal drug for use in a minor species.

II. Significance of Guidance

This level 2 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 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. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. 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.

IV. 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.

Nancy K. Siade,
Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–21908 Filed 9–1–10; 8:45 am]