SUPPORTING STATEMENT
FOR
Unique Device Identification System (UDI)
21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822, and 830
OMB No. 0910-NEW

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting approval of the information collection requirements in 21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822, and 830.

The rule fulfills a statutory requirement of section 519(f) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(f)) that directs FDA to issue regulations establishing a unique device identification system for medical devices. The rule also meets statutory requirements added by section 614 of the Food and Drug Administration Safety and Innovation Act (FDASIA), including a deadline for publication of this final rule and requirements concerning when the rule must apply to devices that are implantable, life-supporting, or life-sustaining.

The recordkeeping, reporting, and third-party disclosure requirements referenced in the UDI regulation and being approved under the PRA are imposed on any person who causes a label to be applied to a device, or who causes the label to be modified, with the intent that the device will be introduced into interstate commerce without any subsequent replacement or modification of the label. In most instances, the labeler would be the device manufacturer, but the labeler may be a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler.

Respondents may also include any private nonprofit organization or State agency that applies for accreditation by FDA as an issuing agency.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information

This rule is intended to substantially reduce existing obstacles to the adequate identification of medical devices used in the United States. By making it possible to rapidly and definitively identify a device and key attributes that affect its safe and effective use, the rule would reduce medical errors that result from misidentification of a device or confusion concerning its appropriate use. The identification system established under this rule would lead to more accurate reporting of adverse events by making it easier to identify the device prior to submitting a report. It would allow FDA, healthcare providers, and industry to more rapidly extract useful information from adverse event reports, pinpoint the particular device at issue and thereby gain a better understanding of the underlying problems, and take appropriate, narrowly-focused, corrective action. The rule will also require dates on medical device labels to conform to a standard format to ensure those dates are unambiguous and clearly understood by device users.

Under the proposed system, the health care community and the public would be able to identify a device through a UDI that will appear on the label and package of a device. The UDI will provide a key to obtain critical information from a new database, the Global Unique Device Identification Database (GUDID). UDIs will appear in both plain-text format and a format that can be read by a bar code scanner or some other AIDC technology. Certain devices would also be directly marked with a UDI, allowing accurate identification even when the device is no longer accompanied by its label or package.

By ensuring the adequate identification of medical devices through distribution and use, the rule would serve several important public health objectives--

Reduce Medical Errors. The presence of a UDI that is linked to device information in the GUDID will facilitate rapid and accurate identification of a device, thereby removing a cause of confusion that can lead to inappropriate use of a device. Using a device's UDI, you will be able to use the GUDID to positively identify the device and obtain important descriptive information, preventing confusion with any similar device which might lead to misuse of the device. Health care providers will no longer have to access multiple, inconsistent, and potentially incomplete sources in an attempt to identify a device, its key attributes, and a designated source for additional information.

Simplify the Integration of Device Use Information Into Data Systems. UDIs, particularly when provided through AIDC technology, will allow rapid and accurate data acquisition, recording, and retrieval. For example, the use of UDIs in computerized physician order entry systems will help ensure that the intended device will be used in the treatment of a patient, rather than some similar device that may not fully meet the needs of the health care professional who ordered the use of the device.

Provide for More Rapid Identification of Medical Devices With Adverse Events. An essential prerequisite to resolving adverse events is the timely and precise identification of the particular device or devices that may have a connection with an adverse event. The inclusion of UDIs in adverse event reports would lead to greater accuracy in reporting by eliminating uncertainty concerning the identity of the device that is the subject of a report.
Provide for More Rapid Development of Solutions to Reported Problems. The rule requires the inclusion of UDIs in adverse event reports that are required under part 803 (21 CFR part

803). This will allow manufacturers and FDA to more rapidly review, aggregate, and analyze related reports regarding a particular device, leading to more rapid isolation and identification of the underlying problems, and development of an appropriate solution to a particular concern.

Provide for More Rapid, More Efficient Resolution of Device Recalls. Delays in identifying recalled devices can result in the continued use of those devices on patients and involves an increased risk for patient harm. A device labeled with a UDI can be identified rapidly and with great precision. The more rapidly a recall is implemented and completed, the more rapidly the risks presented are reduced or eliminated.

Better-Focused and More Effective FDA Safety Communication. By citing UDIs, FDA will be able to more precisely focus safety alerts, public health notifications, or other communications, eliminating confusion with similar devices and allowing more rapid responsive action. Users of similar devices that are not the subject of the safety alert would be relieved of the uncertainty concerning whether they have been exposed to, or are affected by, a problem or risk.

Additional Benefits. FDA expects the UDI system will provide additional benefits. For example, UDIs can be used in educational and informational materials to allow readers to quickly obtain additional information from the GUDID and other FDA databases; UDIs could play an important role in inventory management; and UDIs may be useful in the provision of high-quality medical services. UDIs and GUDID data, when linked with other FDA data, will help identify alternative devices in the event of a shortage and will contribute to better detection of counterfeit devices.

In addition, FDA expects that providers will include the UDIs of a wide variety of devices in patients' Electronic Health Records (EHRs) and Personal Health Records (PHRs). This information will strengthen the health care community's ability to identify the specific devices implanted into patients and will improve response to postmarket surveillance activities, including adverse event reporting and recalls. For example, this information will contribute to the rapid identification of risks and benefits associated with a device within specific subpopulations. Under appropriate study protocols and with appropriate privacy protections, by linking clinical detail and information regarding device use, more effective device safety surveillance and evaluation studies could be conducted, contributing to a more complete safety and effectiveness profile for devices and enabling more appropriate and timely remedies when potential safety concerns are identified.

Standard Format for Dates Provided on a Device Label. The rule will also better ensure dates on device labels are not confusing or misleading to users thereby ensuring the safe use of devices, by requiring that dates on medical device labels conform to a standard format consistent with international standards and international practice--year-month-day (e.g., 2013-09-30). This will ensure dates on medical device labels are unambiguous and clearly understood by device users.

3. Use of Information Technology and Burden Reduction

The UDI system proposed by this rule builds on currently existing, broadly-supported international standards relating to unique identification and data exchange. The FDA will to leverage current international standards, to the extent possible, to ensure the implementation of these requirements into the current business practices in a seamless and transparent manner.

We would require electronic submission except where it is not technologically feasible for a labeler to submit information electronically. We expect this will be extraordinarily rare. As such, the FDA estimates that 99% of the respondents will use electronic means to fulfill the agency's requirement or request." FDA's current thinking is that we would provide two ways to submit data electronically to the GUDID, and we would describe these methods in guidance that will issue at the same time as or shortly following the final rule. We believe this approach will meet the needs of both large and small labelers, will minimize the costs of submitting, receiving, and processing GUDID data, and will ensure a high level of accuracy in the data submitted. There are no technical or legal obstacles to the collection of this information. The process will be a paperless process.

4. Efforts to Identify Duplication and Use of Similar Information

There is currently no centralized publicly available source of the information that would be reported into the GUDID. In developing the database elements, FDA considered other mandatory reporting requirements and tailored the required elements to avoid duplication.

5. Impact on Small Business or Other Small Entities

We propose to establish safeguards to protect small businesses in several ways. First, a business can choose to use any accredited issuing agency, which will give the labeler a choice among a range of services at a range of fees. We anticipate that the participation of multiple issuing agencies will also lead to competition that will help ensure fees are reasonable. Second, FDA may act as an issuing agency if we find that a significant number of small businesses will be substantially harmed by the fees assessed by all accredited issuing agencies. If FDA acts as an issuing agency, any business would be permitted to use the FDA system and, under current law, there would be no fee. We expect this provision will encourage issuing agencies to be sensitive and responsive to the needs of small businesses. In addition, we would require the issuing agency to be a State agency or nonprofit organization in order to minimize potential conflicts of interest and to help assure that the fees assessed are reasonable to small businesses. Third, the rule contains numerous exceptions and provisions for waivers and requests for alternatives, which FDA expects to minimize burden on all entities including small businesses.

We would require electronic submission except where it is not technologically feasible for a labeler to submit information electronically. We expect this will be extraordinarily rare. FDA's current thinking is that we would provide two ways to submit data electronically to the GUDID, and we would describe these methods in guidance to be issued in draft at the same time as or shortly after publication of the final rule. We believe this approach will meet the needs of small labelers, will minimize the costs of submitting, receiving, and processing GUDID data, and will ensure a high level of accuracy in the data submitted.

