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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Unique Device Identification System; Proposed Rule

Docket No. FDA-2011-N-0090

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we are uncertain whether the proposed rule would have a significant economic impact on a substantial number of small entities, this RIA and other sections of the preamble to the proposed rule constitute the Agency's regulatory flexibility analysis.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. The estimated costs of this proposed rule would result in a 1-year expenditure that exceeds this amount.

This proposed rule would require the label and package of medical devices to bear a unique device identifier (UDI) and would provide for alternative placement or an exception for a particular device or type of device. In addition, this proposed rule would require certain devices to be directly marked with a UDI, with exceptions. Medical device records throughout the required device recordkeeping and reporting systems would need to be modified to include the UDI. Under this proposed rule FDA would establish the Global Unique Device Identification Database (GUDID), a public database containing information about devices labeled with a UDI. The proposed rule would require labelers of medical devices to submit information concerning each device to the GUDID. In addition, the proposed rule would also establish the accreditation requirements for agencies that may operate a system for the issuance of UDIs and establish the conditions for when FDA might act as an issuing agency.

A. Summary of Costs

The detailed data for this cost analysis were developed by Eastern Research Group, Inc. (ERG) under contract to FDA and are presented in the full report "Unique Device Identification (UDI) for Medical Devices," 2011 (cited in Ref.11). We refer to this analysis below and welcome comments on the assumptions and estimates contained in the report.

Table 1 of this document presents for each affected sector a summary of the estimated present value and the annualized domestic costs of this proposed rule over 10 years using discount rates of 7 percent and 3 percent. Over 10 years, the present value of the domestic costs would be $514.0 million using a 7 percent discount rate and $588.6 million using a 3 percent rate, and the annualized costs would be $68.4 million using a 7 percent discount rate and $66.9 million using a 3 percent discount rate.

Table 1.--Summary of the Estimated Regulatory Costs of the Proposed Rule (2010 dollars)[1]

Affected Sectors	Total Present Value of Cost over 10 years ($ million)		Total Annualized Costs Over 10 Years ($ million)	
	3 Percent	7 Percent	3 Percent	7 Percent
Domestic Labelers	$571.5	$499.4	$65.0	$66.5
Issuing Agencies	$1.0	$0.9	$0.1	$0.1
FDA	$16.1	$13.7	$1.8	$1.8
Imports	Not quantified	Not quantified	Not quantified	Not quantified
Total Domestic Cost of the Proposed Rule	$588.6	$514.0	$66.9	$68.4

[1] Present value and annualized costs calculated at the beginning of the period.

1. Costs to Domestic Labelers

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 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. Over 10 years, the annualized costs for domestic labelers would be $66.5 million at a 7 percent discount rate and $65.0 million at 3 percent. The largest components of one-time costs would include the costs to integrate the UDI into existing information systems, to install, test and validate barcode printing software and to train employees, and to purchase and install equipment needed to print and verify the UDI on labels. In addition, other significant components of one-time costs include costs to redesign labels of devices to incorporate the date format within 1 year and to allow space for the UDI barcode, and the direct marking of certain devices.

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.

2. Costs to Issuing Agencies

The estimated present value of costs over 10 years for two existing organizations, currently performing functions similar to those of an issuing agency under the proposed rule, to apply for FDA accreditation and comply with the proposed reporting requirements would be $0.9 million at a 7 percent discount rate and $1.0 million at 3 percent. The annualized costs over 10 years would be $0.1 million at both 7 percent and 3 percent discount rates. In addition to these two organizations, there may be other nonprofit organizations or State agencies that might apply to FDA to become an issuing agency. In such cases, the estimated application preparation, legal, and reporting costs would apply to other organizations.

3. Costs to FDA to Establish and Maintain the GUDID

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.

4. Costs to Foreign Labelers

We lack sufficient information to quantify the potential impact of the proposed rule on foreign establishments and thus exclude these establishments from our cost estimate. However, we include a qualitative discussion of the potential impact of this rule on trade and the cost of imported products, whose value is about one-fourth the value of domestic production. We request comment from affected industries about their expected compliance costs and responses to the proposed rule.

5. Uncertainty

In this analysis, the lower and upper bounds of uncertainty surrounding the central estimate of the costs to domestic labelers are about 50 percent lower and 50 percent higher, respectively. Applying a similar range of uncertainty to the total costs of the proposed rule to domestic labelers, issuing agencies, and the FDA, over 10 years the total annualized domestic costs would range from $34.9 million to $101.8 million at 7 percent and $34.1 million to $99.7 million at 3 percent.

6. Alternatives

The Agency analyzed a number of alternatives with varied requirements affecting the coverage of devices, the content of the information required to be encoded in a UDI, and specific provisions of the proposed rule. With respect to device coverage, we analyzed applying the UDI requirements to class III devices only, and to class II and III devices only. The Agency also analyzed costs for requiring the UDI to contain only the device identifier across all device classes. Also included was an alternative that required a UDI labeling change without requiring the submission of data to the GUDID.

