610, 660, 803, and 807 (21 CFR parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 803, and 807). The collections of information in §§ 606.121, 606.122, and 610.40 have been approved under OMB Control No. 0910–0116; § 610.2 has been approved under OMB Control No. 0910–0206; §§ 600.12(e) and 600.80 have been approved under OMB Control No. 0910–0308; §§ 601.2(a), 601.12, 610.60, 610.61, 610.62, 610.67, 660.2(c), 660.28(a) and (b), 660.35(a), (c) through (g), and (i) through (m), 660.45, and 660.55(a) and (b) have been approved under OMB Control No. 0910–0338; §§ 803.20, 803.50, and 803.53 have been approved under OMB Control No. 0910–0437; and §§ 600.14 and 606.171 have been approved under OMB Control No. 0910–0458. The current good manufacturing practice regulations for finished pharmaceuticals (part 211) have been approved under OMB Control No. 0910–0139; the establishment registration regulations (parts 207, 607, and 807) have been approved under OMB Control Nos. 0910–0045, 0910–0052, and 0910–0387; and the labeling regulations (part 201) have been approved under OMB Control Nos. 0910–0340 and 0910–0370.

In the **Federal Register** of July 23, 2007 (72 FR 40157), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received on the information collection.

Dated: November 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–22489 Filed 11–16–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0325]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices: Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 19, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0553. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices: Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use—Section 502 of the Federal Food, Drug, and Cosmetic Act/Section 351 of the Public Health Service Act (OMB Control Number 0910–0553)—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (FFD&C Act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded. Section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), establishes requirements that manufacturers of biological products must submit a license application for FDA review and approval prior to marketing a biological product for introduction into interstate commerce.

In the **Federal Register** of November 30, 2004, FDA published a notice of availability of the final guidance entitled ''Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use.'' The guidance document provides guidance for the voluntary use of selected symbols in place of text in labeling. It provides the labeling guidance required for: (1) In vitro diagnostic devices (IVDs), intended for professional use under 21 CFR 809.10, FDA's labeling requirements for IVDs, and (2) FDA's labeling requirements for biologics, including IVDs under 21 CFR parts 610 and 660. Under section 502(c) of the FFD&C Act, a drug or device is misbranded, ''If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.'' The guidance document recommends that a glossary of terms accompany each IVD to define the symbols used on that device's labels and/or labeling. Furthermore, the guidance recommends an educational outreach effort to enhance the understanding of newly introduced symbols. Both the glossary and educational outreach information will help to ensure that IVD users will have enough general familiarity with the symbols used, as well as provide a quick reference for available materials, thereby further ensuring that such labeling satisfies the labeling requirements under section 502(c) of the FFD&C Act and section 351 of the PHS Act.

In the **Federal Register** of August 31, 2007 (72 FR 50373), FDA published a 60-day notice soliciting public comment on the proposed collection of information provisions. No comments were received.

The likely respondents for this collection of information are IVD manufacturers who plan to use the selected symbols in place of text on the labels and/or labeling of their IVDs.

FDA estimates the burden for this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN[1]

Section 502 FFD&C Act/Section 351 PHS Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Glossary	1,742	1	1,742	4	6,968[2]
Educational Outreach	1,742	1	1,742	16	27,872
Total					34,840

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One time burden.

The glossary and educational outreach activities are inclusive of both domestic and foreign IVD manufacturers. The Center for Devices and Radiological Health's ''Information Retrieval System's Registration and Listing Information'' database listed the total number of IVD manufacturers as 1,742. From this total, 1,206 of the IVD manufacturers were listed as domestic and 536 were listed as foreign manufacturers. Consequently, FDA has based its burden estimate on the maximum possible number of manufacturers choosing to implement the use of symbols in labeling. The number of hours per response for the glossary and educational outreach activities were derived from consultation with a trade association and FDA personnel. The 4-hour estimate for a glossary is based on the average time necessary for a manufacturer to modify the glossary for the specific symbols used in labels or labeling for the IVDs manufactured. The 16-hour estimate for educational outreach, is inclusive of activities manufacturers used to educate the various professional users of IVDs regarding the meaning of the IVD symbols. Further, this estimate is based on FDA's expectation that IVD manufacturers will jointly sponsor many more educational outreach activities.

Dated: November 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–22492 Filed 11–16–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0219]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Drug User Fees and Fee Waivers and Reductions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 19, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0540. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Animal Drug User Fees and Fee Waivers and Reductions–21 CFR Part 740 (OMB Control Number 0910–0540)—Extension

Enacted on November 18, 2003, the Animal Drug User Fee Act (ADUFA) (Public Law 108–130), amended the Federal Food, Drug, and Cosmetic Act and requires FDA to assess and collect user fees for certain applications, products, establishments, and sponsors. It also requires the agency to grant a waiver from, or a reduction of, those fees in certain circumstances. Thus, to implement this statutory provision of ADUFA, FDA developed a guidance entitled ''Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions.'' This document provides guidance on the types of fees FDA is authorized to collect under ADUFA, and how to request waivers and reductions from FDA's animal drug user fees. Further, this guidance also describes the types of fees and fee waivers and reductions, what information FDA recommends be submitted in support of a request for a fee waiver or reduction, how to submit such a request, and FDA's process for reviewing requests. Requests for waivers or reductions may be submitted by a person paying any of the animal drug user fees assessed—application fees, product fees, establishment fees, or sponsor fees.

In the **Federal Register** of June 14, 2007 (72 FR 32851), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Respondents to this collection of information are new animal drug sponsors.

FDA estimates the burden for this collection of information as follows: