

agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

**Recordkeeping and Records Access Requirements for Food Facilities—21 CFR 1.337, 1.345, and 1.352 (OMB Control Number 0910-0560)—Extension**

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 414 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350c), which requires that persons who manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food. Sections 1.326 through 1.363 (21 CFR 1.326 through 1.363) of FDA's regulations set forth the requirements for recordkeeping and records access. The requirement to establish and maintain records improves FDA's ability to respond to, and further contain, threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

*Description of Respondents:* Persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States are required to establish and maintain records, including persons that engage in both interstate and intrastate commerce.

FDA's regulations require that records for non-transporters include the name and full contact information of sources, recipients, and transporters, an adequate description of the food including the quantity and packaging, and the receipt and shipping dates (§§ 1.337 and 1.345). Required records for transporters include the names of consignor and consignee, points of origin and destination, date of shipment, number of packages, description of freight, route of movement and name of each carrier participating in the transportation, and transfer points through which shipment moved (§ 1.352). Existing records may be used if they contain all of the required information and are retained for the required time period.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1.337, 1.345, and 1.352 (records maintenance)	379,493	1	379,493	13.228	5,020,000
1.337, 1.345, and 1.352 (learning for new firms)	18,975	1	18,975	4.790	90,890
Total					5,110,890

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on FDA's estimate of the number of facilities affected by the final rule entitled "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," published in the **Federal Register** of December 9, 2004 (69 FR 71562 at 71630). With regard to records maintenance, FDA estimates that approximately 379,493 facilities will spend 13.228 hours collecting, recording, and checking for accuracy of the limited amount of additional information required by the regulations, for a total of 5,020,000 hours annually. In addition, FDA estimates that new firms entering the affected businesses will incur a burden from learning the regulatory requirements and understanding the records required for compliance. In this regard, the agency estimates the number of new firms entering the affected

businesses to be five percent (5%) of 379,493, or 18,975 firms. Thus, FDA estimates that approximately 18,975 facilities will spend 4.790 hours learning about the recordkeeping and records access requirements, for a total of 90,890 hours annually. Therefore, the total annual recordkeeping burden is estimated to be 5,110,890 hours.

Dated: November 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 1999D-2013]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics**

**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](mailto:baguilar@omb.eop.gov). All comments should be identified with the OMB control number 0910-NEW and title "Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics." Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**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.

**Draft Guidance for Industry:  
Cooperative Manufacturing  
Arrangements for Licensed Biologics—  
(OMB Control Number 0910-NEW)**

The draft guidance document, when finalized, will provide information concerning cooperative manufacturing arrangements applicable to biological products subject to licensure under section 351 of the U.S. Public Health Service Act. The draft guidance addresses several types of manufacturing arrangements (i.e., short supply arrangements, divided manufacturing arrangements, shared manufacturing arrangements, and contract manufacturing arrangements) and describes certain reporting and recordkeeping responsibilities, associated with these arrangements, for the licensed manufacturer(s), contract manufacturer(s), and final product manufacturer(s) including the following: (1) Notification of any proposed change in the product, production process, quality controls or facilities; (2) notification of results of tests and investigations related to or impacting the product; (3) notification of products manufactured in a contract facility; and (4) standard operating procedures.

**A. Notification of Any Proposed Change  
in the Product, Production Process,  
Quality Controls or Facility**

Each licensed manufacturer in a divided manufacturing arrangement or

shared manufacturing arrangement must notify the appropriate FDA Center regarding proposed changes in the manufacture, testing, or specifications of its product, in accordance with § 601.12 (21 CFR 601.12). In the draft guidance, we recommend that each licensed manufacturer that proposes such a change should inform other participating licensed manufacturer(s) of the proposed change.

For contract manufacturing arrangements, we recommend that the contract manufacturer should share with the license manufacturer all important proposed changes to production and facilities (including introduction of new products or at inspection). The license holder is responsible for reporting these changes to FDA (§ 601.12).

**B. Notification of Results of Tests and  
Investigations Related to or Impacting  
the Product**

In the draft guidance, we recommend the following for contract manufacturing arrangements:

- The contract manufacturer should fully inform the license manufacturer of the results of all tests and investigations regarding or possibly having an impact on the product; and
- The license manufacturer should obtain assurance from the contractor that any FDA list of inspectional observations will be shared with the license manufacturer to allow evaluation of its impact on the purity, potency, and safety of the license manufacturer's product.

**C. Notification of Products  
Manufactured in a Contract Facility**

In the draft guidance, we recommend for contract manufacturing arrangements that a license manufacturer cross reference a contract manufacturing facility's Master Files only in circumstances involving certain proprietary information of the contract manufacturer such as a list of all products manufactured in a contract facility. In this situation the license manufacturer should be kept informed of the types or categories of all products manufactured in the contract facility.

**D. Standard Operating Procedures**

In the draft guidance, we remind the license manufacturer that the license manufacturer assumes responsibility for compliance with the applicable product and establishment standards (§ 600.3(t)) (21 CFR 600.3(t)). Therefore, if the license manufacturer enters into an agreement with a contract manufacturing facility, the license manufacturer must ensure that the

facility complies with the applicable standards. An agreement between a license manufacturer and a contract manufacturing facility normally includes procedures to regularly assess the contract manufacturing facility's compliance. These procedures may include, but are not limited to, review of records and manufacturing deviations and defects, and periodic audits.

For shared manufacturing arrangements, each manufacturer must submit a separate biologics license application describing the manufacturing facilities and operations applicable to the preparation of that manufacturer's biological substance or product (§ 601.2(a)) (21 CFR 601.2(a)). In this draft guidance, we expect the manufacturer that prepares (or is responsible for the preparation of) the product in final form for commercial distribution to assume primary responsibility for providing data demonstrating the safety, purity, and potency of the final product. We also expect the licensed finished product manufacturer to be primarily responsible for any postapproval obligations, such as postmarketing clinical trials, additional product stability studies, complaint handling, recalls, postmarket reporting of the dissemination of advertising and promotional labeling materials as required under § 601.12(f)(4) and adverse experience reporting. We recommend that the final product manufacturer establish a procedure with the other participating manufacturer(s) to obtain information in these areas.

**Description of Respondents:** The recordkeeping and reporting recommendations described in this document affect the participating licensed manufacturer(s), final product manufacturer(s), and contract manufacturer(s) associated with cooperative manufacturing arrangements.

**Burden Estimate:** We believe that the information collection provisions in the draft guidance do not create a new burden for respondents. We believe the reporting and recordkeeping provisions are part of usual and customary business practice. Licensed manufacturers would have contractual agreements with participating licensed manufacturers, final product manufacturers, and contract manufacturers, as applicable for the type of cooperative manufacturing arrangement, to address all these information collection provisions.

This draft guidance also refers to previously approved collections of information found in FDA regulations at parts 201, 207, 211, 600, 601, 606, 607,

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.*

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## 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](mailto: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: