before April 28, 2009.[1] The agency may choose not to issue a warning letter or any further warning prior to taking a regulatory action against a firm that is marketing an unapproved exocrine pancreatic insufficiency drug product and not actively pursuing approval.

This notice is issued under sections 502 and 505 of the act (21 U.S.C. 352) and under authority delegated to the Assistant Commissioner for Policy.

Dated: October 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21082 Filed 10–25–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0364]

Draft Guidance for Industry and Food and Drug Administration Staff; Impact-Resistant Lenses: Questions and Answers; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Impact-Resistant Lenses: Questions and Answers.'' This draft guidance document answers manufacturer, importer, and consumer questions on impact-resistant lenses, including questions on test procedures, lens testing apparatus,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: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 24, 2008.

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 (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Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. 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 (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3150.

SUPPLEMENTARY INFORMATION:

I. Background

Eyeglasses and sunglasses are medical devices and are subject to device regulations, including § 801.410 (21 CFR 801.410). This draft guidance document revises the original guidance document entitled ''Impact-Resistant Lenses: Questions and Answers'' (FDA 87–4002), issued September 1987. This draft guidance document also contains detailed and updated discussions of the following: (1) Lens blanks; (2) semi-finished, finished, and plano lenses; and (3) import entry inspections.

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 § 801.410(d)(2). This draft guidance answers questions for manufacturers, importers, and testing laboratories on such topics as test procedures, lens testing apparatus, record maintenance, and exemptions to testing.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 draft 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 240–276–3151 to receive a hard copy. Please use the document number (23) 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 draft 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**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy.

[1] If FDA decides to take enforcement action against a firm's unapproved exocrine pancreatic insufficiency drug product, the agency may at the same time take action relating to any and all of the firm's other violations. For example, if a firm continues to market an unapproved exocrine pancreatic insufficiency drug product but fails to actively pursue approval, to preserve limited agency resources, FDA may take enforcement action relating to any and all of the firm's other unapproved drugs that require applications (see, e.g., *United States* v. *Sage Pharmaceuticals*, 210 F. 3d 475, 479–480 (5th Cir. 2000) (permitting the agency to combine all violations of the act in one proceeding, rather than taking action against multiple violations of the act in ''piecemeal fashion'')).

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: October 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21122 Filed 10–25–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; the Multi-Ethnic Study of Atherosclerosis (MESA) Event Surveillance

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 21, 2007, pages 46640–46641, and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: The Multi-Ethnic Study of Atherosclerosis (MESA) Event Surveillance. *Type of Information Collection Request:* Renewal (OMB No. 0925–0493). *Need and Use of Information Collection:* This project identifies and quantifies factors associated with the presence and progression of subclinical cardiovascular disease (CVD)—that is, atherosclerosis and other forms of CVD that have not produced signs and symptoms. The findings provide important information on subclinical CVD in individuals of different ethnic backgrounds and provide information for studies on new interventions to prevent CVD. The aspects of the study that concern direct participant evaluation received a clinical exemption from OMB clearance (CE–99–11–08) in April 2000. OMB clearance is being sought for the contact of physicians and participant proxies to obtain information about clinical CVD events that participants experience during the follow-up period. *Frequency of Response:* The participants will be contacted annually. *Affected Public:* Individuals or households; Businesses or other for profit; Small businesses or organizations. *Type of Respondents:* Individuals or households; physicians. The annual reporting burden is as follows: *Estimated Number of Respondents:* 550; *Estimated Number of Responses per Respondent:* 1.0; *Average Burden Hours Per Response:* .2; and *Estimated Total Annual Burden Hours Requested:* 36.7. The annualized cost to respondents is estimated at $5,595, assuming respondents time at the rate of $18.65 per hour and physician time at the rate of $75 per hour. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATES OF HOUR BURDEN

Type of respondent	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Physicians	250	1	0.20	16.7
Proxies	300	1	0.20	20
Total	550	1	0.20	36.7

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Jean Olson, Epidemiology Branch, Division of Prevention and Population Sciences, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, Suite 10018, MSC # 7936, Bethesda, MD, 20892–7936, or call 301–435–0397 (non-toll-free number), or e-mail your request, including your address to: *OlsonJ@nhlbi.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: October 16, 2007.

Mike Lauer,

Director, Division of Prevention and Population Sciences, NHLBI, National Institutes of Health.

Dated: October 18, 2007.

Suzanne Freeman,

OMB Clearance Officer, NHLBI, National Institutes of Health.

[FR Doc. E7–21103 Filed 10–25–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.