U.S. Food and Drug Administration
Prominent and Conspicuous Mark of Manufacturers
On Single-Use Devices

OMB Control No. 0910-0577

Supporting Statement **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection covers the third-party disclosures associated with section 502 (21 U.S.C. 352) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which, among other things, establishes requirements that the label or labeling of a medical device must meet so it is not misbranded and subject to regulatory action. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250) amended section 502 of the FD&C Act to add section 502(u) (21 U.S.C. 352(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. Further revision to section 502(u) (21 U.S.C. 352(u)) arose from section 2(c) of The Medical Device User Fee Stabilization Act of 2005 (MDUFSA) (Public Law 109-43) which limited 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. As directed by MDUFSA, FDA issued the guidance entitled "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" to identify circumstances in which the name or symbol of the original SUD manufacturer is not prominent and conspicuous, as used in section 502(u) of the FD&C Act.

Information concerning the identification of the name of a reprocessor of single-use devices is necessary so that users do not misattribute adverse events associated with a reprocessed device to the original manufacturer. When reporting adverse events involving the use of reprocessed single-use devices, health care providers may mistakenly believe that the reprocessed device is a new product from the original manufacturer of the device and not from the reprocessor.

2. Purpose and Use of the Information Collection

The primary users of the device labeling information are the health professionals who use or prescribe the device. It is essential to require the specific identification of reprocessed

SUDs to ensure that physicians, nurses, users, and hospital administrators know that a device was reprocessed. The intent of the labeling requirement is to ensure that physicians, hospital staff, and patients can identify the reprocessor of a SUD when an adverse event or risk to health information should be attributed to the responsible manufacturer. The information and records generated under this labeling requirement can be used to associate a particular device with a particular manufacturer. This is especially important in the event of a recall, warning, patient injury, or product malfunction.

Section 519 of the FD&C Act requires manufacturers to report patient injuries and product malfunctions to FDA, and device user facilities to report these adverse events to FDA or the manufacturer. FDA's post-marketing surveillance program cannot work as intended unless health care providers, original manufacturers, device reprocessors, and FDA can readily and accurately identify when a SUD has been reprocessed. The lack of specific labeling to identify reprocessed devices may lead to incomplete and inaccurate reporting of patient injuries and product malfunctions involving reprocessed SUDs, particularly in an instance where a reprocessed device bears only the name or mark of the original manufacturer. The lack of adequate labeling to identify a reprocessor undercuts the purpose and effectiveness of section 519 of the FD&C Act and FDA's medical device reporting regulations such that FDA lacks accurate information of the postmarket safety and effectiveness of reprocessed SUDs.

Failure of the reprocessor to label the SUD; whether on the device itself, an attachment to the device, or with a detachable label; may result in the product being misbranded under the FD&C Act, subjecting the firm and the product to regulatory action. Any SUD reprocessed from an original device that the original manufacturer has prominently and conspicuously marked must be prominently and conspicuously remarked with the reprocessor's name, a generally recognized abbreviation of its name, or a unique and generally recognized symbol for it.

The information collection will be used by individuals, by the private and public institutions providing healthcare, and by FDA post-market surveillance analysts.

3. Use of Improved Information Technology and Burden Reduction

Manufacturers, including reprocessors, of SUDs may use any appropriate information technology to develop and distribute the required labeling. Manufacturers may use paper labeling or any technology such that the SUD itself, or an attachment to the SUD, bears prominently and conspicuously the name of manufacturer. Manufacturers may use appropriate information technology to keep records of labeling required by section 502(u) of the FD&C Act. We estimate that approximately 99% of the respondents will use some form of electronic means to fulfill the agency's requirement.

4. Efforts to Identify Duplication and Use of Similar Information

The information required to be disclosed by this statutory labeling provision is available only from the manufacturer of a SUD and the reprocessor of a SUD and is not otherwise available to the user or prescriber of the devices.

5. Impact on Small Businesses or Other Small Entities

Approximately 95% of U.S. medical device manufacturing establishments have under 500 employees and may, therefore, be considered small businesses under the guidelines set by the Small Business Administration.

The labeling information is required in order to comply with section 502(u) of the FD&C Act. The information that is required to be disclosed is information that is available to the firm, including a small business, as a normal course of its doing business. FDA aids small businesses and manufacturers to comply with applicable statutes and regulations by providing guidance and information through the Division of International and Consumer Education (DICE) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DICE provides workshops, onsite evaluations and other technical and nonfinancial assistance to small manufacturers. The workshops make available publications and educational materials, which include medical device labeling information. The Division also maintains a toll-free 800 telephone number and a website, which firms may use to obtain regulatory compliance information.

6. Consequences of Collecting the Information Less Frequently

The frequency of response to the information collection is determined by the frequency with which reprocessed SUDs are produced; therefore, occasionally.

The statutes and regulations generally require that labeling accompany each shipment of a device. If this were not done, the device user may not have the necessary information for the safe and effective use of the device.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of December 19, 2017 (82 FR 60207). No comments were received in response to the notice.

FDA regularly consults with representatives of industry to discuss various regulatory issues including labeling issues in general and with regard to specific devices. The statutory labeling provisions and labeling regulations are generally very flexible and FDA is often able to work with industry to accommodate concerns without changing labeling

requirements. FDA also regularly makes available guidance documents with device specific recommendations for conforming to labeling requirements. When FDA makes these guidance documents available, FDA provides an opportunity for interested persons to comment. FDA revises the guidance documents as the comments warrant.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information that is made available in labeling is, by its nature, public information. Information that is trade secret or confidential is subject to FDA's regulations on the release of information, 21 CFR Part 20.

11. Justification for Sensitive Questions

This information collection does not include questions that are of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Third-Party Disclosure Burden

Type of Respondent	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Establishments listing less than 10 SUDs	58	2	116	0.1	12
Establishments listing 10 or more SUDs	9	34	306	0.1	31
Total					43

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 FDA's Unified Registration and Listing System (FURLS) database, FDA estimates that there are 67 establishments that distribute approximately 427 reprocessed SUDs. The majority of establishments (58) distribute an average of 2 SUDs per establishment. The remaining 9 establishments distribute an average of 34 SUDs per establishment. Each response is anticipated to take 0.1 hours (6 minutes) resulting in a total burden to industry of 43 hours.*

* Numbers have been rounded.

12b. Annualized Cost Burden Estimate

FDA believes a manufacturing associate will originate and place labels on the labeling of reprocessed SUDs. At $35 per hour, respondents would incur costs of $1,505 after 43 burden hours.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Manufacturing associate	43	$35.00	$1,505

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Generally, FDA would review compliance with the new labeling requirement under section 502(u) of the FD&C Act as part of a postmarket program. FDA estimates from its time reporting system that labeling reviews currently expend approximately 10 FTEs. Review of the labeling provision under section 502(u) of the FD&C Act would expend approximately 0.5 FTE. Based on a cost of $292,885 per position (which is the agency's projected average cost of an FTE including their benefits*), the estimated annual Federal cost is $3,075,291.

*Based on the Department of Health and Human Services, Fiscal Year 2018, Food and Drug Administration, Justification of Estimates for Appropriations Committees--ALL PURPOSE table (pp. 9-11).

15. Explanation for Program Changes or Adjustments

This is a request for extension without change to the burden hour estimate. There are no adjustments or program changes.

16. Plans for Tabulation and Publication and Project Time Schedule

No tabulation of the data is planned or anticipated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.