Over 10 years at 7 percent, the annualized present value of the highest cost alternative is about $95 million. This alternative would apply the UDI requirements to class I, II, and III devices, as well as unclassified devices, unless excepted by proposed 801.30(a)(3) through (12). The lowest cost alternative would apply the UDI requirements to class III devices only. The annualized present value of this alternative is about $11 million.

B. Summary of Regulatory Flexibility Analysis

FDA conducted a regulatory flexibility analysis of the impact of the proposed rule on small entities. Ninety-six percent of the 4,693 affected labeler firms (i.e., 4,483 firms) are small

according to Small Business Administration (SBA) size standards. Costs of compliance for domestic labelers as a percentage of revenues exceed 1 percent for about 32 firms with fewer than 19 employees that label devices subject to the direct marking requirements. Moreover, for an estimated 8 firms with fewer than 5 employees, the burden of the proposed rule would represent about 8 percent of their average revenues. If direct marking of devices were not required, no firms would experience costs exceeding 1 percent of revenues.

C. Summary of Benefits

The proposed rule would standardize how medical devices are identified and would contribute to future potential public health benefits from initiatives associated with the increased use of automated systems in healthcare. Most of these benefits, however, require complementary developments and innovations in the private and public sectors, and investments by the healthcare industry that are beyond the scope of this rule. Because such actions are uncertain, we restrict our discussion of the potential public health benefits to those most likely to occur as results of probable responses to the proposed rule in the private and public sectors.

The public health benefits from the UDI would be related to reductions in medical device-related patient injuries and deaths. More accurate and prompt identification of problems would enable more rapid action to reduce the incidence of the adverse events. Public health safety alerts, for example, could be more accurate and timely. Recall actions could more effectively target the problem device. The increased accuracy of adverse medical device reporting and improved recalls should reduce the total number of adverse medical device events, although we are unable to quantify that reduction.

Table 2. Economic Data: Costs and Benefits Accounting Statement (2010 dollars)

				Units			
Category	Primary Estimate	Low Estimate	High Estimate	Year Dollars	Discount Rate	Period Covered	Notes

Benefits							
Annualized Monetized $millions/year					7%		
					3%		
Annualized Quantified					7%		
					3%		
Qualitative	More accurate and prompt identification of device related adverse events would lead to more rapid action to reduce the incidence of the adverse events and to more effectively target and manage medical device recalls.						
Costs							
Annualized Monetized $millions/year	$68.4	$34.9	$101.8	2011	7%	10 years	Costs to foreign labelers are not included.
	$66.9	$34.1	$99.7	2011	3%	10 years	
Annualized Quantified					7%		
					3%		
Qualitative							
Transfers							
Federal Annualized Monetized $millions/year					7%		
					3%		
From/ To	From:			To:			
Other Annualized Monetized $millions/year					7%		
					3%		
From/To	From:			To:			
Effects							
State, Local or Tribal Government: No effect							
Small Business: The proposed rule may have a significant economic impact on a substantial number of small entities that label medical devices.							
Wages: No effect							
Growth: No effect							

D. Need for Regulation and Summary of the Proposed Rule

There currently is an imbalance between the entities that would incur the cost of establishing a standardized system to uniquely identify medical devices and the entities that might benefit from the use of such a system. Medical device labelers would incur the costs of

placing a unique identifier on device labels and of providing medical device information to a device database. Distributors, hospitals, GPOs, insurers and other groups could benefit from the availability of a standardized device identifier and database. The medical device supply and use chain is a disaggregated set of disparate industries. The transaction costs of bringing these disparate parties together to create a standardized system are high. To date, the market has failed to establish a standardized UDI system that meets the basic needs of medical device producers and the users of medical devices. Government can reduce transaction costs and increase net social benefits by defining the basic requirements and structure of a UDI system and by providing oversight to ensure that standards are followed. Once established, a standardized UDI system may be used as a platform for investment in information technology enhancements that can improve patient safety. Although the decisions to invest in health information systems that would use a UDI would be made independently of the proposed rule, the availability of a standardized UDI system would advance the development of analytic tools and other information technology dependent on device identifiers in health information systems, including database querying and networking.

Section 226(a) of the FDAAA (Public Law 101-85) created a new section of 519 (f) of the FD&C Act (21 U.S.C. 360i(f)) stating that: "The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number."

The proposed rule would implement this provision of FDAAA by requiring a UDI to appear on the label and on the package of affected medical devices in an easily-readable plain-text form and in a form using automatic identification and data capture (AIDC) technology (note: this analysis uses the term "barcode" as shorthand to refer to all forms of AIDC technology, because that is the most commonly-used form of AIDC at present), by establishing a GUDID, and by requiring device labelers to submit descriptive information about each version or model of device labeled with a UDI to the GUDID. The agency has specified certain types of devices that would be excepted from some or all of the UDI requirements.