FDA will aid small business in dealing with the requirements of the regulation by providing guidance and information through the Division of Small Manufacturers, International, and

Consumer Assistance (DSMICA), and through the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DSMICA provides workshops and other technical and non-financial assistance to small manufacturers. The workshops make available publications and educational materials, which include medical device establishment and listing requirements. The Division also maintains a toll-free "800" telephone number which firms may use to obtain regulatory compliance information. These efforts help to assure that the burden on small manufacturers is minimized.

6. Consequences of Collecting the Information Less Frequently

Respondents would first have to submit data concerning a version or model of a device no later than the date the label of the device must bear a UDI. Once a device becomes subject to our UDI labeling respondents would be required to update the information reported whenever the information changes. A less frequent collection of information would not be responsive to the requirements of the FD&C Act or provide current information relative to the device.

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

This information collection is consistent with the guidelines prescribed in 5 CFR 1320.5.

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

In accordance with 5 CFR 1320.8(d), on 07/10/2012 (77 FR 40735) a proposed rule was published in the Federal Register soliciting public comment on the information collection. Four comments were received addressing a total of four areas of concern.

Public Comments and Response:

801.18—To reduce burden commenters suggested that the date format requirement be revised to be consistent with the requirements of the European Union (EU) and other nations. FDA accepted this comment and the format as changed to be consistent with EU and other national standards (See § 801.18 of the final rule).

801.20—Commenters suggest that the burden estimate for the labeling requirement is underestimated. FDA believes that while the burden associated with this requirement may be higher for some and lower for others, based on the economic impact research conducted prior to the publication of the proposed regulation, the aggregated average burden estimate is accurate.

801.35— Commenters believe the proposed rule was not clear regarding the process for requesting an exception or alternative to some UDI labeling requirements and is overly burdensome. In response to this comment the final rule provides a single process for all types of requests, and provides a more comprehensive process. (See § 801.55 of the final regulation). Also in response to concerns expressed, the final rule adds the following provisions:

- FDA may grant a 1-year extension of the compliance date applicable to class III devices and devices licensed under the Public Health Service Act; see § 801.55(b), discussed previously;
- FDA may initiate and grant an exception or alternative if we determine that the exception or alternative is in the best interest of the public health; see § 801.55(e);
- FDA may rescind an exception or alternative; see § 801.55(f);

any labeler may make use of an exception or alternative that FDA has granted (FDA plans to make all decisions available to the public on FDA's Web site); see § 801.55(d).

801.50—Commenters suggest that the direct marking requirement for implantable devices is overly burdensome and in some cases impractical. FDA agrees and has withdrawn this proposed requirement.

Unidentified Burden—One commenter suggested that the burden associated with a new version or model of a device has not been considered. As part of the economic impact analysis study conducted prior to the publication of the proposed rule, the FDA considered version or model control. The burden estimates formulated from the economic analysis for a device currently reflect a new version or model of a device as a new product, without distinction from a novel device.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts shall be provided to respondents under this regulation.

10. Assurance of Confidentiality Provided to Respondent

Confidentiality of information submitted to FDA is governed by the provisions of 21 CFR 807.95. All registration and some data collected is available upon request under the Federal Freedom of Information Act, subject to FDA's implementing regulations, 21 CFR Part 20, Public Information. In addition, all information filed by a registrant is available for public inspection as required by 21 CFR 807.37.

11. Justification for Sensitive Questions

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Proposed § 801.18 Format of dates provided on a medical device label.

Proposed section 801.18 would require that whenever a labeler of a medical device includes an expiration date, a date of manufacture, or any other date intended to be brought to the attention of the user of the device, the labeler must present the date on the label in a format that meets the requirements of this section.

Proposed § 801.20 Label to bear a unique device identifier.

Proposed section 801.20 would require every medical device label and package to bear a UDI that meets the requirements of this subpart and part 830. In summary, a UDI would have to be provided on a device label and package in both plain-text alpha-numeric characters and through AIDC technology. In addition to providing the plain-text version of its UDI of its label and package, § 801.40 would require the label or package to include a symbol that provides notice of the presence of an AIDC technology.

