

Action Program Legal Services, Inc. (CAPLAW).

CFDA Number: 93.710.

Legislative Authority: The legislative authority for this grant is provided by the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5). Additional legislative authority and requirements are provided in Sections 674(b)(2)(A) and 678A of the Community Services Block Grant (CSBG) Act, as amended (42 U.S.C. 9903(b)(2)(A) and 9913).

Amount of Award: \$219,445.

Project Period: August 15, 2010 through August 14, 2011.

SUMMARY: The Administration for Children and Families (ACF), Office of Community Services (OCS) has awarded a single source expansion supplement to Community Action Program Legal Services, Inc. (CAPLAW), located in Boston, MA. The project is designed to support T/TA that strengthens the ability of the Community Action Network to comply with and carry out the programs funded by ARRA. The objectives of the project are to: (1) clarify CSBG policy issues, and (2) strengthen CSBG-eligible entity governance and accountability. It will do so by analyzing CSBG policy issues needing clarification, as identified by OCS; developing policy recommendations to address CSBG policy issues applicable to ARRA and "regular" CSBG funds; and responding to the legal, financial, and management T/TA needs among the recipients of CSBG ARRA funds. The project resources developed by CAPLAW, Inc. will promote accountability and help CSBG-eligible entities and States enhance the overall administration of ARRA-funded programs. These resources include issue-specific T/TA and individualized financial consultation; online interactive tutorials; financial network conference calls; online governance and financial management toolkit(s); and T/TA on CSBG ARRA guidance via webinars and audio conferences. The T/TA CAPLAW, Inc. will provide under this award is particularly critical at this time due to the large temporary increase in CSBG funding to CSBG-eligible entities and the need to ensure adherence to high standards of accountability and tracking of the funds and results. The activities funded by this single source expansion supplement expand upon prior activities provided by CAPLAW under their cooperative agreement. A new grant award number will be issued to allow CAPLAW to track and report separately on expenditures from funds made available by ARRA.

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.

[FR Doc. 2010-21977 Filed 9-1-10; 8:45 am]

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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>. 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 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>. Guidance documents are also available at <http://www.regulations.gov>.

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]

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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 guidances 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-50), 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 section 572 of the MUMS act have been approved under OMB Control No. 0910-0620.

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.