This proposed rule would establish requirements for the UDI that must appear on each label, and for procedures for using, changing, and discontinuing UDIs. A UDI would consist of a fixed device identifier (a mandatory portion of a UDI that could be used to access data that identifies the specific version or model of a device and the labeler of that device), and a variable production identifier (a portion of the UDI that would be required to identify certain labeled production information including: the lot or batch within which a device was manufactured, the serial number, the expiration date, or the date of manufacture). The proposed rule identifies general exceptions from the requirement for a label of a device to bear a UDI and describes the process for other labelers to request an exception or alternative placement of the UDI. Class I devices would not be required to bear a production identifier. Moreover, those class I devices that FDA has by regulation exempted from the good manufacturing practice (GMP) requirements would not be required to bear a UDI. Certain devices for which the labeling requirement may not be sufficient, for example, those that remain in use for an extended period of time and devices that are likely to become separated from their labeling, would be directly marked with a UDI. The proposed rule lists criteria for exceptions to the requirement for direct marking of

devices. This proposed rule would also establish the accreditation requirements for agencies that operate a system for the issuance of UDIs and explains when FDA might act as an issuing agency.

The proposed rule specifies the data for each version or model of a device that would have to be submitted to the publicly available GUDID. Users of the GUDID would use the device identifier portion of the UDI to query descriptive data about a specific device at any time during the distribution and use of the medical device, including a generic descriptor (the GMDN), the proprietary, trade, or brand name of the device, and other identifying information and contact information.

E. Medical Device Manufacturing Industry Profile

The medical device industry is among the most competitive sectors in the United States. It is characterized by a large number of innovative firms that produce a wide array of products. As measured by the total value of shipments, medical device manufacturing industry production was about $117.5 billion in 2007 (see table 3 of this document), or about 2.2 percent of the total value of shipments for all manufacturing industries in the United States. A large majority of domestic medical device manufacturing establishments have fewer than 500 employees, and roughly 75 percent of establishments have fewer than 50 employees, according to the U.S. Census of Manufactures.

Medical device manufacturers are categorized within a number of distinct industries or NAICS (North American Industry Classification System) codes by the Census of Manufacturers. Medical devices vary in size, complexity and packaging. The vast array of medical device types covers implants (e.g., heart valves, stents, artificial knees), screening technologies (e.g., CT scanners, MRI equipment), diagnostic tests, surgical instruments, hospital equipment and

supplies, and devices sold at retail (glucose monitors and strips, bandages, canes). We include this information for background, but note that the proposed rule includes an exception for over-the-counter devices sold at retail. Medical devices might be packaged individually or in boxes of hundreds. The useful life of a device ranges from a brief single use for some disposable items to use over many years for capital equipment, implants, and other multiple-use devices. End users of medical devices range from highly skilled specialists and medical practitioners working in a number of different healthcare and emergency care settings, to consumers. Table 3 of this document presents the major medical device manufacturing industries and the 2007 domestic total value of shipments by the NAICS code as reported by the U.S. Census Bureau.

Table 3.--Medical Device Manufacturing Industry Total Value of Shipments (2007 Dollars)

Industry by NAICS	Value of Shipments ($ billion)
NACIS 325413, In vitro diagnostic substances manufacturing	$13.0
NAICS 334510, Electromedical and electrotherapeutic apparatus mfg.	$22.5
NAICS 334517, Irradiation apparatus manufacturing	$10.8
NAICS 339112 Surgical and medical instrument manufacturing	$29.6
NAICS 339113 Surgical appliance and supplies manufacturing	$31.5
NAICS 339114, Dental equipment and supplies manufacturing	$4.4
NAICS 339115, Ophthalmic goods manufacturing	$5.7
Total	$117.5

Source: ERG Report, Table 3-2 (Ref. 1).
Note: Numbers may not sum due to rounding.

1. Number of Labeler Establishments and Firms[1]

The diversity of products in the medical device industry prevents basing the cost analysis on cost per product. Therefore, this analysis contains a simplifying assumption that costs would be incurred by labelers of affected medical devices on an establishment or firm basis, depending on the type of cost. The proposed rule would affect initial labelers of medical devices: that is, those entities that manufacture, reprocess, or develop specifications for medical devices and that cause a label to be applied to a medical device intended for interstate commerce. Repackagers

[1] An establishment is a business unit at a single location. A firm is comprised of all the establishments that operate under the ownership or control of a single organization.

and relabelers, or non-manufacturing labelers, would also be subject to requirements of the proposed rule.

Based on the FDA registration and listing database, table 4 of this document shows the estimated total number of labeler establishments by type of FDA registrant and whether the establishment is located in the United States or in another country. Although not included in table 4 of this document, these establishments are owned by about 12,484 firms: 6,569 domestic and 5,915 foreign firms (ERG Report, Table 3-6, Ref. 1).

Table 4.--Number of Registered Establishments Considered Labelers under the Proposed Rule[1]

Type of Registrant	Domestic	Foreign	Total Registrants
Manufacturers	4,901	6,492	11,393
Reprocessors	21	3	24
Specification Developers	1,346	276	1,622
Relabelers and Repackagers	1,310	320	1,630
Total Labelers	7,578	7,091	14,669

[1] Source: ERG Report, Appendix A (Ref. 1).

To further characterize domestic labelers, Table 5 of this document presents a breakdown of registered establishments by employment size. We use the same employment size categories as the U.S. Census Bureau, whose size categories are more detailed for initial labelers than for non-manufacturing labelers.