However, the final rule provides that a combination product that properly bears a National Drug Code (NDC) number is not subject to § 801.20.

While we propose to require use of an AIDC technology whenever a device is labeled or packaged with a UDI, we do not specify what technology must be used. Instead we leave technology determinations to the labeler and the issuing agency. Our intent is to allow for the advancement of technologies and permit current and future business practices to continue and evolve as needed to meet industry needs.

We believe most device labelers would choose to meet the requirement for AIDC technology by providing a bar code on the device label and packaging of the device. In such instances, the bar code may be formatted in any way that meets the technical requirements of the bar coding system that is employed.

To allow labelers to prepare for and implement the requirements in an orderly, efficient manner and provide FDA the opportunity to clarify any confusion, the UDI labeling requirements would be phased in over several years. One year after publication of a final rule, Class III medical devices would be required to display an UDI. Class II and Class I medical devices would be required to display a UDI 5 years and 7 years after publication of a final rule, respectively.

To fulfill these third-party disclosure requirements, the burden associated with these requirements must be considered. The information collection burden for these requirements will most likely include: (1) The updating of Standard Operating Procedures to include process changes for placing UDIs on labels; (2) the time and effort necessary to update/redesign labels; and (3) the verification of barcodes and the documentation of the proper encoding of the barcode information.

Also, in most cases UDI implementation and related controls would need to be integrated throughout the respondent's information systems and employees would need to be trained and the training documented.

Proposed § 801.45 Devices that must be directly marked with a unique device identifier.

A device that must bear a unique device identifier (UDI) on its label must also bear a permanent marking providing the UDI on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use.

However, the requirement would not apply to any device that meets any of the four exception criteria outlined in this section. If a labeler decides not to mark a device after determining that one of the four exceptions apply, it would have to document the basis of its decision in the design history file as required by § 820.30(j) of the QSR.

Proposed § 801.50 Labeling requirements for stand-alone software.

Stand-alone software that is not distributed in packaged form (e.g., when downloaded from a Web site) is deemed to meet the UDI labeling requirements of this subpart if it complies with the requirements of paragraph (b) of this section and conveys the version number in its production identifier. However, regardless of whether it is or is not distributed in packaged form, stand-alone software regulated as a medical device must provide its unique device identifier through either or both of the following, 1) An easily readable plain-text statement displayed whenever the software is started and/or 2) An easily readable plain-text statement displayed through a menu command (e.g., an "About * * *" command). In addition, stand-alone software that is distributed in both packaged form and in a form that is not packaged (e.g., when downloaded from a Web site) may be identified with the same device identifier.

Proposed § 801.55 Request for an exception from or alternative to a unique device identifier requirement.

A labeler may submit a request for an exception from or alternative to the requirement of § 801.20 or any other requirement of this subpart for a specified device or a specified type of device. A written request for an exception or alternative must; 1) Identify the device or devices that would be subject to the exception or alternative; 2) Identify the provisions of this subpart that are the subject of the request for an exception or alternative; 3) If requesting an exception, explain why you believe the requirements of this subpart are not technologically feasible; 4) If requesting an alternative, describe the alternative and explain why it would provide for more accurate, precise, or rapid device identification than the requirements of this subpart or how the alternative would better ensure the safety or effectiveness of the device that would be subject to the alternative; 5) Provide, if known, the number of labelers and the number of devices that would be affected if we grant the requested exception or alternative; and 6) Provide other requested information that the Center Director needs to clarify the scope and effects of the requested exception or alternative.

All requests for an exception or alternative must be submitted via email to cberudirequests@fda.hhs.gov if the device is regulated by the Center for Biologics Evaluation and Research (CBER). In all other cases the email request must be submitted to udi@fda.hhs.gov.

Proposed § 830.60 Relabeling or modification of the label of a device that bears a UDI.

If a labeler relabels or modifies a label of a device that is required to bear a UDI, it would have to assign a new device identifier to the device and keep a record showing the relationship of the original device identifier to the new device identifier. The requirements of this section would be considered a reasonable and customary business practice and there would be no information collection burden as defined under 5 CFR 1320.3(b)(2).

