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**SUPPLEMENTARY INFORMATION:** On March 23, 2010, the President signed into law the Affordable Care Act (ACA), Public Law 111-148. ACA is designed to improve and expand the scope of health care coverage for Americans. Cost savings through disease prevention is an important element of this legislation and ACA has established a Prevention and Public Health Fund (PPHF) for this purpose. Specifically, the legislation states in Section 4002 that the PPHF is to “provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs.” ACA and the Prevention and Public Health Fund make improving public health a priority with investments to improve public health.

The PPHF states that the Secretary shall transfer amounts in the Fund to accounts within the Department of Health and Human Services to increase funding, over the fiscal year 2008 level, for programs authorized by the Public Health Service Act, for prevention, wellness and public health activities including prevention research and health screenings, such as the Community Transformation Grant Program, the Education and Outreach Campaign for Preventative Benefits, and Immunization Programs.

Therefore, increasing funding available to applicants under this FOA using the PPHF will allow them to sustain their existing to provide for a national investment in prevention and public health programs. Further, The Secretary allocated funds to CDC, pursuant to the PPHF, for the types of activities this FOA is designed to carry out.

Dated: September 16, 2011.

**Tanja Popovic,**

*Deputy Associate Director for Science,  
Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0672]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reprocessed single-use device labeling.

**DATES:** Submit either electronic or written comments on the collection of information by November 28, 2011.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal 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.

#### Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices (OMB Control Number 0910-0577)—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. Section 301 of the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250) amended section 502 of the FD&C Act to add section 502(u) to require devices (both new and reprocessed) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. Thus, the name for this information collection activity has been changed to more accurately describe the information collection content.

Section 2(c) of the Medical Device User Fee Stabilization Act of 2005 (Pub. L. 109-43) amends section 502(u) of the FD&C Act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol, in a prominent and conspicuous manner on the device or attachment to the device. If the original

SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may

identify itself using a detachable label that is intended to be affixed to the patient record.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

FD&C Act Section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
502(u) .....	10	100	1,000	0.1	100

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

The requirements of section 502(u) of the FD&C Act impose a minimal burden on industry. This section of the FD&C Act only requires the manufacturer, packer, or distributor of a device to include their name and address on the labeling of a device. This information is readily available to the establishment and easily supplied. From its registration and premarket submission database, FDA estimates that there are 10 establishments that distribute approximately 1,000 reprocessed SUDs. Each response is anticipated to take 0.1 hours resulting in a total burden to industry of 100 hours.

Dated: September 22, 2011.

**David Dorsey,**

*Acting Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0108]

#### Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “User Fee Waivers, Reductions, and Refunds for Drug and Biological Products.” This guidance provides recommendations to applicants considering whether to request a waiver or reduction in user fees. This guidance is a revision of the draft guidance entitled “Draft Interim Guidance Document for Waivers of and Reductions in User Fees,” issued July 16, 1993.

**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 Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. 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 this 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:**

Michael Jones, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6216, Silver Spring, MD 20993-0002, 301-796-3602; or

Stephen Ripley, Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a guidance for industry entitled “User Fee Waivers, Reductions, and Refunds for Drug and Biological Products.” This guidance provides recommendations for applicants planning to request waivers or reductions in user fees assessed under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379g and 379h, respectively). This guidance describes the types of waivers and

reductions permitted under the user fee provisions of the FD&C Act and the procedures for submitting requests for waivers or reductions and requests for reconsideration and appeal. The guidance also provides clarification on related issues such as user fee exemptions for orphan drugs.

In the **Federal Register** of March 14, 2011 (76 FR 13629), FDA announced the availability of a revised draft guidance entitled “User Fee Waivers, Reductions, and Refunds for Drug and Biological Products.” The notice gave interested persons the opportunity to comment by June 13, 2011. We received no comments on the revised draft guidance; however, we have made minor editorial changes and a small clarification to the guidance document.

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 user fee waivers and reductions for drug products. 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.

#### II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 this guidance were approved under OMB control number 0910-0639. The guidance also refers to collections of information for filling out and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet), previously approved under OMB control number 0910-0297, and collections of information associated with new drug applications or biologics license applications approved under OMB control numbers 0910-0001 and 0910-0338, respectively.