Table 5.--Number of Domestic Labeler Establishments by Employment Size

Type of Labeler	Employment Size									
Initial Labelers	1-4	5-9	10-19	20-49	50-99	100-249	250-499	500-999	1,000 or more	Total
Manufacturers	1,630	794	695	698	419	369	185	68	42	4,901
Single-Use Device Reprocessors	0	11	0	2	2	2	4	0	0	21
Specification Developers	722	210	184	146	51	25	6	2	1	1,346

Non-Manufacturing Labelers	1-4	5-9	10-49	50-99	100-249	250-499	500 or more	Total
Repackagers and Relabelers	736	212	272	47	28	10	4	1,310

Source: ERG Report, Tables 3-5, 3-8, and 3-10 (Ref. 1).
Numbers may not add due to rounding.

Using the FDA registration and listing data, the number of affected domestic firms by size and type of labeling activity is shown in table 6 of this document.

Table 6.--Number of Domestic Labeler Firms by Size and Type of Labeling Activity[1]

Type of Labeler	Employment Size							
Initial Labelers	1-4	5-19	20-99	100-199	200-499	500-999	1,000 or more	Total
Manufacturer	1,455	1,312	873	190	145	63	202	4,241
Single-Use Device Reprocessors	0	11	4	2	3	1	0	19
Specification Developer	769	351	143	19	11	4	9	1,306
Non-manufacturing Labelers	1-4	5-19	20-499			500 or more		Total
Repackagers and Relabelers	727	318	144			24		1,212

Source: ERG Report, Tables 3-7, 3-9, and 3-11 (Ref. 1).

[1] This table 6 counts a firm more than once if it is engaged in more than one type of labeling activity. Consequently, 209 labeling firms are double-counted in the totals. However, when total counts are distributed by employment size, rounding increases this number of double-counted firms to 210. The cost calculations exclude these 210 firms.

2. Baseline Practice

To determine baseline practices, FDA and ERG contacted a number of medical device facilities and participated in industry meetings regarding unique device identification systems. ERG also reviewed the most common industry practices with a variety of industry consultants and with vendors of label printing equipment. As a starting point for this analysis, we generally assume that many medical device labelers have at least some experience with the components of labeling, although there may be limited experience with the full range of requirements of the UDI system specified in the proposed rule. Two-thirds of AdvaMed (a trade association) members apply some form of barcode on device packages. Nevertheless, only a small subset of labelers currently prints unique identifiers with variable barcodes on their device labels and device packages. We assume that the current practices of this small subset of labelers are generally in line with the proposed UDI label requirements, though we recognize that they may have some differences. Reprocessors, specification developers, repackagers, and relabelers were assumed not to have implemented any portion of the proposed UDI requirements.

The detailed assumptions, calculations, and references supporting the cost analysis can be found in the ERG report (Ref. 1). For more detail on baseline practices and costs, see section 4.2 and 4.3 of the ERG report.

For certain cost components, such as label printing equipment, a wide variety of possible compliance strategies exist. To respond to the rule, firms would follow strategies that account for their specific situation, including their production and packaging methods, the number of lines and production speed, and the nature of existing labeling practices and systems.

F. Costs of the Proposed Rule

The proposed rule would require labelers of medical devices to place a UDI on the label of a device, in an easily-readable plain-text form and in a form that uses AIDC technology. A UDI would consist of a fixed device identifier (a mandatory portion of a UDI that could be used to access data that identifies the specific version or model of a device and the labeler of that device) and, for class II and class III devices, a variable production identifier (a portion of the UDI that would be required when certain production information is displayed on the label including: the lot or batch within which a device was manufactured, the serial number, the expiration date, or the date of manufacture). The UDI would identify the device throughout its distribution and use. Proposed section 801.30(a) lists general exceptions from the requirement for the label of a device to bear a unique device identifier. Proposed 801.30(a)(1) would except over-the-counter devices sold at retail. The second exception is for class I devices that FDA has exempted from the GMP regulations. The remaining exceptions list specific types of devices that would be excepted. Under proposed 801.30(c) labelers of class I devices would not be required to include the variable production identifier in their UDIs. If the device is an implantable device, is intended for more than a single use and must be sterilized before each use,

or is stand-alone software, the UDI would also have to appear on the device itself. The proposed rule would establish a public database of information for devices labeled with a UDI and would require the submission of information about each device to FDA.

To build the cost estimate for the proposed rule, we first estimate the costs of subjecting most medical devices to the UDI requirements. These costs are shown in section F1 and F2 of this document. For purposes of analysis, this does not include devices excepted from the proposed rule by proposed 801.30(a)(3) through (12). Throughout this document, for simplicity, we use "excepted devices" to refer to device types listed in proposed 801.30(a)(3) through (12). In section F3 of this document, we adjust and redistribute the total number of affected establishments. We separate counts of those establishments that would have lower burdens and costs because of three additional exceptions. The first exception is that the label of class I device would need to bear only the device identifier and not the production identifier in the UDI. The second is that class I GMP exempt devices would be excepted from the proposed rule. Finally, over-the-counter devices sold at retail, including such devices when delivered directly to hospitals and other health care facilities, would not be required to bear a UDI. The total costs of the proposed rule for all domestic labelers with immediate implementation are shown in section F4. Section F5 shows the total costs of the proposed rule for all labelers using the phased-in implementation schedule.