Proposed § 830.110 Application for and renewal of accreditation as an issuing agency.

An applicant seeking initial FDA accreditation as an issuing agency would have to notify FDA of its desire to be accredited and furnish to FDA, via electronic mail to the email address we provide, an application containing the information, materials, and supporting documentation outlined in proposed § 830.120(a).

An issuing agency that does not apply for renewal of its accreditation, is denied renewal of accreditation by FDA, or relinquishes its accreditation and duties before expiration of the current term of accreditation, would be required to notify all labelers that are participating in the issuing agency's UDI system, in a manner and time period approved by FDA, of the date that the issuing agency will cease to serve as an FDA-accredited issuing agency.

Proposed § 830.120 Responsibilities of an issuing agency.

An FDA-accredited issuing agency would be required to:

1. Make available information concerning its system for the assignment of UDIs;
2. Maintain a list of labelers that use its system for the assignment of UDIs and provide FDA a copy of such list in electronic form by December 31 of each year; and
3. Upon request, provide FDA with information concerning a labeler that is employing the issuing agency's system for assignment of UDIs.

Because entities that currently perform functions 1 and 2 above, routinely retaining or disclosing this information as part of their normal business practices in the absence of this proposed regulation, we believe that an issuing agency accredited under the proposed rule would

continue to do so after becoming an issuing agency. Therefore, while this requirement is subject to the PRA, the burden associated with this requirement is exempt and no information collection burden is associated with maintaining this documentation as stipulated under 5 CFR 1320.3(b)(2).

In regard to number 3 above, the requirement to provide FDA with information concerning a labeler that is employing the issuing agency's system for assignment of UDIs is envisioned as a means to obtain information from an issuing agency to support an administrative action, audit, or investigation as defined in 5 CFR 1320.4 and would be utilized on an extremely limited basis. Therefore we believe this requirement does not meet the definition of an information collection as defined under in 5 CFR 1320.4 and 5 CFR 1320. 3(c) and as such FDA is not seeking OMB approval of this requirement at this time.

Proposed § 830.310 Information required for unique device identification.

The contact for device identification designated under § 830.320(a) shall provide FDA with the following information concerning each version or model of a device required to bear a unique device identifier (UDI) on its label:

Concerning the labeler--the name of the labeler; a telephone number or email address that will allow FDA to communicate with the contact for device identification designated under § 830.320(a); and the name of each issuing agency whose system is used by the labeler to assign UDIs used by the labeler.

Concerning each version or model of a device with a UDI on its label--

1) The device identifier portion of the UDI assigned to the version or model;

2) When reporting a substitution of a new device identifier that will be used in lieu of a previously reported identifier, the device identifier that was previously assigned to the version or model;

3) If § 801.45 of this chapter requires the device to bear a UDI as a permanent marking on the device itself, either:

(i) A statement that the device identifier that appears as a permanent marking on the device is identical to that reported under paragraph (b)(1) of this section, or

(ii) The device identifier portion of the UDI that appears as a permanent marking on the device;

4) The proprietary, trade, or brand name of the device as it appears on the label of the device;

5) Any version or model number or similar reference that appears on the label of the device;

6) If the device is labeled as sterile, a statement to that effect;

7) If the device is labeled as containing natural rubber latex that contacts humans, or is labeled as having packaging containing natural rubber latex that contacts humans, as described by §§ 801.437(b)(1), 801.437(b)(3), and 801.437(f) of this chapter, a statement to that effect;

8) Whether a patient may be safely exposed to magnetic resonance imaging, nuclear magnetic resonance imaging, or magnetic resonance tomography while using the device, or while the device is implanted in patient.

9) If the device is available in more than one size, the size of the particular version or model, together with the unit of measure, as it appears on the label of the device;

10) The type of production identifiers that appear on the label of the device;

11) The FDA premarket submission number of a cleared or approved device, or a statement that FDA has by regulation exempted the device from premarket notification;

12) The FDA listing number assigned to the device;
13) The Global Medical Device Nomenclature (GMDN) term or code for the device;
14) The total number of individual devices contained in the device package.

Proposed § 830.320 Submission of unique device identification information (Waivers).

