

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0571]

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Certifier D. Hawkins

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Compliance With the Medical Device User Fee and Modernization Act of 2002, as Amended: Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices (formerly "Reprocessed Single-Use Device Labeling")

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 *[insert 30 days after date of publication in the Federal Register]*.

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 *oira_submissions@OMB.eop.gov*. All comments should be identified with the OMB control number 0910-0577. Also include the FDA docket number found in brackets in the heading of this document.

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FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

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.

Guidance for Industry and Food and Drug Administration Staff; Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as Amended: Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices (formerly “Reprocessed Single-Use Device Labeling”) (Federal Food, Drug and Cosmetic Act, Section 502(u)) (OMB Control Number 0910-0577)—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (the 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 (Public Law 107-250) amended section 502 of the 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 (Public Law 109-43) amends section 502(u) of the 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.

The requirements of section 502(u) of the act impose a minimal burden on industry. This section of the 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.

In the **Federal Register** of November 17, 2008 (73 FR 67873), FDA published a 60-day notice requesting public comment on the information collection provisions. The agency received one comment in support of the collection of information stating that it is necessary to help reproprocessors of SUDs comply with section 502(u) of the act. The comment further stated that the estimated reporting burden did not appear excessive.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
502(u)	10	100	1,000	.1	100

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

JAN 26 2009

Dated: _____

January 26, 2009.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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Dawn P. Hawkins