Certain types of labelers would incur only some of the estimated regulatory costs. Although included in the total number of affected labelers, the cost estimate generally excludes any labeler that exclusively handled excepted devices. In this analysis, we assumed that 70 percent of the smallest device manufacturers with fewer than 5 employees and 30 percent of device manufacturers with 5 to 9 employees would handle only excepted devices. Therefore, of

the 2,424 manufacturing establishments with fewer than 10 employees shown in table 5 of this document (1,630 establishments with 1-4 employees + 794 establishments with 5-9 employees), 1,379 establishments (70 percent x 1,630 establishments + 30 percent x 794 establishments) would incur only the minimal costs necessary to determine that all of their devices would be excepted from the UDI requirements.

Furthermore, over-the-counter devices sold at retail are exempt from the requirements for a UDI. However, these devices would still be subject to other requirements of the proposed rule, such as the date change. Although over-the-counter devices sold at retail are excepted, only establishments that exclusively label such retail devices would avoid the UDI labeling costs. Excluding establishments exclusively labeling excepted devices, this analysis assumes that approximately 10 percent of establishments with fewer than 10 employees manufacture devices exclusively for the retail market. Consequently, we estimate that only 104 labelers ((2,424 establishments - 1,379 establishments) x 10 percent) market exclusively to retail sector.

The analysis also estimates that 3 percent of manufacturing establishments already provide variable barcode information (lot number, serial number or dates) on their medical device labels. This percentage represents roughly 108 manufacturing establishments that use variable barcodes and have incorporated these barcodes into their electronic recordkeeping and reporting systems. The 3 percent estimate is based on information from AdvaMed about the current barcoding practices of their members. As noted in the ERG report, AdvaMed members primarily own establishments with 50 or more employees; 15 percent of member establishments use variable barcodes and 85 percent of member establishments use only static barcodes (that represent the fixed device identifier only). For this analysis, we assume that none of the manufacturers with fewer than 50 employees use variable barcodes, but about 5 percent of these

manufacturers use static barcodes. The manufacturers using variable barcodes may need to make some modifications to their administrative systems, but we assume they are likely to have previously absorbed most of the costs for complying with the proposed UDI regulations. For more detail on our assumptions, see section 4.2 of the ERG report.

The costs of developing and installing a UDI capability would include:

Administration and Plan Development.--Develop a facility plan for implementing a UDI system and prepare new or modified Standard Operating Procedures (SOPs) to meet FDA's Quality System regulation.

Participate in a UDI System Operated by an Issuing Agency.--The labeler will choose among systems offered by FDA-accredited issuing agencies. All issuing agencies will provide access to, and technical advice concerning, their systems for the assignment of device identifiers, and will charge a fee for their services.

Purchase Equipment.--Select and purchase equipment to print or place the UDI on products or packages and verify the quality of the UDI marking. Printing labels may be conducted in-house or by a contract printer.

Direct Marking.--Select and purchase equipment to etch or otherwise permanently mark the specific devices that would be subject to direct marking requirements, or apply for an exception.

Label Redesign.--Redesign and print labels (or add a supplemental label) to add:

- A plain-text UDI
- A static barcode (or other AIDC technology) that represents the device identifier (i.e., the version or model) when no production identifier appears on the label

- A variable barcode that represents the device identifier and production identifier when any production identifier appears on the label
- A symbol indicating the use of AIDC technology other than a barcode
- Correct date formats.

Software and Data Integration.--Integrate the UDI data into certain FDA-required device records, which may require software or other IT changes.

Recordkeeping and Reporting.--Provide initial information and ongoing updates to the GUDID.

Table 7 of this document shows each major cost component and whether it accrues at the level of the establishment or the firm. Current practices and device types determine which cost components would apply to a specific labeler. For example, a labeler applying variable barcodes to device labels and packages, but not subject to direct marking requirements, would incur only the costs for administration and plan development, label redesign, and submitting data to the GUDID.

Table 7.--Major Cost Components by Organizational Level Incurring Costs

Organizational Level	Cost Component						
	Admin. & Plan Develop-ment	Register with an Issuing Agency	Purchase Equip-ment	Direct Marking	Label Redesign	Software & Data Integration	Record-keeping & Reports
Establishment	X		X	X	X		X
Firm		X				X	

1. Costs for Initial Labelers

Administration and Plan Development.

All labelers of medical devices would need to read and understand the proposed rule to determine how the rule will affect them. These costs would be incurred on an establishment basis. Larger establishments with more complex operations involving many devices would need

more time than smaller establishments with few devices. Once labelers understand the UDI requirements of the proposed rule, they would evaluate their operations and devices and, if subject to the UDI requirements, would develop a plan to implement these requirements and to modify their SOPs. Some labelers of devices with identifiers that fully conform to the UDI requirement would not need to develop an implementation plan to add the UDI to their device labels and device packages. However, all labelers with devices subject to the UDI requirements would need to modify their SOPs to include the UDI in certain records and reports and to add procedures to report device data to the GUDID. In addition to the UDI requirements, labelers would need to review their device labels to determine whether they would need to modify the date format on their device labels within 1 year.