The labeler would have to submit all of the information required by proposed § 830.310 electronically unless it has obtained a waiver under proposed § 830.320(c). A labeler would be able to request a waiver from electronic submission of UDI data by submitting a letter addressed to the appropriate FDA Center Director explaining why electronic submission is not technologically feasible.

Because a labeler that has obtained a waiver from electronic submission of registration and listing information pursuant to section 510(p) of the FD&C Act would be deemed to have a waiver from electronic submission of UDI data, we expect very few waiver requests annually and therefore we are not seeking PRA approval at this time.

Proposed § 830.360 Records to be maintained by the labeler.

Each labeler would have to retain records showing all UDIs used to identify devices that must be labeled with a UDI and the particular version or model associated with each device identifier, until three years after it ceases to market a version or model of a device. This requirement amends current Quality Systems Regulations for a manufacturer to maintain device identifier related information. As such, FDA will amend the current PRA package (OMB 0910-0073) to include the addition of the revised data element to be maintained and any related burden. Given the usual and customary nature of these records, there would be no information collection burden associated with this requirement as defined under 5 CFR 1320.3(b)(2).

Part 803 If I am a user facility or manufacturer, what information must I submit in my individual adverse event reports?

This section is being amended to require a user facility or manufacturer to include the UDI of the device on Form FDA 3500A. FDA will amend the current PRA package (OMB 0910-0437) to include the addition of the new data element to be reported in Block D of the form and related burden.

Part 806 Reports of corrections and removals.

This section is being amended to require a manufacturer to include the UDI of the device in the report. FDA will amend the current PRA package (OMB 0910-0359) to include the addition of the new data element to be reported and related burden.

Part 814 Reports. [Post-approval Requirements].

This section is being modified to require any periodic report submitted by a manufacturer to identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report, unless otherwise specified by FDA.

FDA will amend the current PRA package (OMB 0910-0231) to include the addition of the new reporting requirements and related burden.

Part 820 Device history record.

This section is being modified to require manufacturers to include UDIs or UPCs in device history records.

FDA will amend the current PRA package (OMB 0910-0073) to include the addition of these new recordkeeping requirements and related burden.

Part 820 Complaint files.

When an investigation is made under this section, a record of the investigation shall be maintained by the manufacturer. Section 820.198(e)(3) is being modified to require the record of investigation to include any UDI or UPC used. FDA will amend the current PRA package (OMB 0910-0073) to include the addition of the new data element to be reported and related burden.

Part 820 Servicing.

This section is being amended to require a manufacturer to include in service reports any UDI or UPC used. FDA will amend the current PRA package (OMB 0910-0073) to clarify the new device identifier elements to be reported.

Part 821 Tracking obligations.

This section is being amended to require manufacturers and distributors of tracked devices to include and maintain UDI documentation in their records and reports.

FDA will amend the current PRA package (OMB 0910-0442) to address these changes. We believe the time needed to include the UDI is negligible and that there will be time savings, since any miscommunications about which device is involved will be reduced, along with the time needed to ensure that the device has been adequately identified.

Part 822 What must I include in my submission? (Postmarket Surveillance Plan)

This section is being amended to require a manufacturer, as part of their submission, to report any device identifiers for their device. FDA will amend the current PRA package (OMB 0910-0449) to include the addition reporting requirement and related burden.

The following is the estimated annual burden hours for medical device establishments to comply with the information collection requirements imposed by this regulation.

The table below represents one time burden in the first year of the information collection. The total first year estimates are indicated in Table 5 below. For the purpose of entering the information collection request in ICRAS/ROCIS the total number of respondents has been divided by three (indicated in the parenthetical) in order to arrive at the correct annual burden hour total for the three year approval period.

Table 5.--1ST Year Estimated Burdens[1]

	No. of Respondents [2]	No of Responses per Respondent [3]	Total Annual Responses[4]	Average Burden per Response (in hours)[5]	Total Hours[6]
Reporting	372 (124)	102	37,938 (12,646)	0.070 [4 minutes]	2,662 (887)
Recordkeeping	366 (122)	371	135,652 (45,217)	0.081 [5 minutes]	11,055 (3,685)

Third-Party Disclosure (UDI)	359 (120)	5,304	1,905,303 (635,101)	0.012 [1 minute]	23,790 (7,930)
Third-Party Disclosure (Date Format)	6,199 (2066)	102	632,298 (210,766)	1.000 [60 minutes]	632,298 (210,766)
Total First Year Burden					669,805 (223,268)

Table 5 shows the burden to labelers affected in the first year.

