Recommended Glossary and Educational Outreach To Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use—(OMB Control Number 0910–0553)—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&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 (69 FR 69606), FDA published a notice of availability of the 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 FD&C Act, a drug or device is misbranded, ''. . . If any word, statement, or other information required by or under authority of this chapter 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 help to ensure that IVD users 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 FD&C Act and section 351 of the PHS Act.

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.

The glossary activity is inclusive of both domestic and foreign IVD manufacturers. FDA receives submissions from approximately 689 IVD manufacturers annually. 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.

In the **Federal Register** of September 11, 2013 (78 FR 55724), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Glossary	689	1	689	4	2,756

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

Dated: January 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01220 Filed 1–22–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0530]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Requests for Feedback on Medical Device Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Requests for Feedback on Medical Device Submissions'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On November 08, 2013, the Agency submitted a proposed collection of information entitled ''Requests for Feedback on Medical Device Submissions'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0756. The approval expires on December 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: *January 17, 2014.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01311 Filed 1–22–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0578]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On November 13, 2013, the Agency submitted a proposed collection of information entitled ''Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0338. The approval expires on January 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01233 Filed 1–22–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0731]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Form FDA 3356; Eligibility Determination for Donors; and Current Good Tissue Practice

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 February 24, 2014.

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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0543. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

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.

Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Form FDA 3356; Eligibility Determination for Donors; and Current Good Tissue Practice—(OMB Control Number 0910–0543)—Extension

Under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or possessions or from foreign countries into the States. As derivatives of the human body, all Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) pose some risk of carrying pathogens that could potentially infect recipients or handlers. FDA has issued regulations related to HCT/Ps involving establishment registration and listing using Form FDA 3356, eligibility determination for donors, and Current Good Tissue Practice (CGTP).

Establishment Registration and Listing; Form FDA 3356

The regulations in part 1271 (21 CFR part 1271) require domestic and foreign establishments that recover, process, store, label, package, or distribute an HCT/P described in § 1271.10(a), or that perform screening or testing of the cell or tissue donor to register with FDA (§ 1271.10(b)(1)) and submit a list of each HCT/P manufactured (§ 1271.10(b)(2)). Section 1271.21(a) requires an establishment to follow certain procedures for initial registration and listing of HCT/Ps, and § 1271.25(a) and (b) identifies the required initial registration and HCT/P listing information. Section 1271.21(b), in brief, requires an annual update of the establishment registration. Section 1271.21(c)(ii) requires establishments to submit HCT/P listing updates if a change as described in § 1271.25(c) has occurred. Section 1271.25(c) identifies the required HCT/P listing update information. Section 1271.26 requires establishments to submit an amendment if ownership or location of the establishment changes. FDA requires the use of a registration and listing form (Form FDA 3356: Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)) to submit the required information (§§ 1271.10, 1271.21, 1271.25, and 1271.26). To further facilitate the ease and speed of submissions, electronic submission is accepted at (*http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/default.htm*).

Eligibility Determination for Donors

In brief, FDA requires certain HCT/P establishments described in § 1271.1(b) to determine donor eligibility based on donor screening and testing for relevant communicable disease agents and diseases except as provided under § 1271.90. The documented determination of a donor's eligibility is made by a responsible person as defined in § 1271.3(t) and is based on the results of required donor screening, which includes a donor medical history interview (defined in § 1271.3(n)), and testing (§ 1271.50(a)). Certain records must accompany an HCT/P once the donor-eligibility determination has been made (§ 1271.55(a)). This requirement applies both to an HCT/P from a donor who is determined to be eligible as well as to an HCT/P from a donor who is determined to be ineligible or where the donor-eligibility determination is not complete if there is a documented urgent medical need, as defined in § 1271.3(u) (§ 1271.60). Once the donor-eligibility determination has been made, the HCT/P must be accompanied by a summary of records used to make the donor-eligibility determination (§ 1271.55(b)), and a statement whether,