The proposed rule includes effective dates for UDI requirements based on the class of a device. Labelers with devices from more than one class would decide whether to develop an implementation plan that follows the staggered effective dates or a plan to implement the UDI requirements for all devices at one time, regardless of class. To minimize potential disruptions in establishment operations, we assume that most labelers would likely opt for a plan that implements the UDI requirements for all of their devices at the same time. As explained in more detail in section 4.3 of the ERG report, we estimate that labelers would spend between 2.5 hours and 720 hours to read and understand the proposed rule, to evaluate their devices and operations, to develop an implementation plan and to modify SOPs, depending on the size of the establishment and the level of effort required by the proposed rule. For example, establishments that exclusively label excepted devices need only read and understand the rule and would have the smallest burden of 2.5 hours. Establishments with more than 500 employees that label

devices that need to develop a full UDI implementation plan and to modify SOPs would have the largest burden of 720 hours.

We anticipate that managers would perform these tasks. With an average hourly wage of $75, including benefits, a very small establishment with fewer than 5 employees would spend from $190 (2.5 hours x $75 per hour) to $2,250 (30 hours x $75 per hour), depending on the types of devices labeled and the level of effort required. Similarly, a very large establishment with more than 500 employees would spend from $2,250 (30 hours x $75 per hour) to $54,000 (720 hours x $75 per hour).

Costs for the estimated 1,379 establishments that exclusively label excepted devices would equal about $0.3 million ($190 per establishment x 1,379 establishments). Establishments that currently print UDI-compliant identifiers on their device labels and packages would spend about $0.1 million ($190 per establishments x 105 establishments + $375 per establishment x 21 establishments + $750 per establishment x 37 establishments + $1,500 per establishment x 28 establishments + $2,250 per establishment x 22 establishments.) The remaining 4,677 establishments would incur costs equaling about $42.8 million ($2,250 per establishment x 1,162 establishments + $4,500 per establishment x 721 establishments + $9,000 per establishment x 2,176 establishments + $18,000 per establishment x 359 establishments + $36,000 per establishment x 167 establishments + $54,000 per establishment x 91 establishments.) As shown in table 8 of this document, one-time costs for administration and plan development would total $43.2 million ($0.3 million + $0.1 million + $42.8 million).

Table 8.--Total One-Time Administration and Plan Development Costs (2010 dollars)

Establishment Size (# of employees)	Estimated Hours and Number of Affected Establishments by Level of Effort						Total One-Time Cost ($ mil) [4]
	Read and Understand the Proposed Rule [1]		Modify SOPs to include UDIs in records and to report device data to the GUDID [2]		Develop a Full UDI Implementation Plan and Modify SOPs [3]		
	Hours	Number	Hours	Number	Hours	Number	
<5	2.5	1,141	2.5	49	30	1,162	$2.8
5-9	2.5	238	2.5	56	60	721	$3.3
10-99	NA	NA	5	21	120	2,176	$19.6
100-249	NA	NA	10	37	240	359	$6.5
250-499	NA	NA	20	28	480	167	$6.1
500+	NA	NA	30	22	720	91	$5.0
Total		1,379		212		4,677	$43.2

Source: ERG Report section 4.3.1.1 and Table 4-2 (Ref. 1).
Note: Numbers may not sum due to rounding.
[1] Includes establishments that exclusively label excepted devices.
[2] Includes establishments that currently use variable barcodes that conform to the UDI requirements.
[3] Includes establishments with device labels that lack barcodes and establishments with devices that are labeled with static barcodes.
[4] One-time costs are calculated with an hourly wage of $75, including benefits.

Participate in a UDI System Operated by an Issuing Agency

Every firm labeling medical devices subject to the UDI requirements would have to participate in one of the UDI systems operated by FDA-accredited issuing agencies. To develop the estimate the number of firms that would need to apply to issuing agencies, we distributed the number of registered labeler firms shown in table 6 of this document into three employment size categories (fewer than 20, 20-499, and greater than 500 employees). We then adjusted the firm count to remove firms that we assumed would exclusively label excepted devices (e.g., custom and investigational devices) and over-the-counter devices sold at retail). The counts for manufacturing firms and specification developers were adjusted to account for firms that already participate with existing organizations currently performing functions similar to those of an issuing agency under the proposed rule: 85 percent of labeling firms with fewer than 20 employees and that would be subject to proposed UDI requirements, 95 percent of the mid-sized firms with 20-499 employees, and 99 percent of firms with more than 499 employees. The final

count of firms not participating with existing organizations that would incur costs to apply to issuing agencies equals 476.

To estimate participation fees, we relied on publicly available information from HIBCC (Health Industry Business Communications Council®), an organization that provides services similar to those that would be provided by an issuing agency under this proposed rule. HIBCC charges one-time fees according to gross sales revenue and not by the number of products requiring a unique identifier. HIBCC fees do not include recurring charges. The fee schedule for GS-1, an organization that also provides similar services, is not publicly available. Using data from the 2007 Census of U.S. Manufacturers, we estimate the average sales revenue for each size category to estimate possible participation fees. The average sales revenue used to calculate the three categories of firm fees are: less than $2 million for the smallest size, under $30 million for the middle size, and over $500 million for the largest size firms.