[2]Maximum No. of Respondents for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer respondents.

[3] Maximum No. of Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer responses.

[4] Maximum Total Annual Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer total annual responses.

[5] Rounded to three decimals. Total Hours reflects a more precise, non-rounded Average Burden per Response. An approximate (non-rounded) conversion to minutes is shown in square brackets.

[6] Total Hours is based on a more precise Burden per Response than the rounded value shown in these tables.

Table 6.--Ongoing Estimated Annual Burdens

	No. of Respondents[1]	No of Responses per Respondent[2]	Total Annual Responses[3]	Average Burden per Response (in hours)[4]	Total Hours [5]
Reporting	6,199	51	316,149	0.023 [1 minute]	7,289
Recordkeeping	5,987	51	305,337	0.989 [59 minutes]	302,121
Third-Party Disclosure	5,987	51	305,337	0.885 [53 minutes]	270,143

[1] Maximum No. of Respondents for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer respondents.

[2] Maximum No. of Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer responses.

[3] Maximum Total Annual Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer total annual responses.

[4] Rounded to three decimals. Total Hours reflects a more precise, non-rounded Average Burden per Response. An approximate (non-rounded) conversion to minutes is shown in square brackets.

[5] Total Hours is based on a more precise Burden per Response than the rounded value shown in these tables.

12b. Annualized Cost Burden Estimate

The majority of the costs of this proposed rule would be incurred by labelers of medical devices. Labelers include manufacturers, reprocessors, specification developers, repackagers and relabelers that cause a label to be applied to a medical device. The largest annual cost components include labor, operating, and maintenance associated with equipment for printing operations, and labor related to software maintenance and training needed to maintain the UDI information system. The estimated present value of the costs for domestic labelers over 10 years would be $499.4 million at a 7 percent discount rate and $571.5 million at 3 percent.

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

The annual cost components associated with the these requirements include labor, operating, and maintenance associated with equipment for printing operations, and labor related to software maintenance and training needed to maintain the UDI information system. However, these costs are associated with normal business practices and as such there are no additional capital costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated present value over 10 years of the costs to FDA to establish and maintain the GUDID would be $13.7 million at a 7 percent discount rate and $16.1 million at 3 percent. The annualized costs over 10 years would be $1.8 million at 7 percent and 3 percent.

FDA anticipates the total first year costs to the federal government would be $1.6 million. This cost was calculated by multiplying the estimated number of hours of contractor and FDA personnel time by an average hourly wage of $103. Once the data base is operational, there is an annual cost of $1.9 million to run and maintain the database. This is calculated using 18,100 hours x $103 per hour.

15. Explanation for Program Changes or Adjustments

This is a new collection. As such there are no program changes or adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA has determined that free, easy, and unlimited access to information in the GUDID is essential to the adequate identification of devices through their distribution and use, that health care professionals, patients, and the general public all have substantial needs for access to such information, and that the public health objectives of this rule would be significantly harmed if we attempted to impose any restrictions on access. Consequently, FDA intends to post all information in the GUDID (with one exception, discussed at the end of this paragraph) on our Web site, subsequent the publication of the final UDI rule, so that it will be readily available to the public, and we intend to include features in the UDI Web site to facilitate inquiries concerning a specific device and searches for general or specific information. This includes information that you would be required to submit pursuant to proposed § 830.310 and ancillary information that you would be permitted to submit pursuant to § 830.340.

We have also determined that none of the information that would be required to be submitted under this rule would constitute trade secret, confidential commercial information, or personal privacy information, or would otherwise be prohibited from public release. We would not add any categories of ancillary information that might include information that is prohibited from public disclosure. The one type of information we would not post is listing numbers because they serve important governmental functions that would be harmed if they were made public.

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

This collection does not lend itself to an expiration date. Therefore, FDA requests an exception from the expiration date requirement.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to Item 19 of OMB Form 83-I.