One-time costs to participate in an issuing agency's system would be $500 for the smallest firms with 19 or fewer employees, $4,000 for firms with 20 to 499 employees, and $20,000 for firms with 500 or more employees. Therefore, we estimate that the total one-time costs for 476 firms to apply to issuing agencies would be approximately $0.6 million. See table 9 of this document. The agency seeks comments on this estimate.

The proposed rule would require that issuing agencies be private nonprofit organizations or State government agencies. Moreover, FDA would be able to act as an issuing agency if a significant number of small businesses would be substantially affected by the fees charged by all accredited issuing agencies. Although we anticipate that these conditions would limit any oligopoly power, we request comment from labelers on their experience with participation fees, including recurring fees, charged by existing organizations.

Table 9.--Costs to Participate in an Accredited UDI System (2010 dollars)

Firm Employment Size	Adjusted Number of Firms	Cost per Firm To Participate	Aggregate Costs to Participate ($ million)
Fewer than 20 employees	397	$500	$0.2
20-499 employees	76	$4,000	$0.3
500 or more employees	4	$20,000	$0.1
Total	476		$0.6

Note: Numbers may not sum due to rounding.
Source: ERG Report, Table 4-4 (Ref. 1).

Purchase Equipment

The costs to implement required label changes would vary widely depending on printing capabilities and equipment. We generally assume, however, that the methods used and presentation of a machine readable UDI on labels are the same as those currently used for trade purposes (e.g., standard linear or 2-D barcode). These barcodes allow for the representation of the human readable form of the UDI above or below the barcode.

Baseline conditions for large establishments with complex automated production lines would differ from baseline conditions for very small establishments with manual production lines. The primary basis for the difference in manufacturer response is the prevalence of baseline digital printing technology. This technology allows for on demand printing of new labels with both plain text and barcoded UDIs that would incorporate the frequent changes needed to include the variable component of the UDI (e.g., lot number, serial numbers, manufacturing date and expiration date). We assume that about 3 percent of all manufacturers with automated lines have installed equipment to print both static and variable barcodes on medical device labels and would not need to invest in labeling equipment. Some labelers currently apply barcodes with only static information (e.g., a device identifier that could be used to access information about the labeler and the specific version or model of the device) that does not include a barcode equivalent of the variable identifiers.

Larger manufacturers, which are assumed to operate automated lines, indicated that the two most commonly used labeling methods are (1) use of preprinted labels (including labels produced by outside contractors) and (2) use of in-line printing systems, such as flexographic printers (which use printing plates). A UDI requirement that includes variable information would impose more frequent changes of the UDI on the label than would be required with a UDI that only includes static information. More frequent changes would create a challenge for many printing technologies, such as printing press technology, which is designed to produce large numbers of labels or other printed material very cheaply, but is not designed to produce the frequent label changes that would be necessary to produce barcoded production identifiers.

In response to the proposed rule, labelers may choose to do the following: (1) Continue using outside contractors to print device labels that incorporate variable information; (2) purchase and install equipment to print in-house a separate supplemental label with variable information; (3) purchase and install equipment to move the entire label printing system in-house; or (4) modify their current in-house label printing system. The agency requests comments on how industry expects to implement these provisions, as this may influence the cost estimates at the final rule stage.

The equipment investment necessary to comply with the proposed rule would vary according to the type and number of production lines. Costs would be higher for establishments with multiple production lines. The cost to add new equipment ranges from $450 (to add a verifier in an establishment with 1 manual production line), to about $120,000 (to install a complete printing system in an establishment with 6 or more automated production lines). Adding supplemental label printing capabilities requires an investment of $450 in an

establishment with 1 manual line, and from about $21,100 in an establishment with 1 automated production line to about $31,700 in an establishment with 6 or more automated production lines.

Table 10 of this document presents a summary of the costs for purchasing, installing and maintaining equipment to add the UDI barcode to device labels. Taking into account current baseline practices, table 10 shows the probabilities and costs of possible compliance responses for establishments with one manual production line and for establishments with one or more automated production lines. The costs were calculated by first multiplying the percentage of establishments in a size category anticipated to choose a particular compliance response by the percentage of all establishments in that category. For example, 35 percent (88 percent of 40 percent) of establishments currently using outside label printers would decide to add supplemental label printing equipment. For this case, the costs for establishments with one automated production line would equal about $16.2 million (35 percent x 2,176 establishments with 1 automated production line x $21,094 supplemental label printing equipment cost). Similarly, the costs for establishments with 6 or more automated lines would equal about $1.2 million (35 percent x 110 establishments with 6 or more lines x $31,719). As shown in table 10 of this document, the estimated total 1-year investment in equipment would cost about $71.5 million for all affected establishments.

In addition to the one-time investment, labelers would incur annual labor costs of $29.3 million (cost per establishment to operate verifiers x the number of establishments for each type of production line) and annual equipment operating costs of $7.2 million (10 percent of the $71.5 million investment cost). The estimated total annual costs to operate and maintain label printing equipment would be $36.5 million ($29.3 million + $7.2 million). We request detailed

comments from industry on these cost estimates, including the assumptions, many of which are detailed in the ERG report.

Table 10.--Equipment Investments for UDI Requirements (2010 dollars)

Establishments, by Baseline Label Printing System	Manual Lines (% Establish-ments)	Automated Lines (% Establish-ments) [2]	Per Establishment Equipment and Labor Costs, by Number of Lines [1]					Total
			Manual	Automated				
			1 line	1 line	2-3 lines	4-5 lines	6+ lines	
Number of establishments, by assumed number of production lines			1,883	2,176	359	148	110	4,677
Install full on-line label printing system on automated line			NA	$43,594	$46,813	$93,625	$119,438	
Install supplemental label system on automated line			NA	$21,094	$21,094	$24,063	$31,719	
FTEs to operate verifiers			$0	0.15	0.30	0.60	1.00	
Annual labor cost to operate verifiers on automated line [3]			$0	$6,947	$13,894	$27,787	$46,312	
Equipment costs to print labels--manual lines			$450	NA	NA	NA	NA	
Establishments using outside label printers	40%	40%	Equipment Costs ($ million), by Number of Lines [1]					
Switch to new outside label printer, add lot #s (10% of 40%) [4]	NA	4%	NA	NA	NA	NA	NA	NA
Move entire label operation in-house (2% of 40%)	NA	1%	NA	$0.8	$0.1	$0.1	$0.1	$1.1
Add small supplemental label, applied in-house (88% of 40%)	NA	35%	NA	$16.2	$2.7	$1.3	$1.2	$21.3
Man. line: switch to new outside label printer, add lot #s (20% of 40%)	8%	NA	NA(d)	NA	NA	NA	NA	NA
Man. line: move entire label operation in-house (75% of 40%)	30%	NA	$0.3	NA	NA	NA	NA	$0.3
Man. line: add small supplemental label, applied in-house (5% of 40%)	2%	NA	$0.0	NA	NA	NA	NA	$0.0
Establishments printing labels in-house with printing systems that do not accommodate variable information	0%	45%						
Modify entire label printing operation (60% of 45%)	0%	27%	$0	$25.6	$4.5	$3.7	$3.6	$37.4
Add small supplemental label, applied in-house (40% of 45%)	0%	18%	$0	$8.3	$1.4	$0.6	$0.6	$10.9
Establishments w/label printing systems accommodating var. data	60%	15%						
Modify label with existing printing equipment (100% of 15%)	NA	15%	$0	NA	NA	NA	NA	NA
Man. line: modify label w/existing equipment (100% of 60%)	60%	NA	$0.5	NA	NA	NA	NA	$0.5
Total Investment								$71.5
Total labor			$0	$15.1	$5.0	$4.1	$5.1	$29.3
Total O&M (10 percent of equipment cost) plus Labor								$36.5

Source: ERG Report, Table 4-7 (Ref. 1)

Note: Numbers may not sum due to rounding.

[1] From ERG Table 4-6. Numbers of establishments are from ERG Table 3-8, adjusted for the 3 percent of manufacturers who are assumed to be printing variable barcodes. These counts exclude small manufacturers assumed to be exclusively manufacturing excluded devices or who are assumed to be using UPCs exclusively.

[2] From ERG Table 4-5 and ERG assumptions (see text).

[3] Assumes a wage rate plus 29 percent fringe of $22.27 per hour (BLS, 2009) for inspectors in NAICS 339.

[4] Incremental costs for outside printer labels assumed primarily costs of coordination, which is passed through to labelers. See ERG Table 4-12.

Direct Marking.

The proposed rule would require manufacturers of implanted devices (devices intended to be left in the body continuously for 30 days or more) and devices intended for multiple uses (referred to as multiple-use devices) that require sterilization before each use to be permanently marked with a UDI. The proposed rule would also require stand-alone software devices to be directly marked.

Exceptions to Direct Marking of Devices.

The proposed regulation provides exceptions to the direct marking requirements. Exception criteria for devices apply as follows: when marking would interfere with the safety or effectiveness of the device; when a device cannot be marked because it is not technologically feasible to mark the device; when a device is intended to remain implanted continuously for a period of less than 30 days, unless the Commissioner determines otherwise in order to protect human health; when the device has been previously direct-marked; when the device is sold at retail and bears a UPC; and software that is not stand-alone software, but which is a component of a medical device.

Exceptions from direct marking devices are expected because of the size of the device, the difficulty in marking certain material, or to the lack of adequate surface space. We assume that if no machine-readable mark can technologically be applied to the device, then no easily readable plain-text UDI could be applied either. Thus, marking the device would not be technologically feasible. We further assume that easily readable does not mean "with magnification." With the diverse types of medical devices, we acknowledge that this conclusion may overly simplify the challenges some labelers would face when deciding how to directly mark devices. Because we lack detailed information about this issue, the agency requests

comments on the technological feasibility of direct marking, the costs of technologically feasible direct marking, and about the challenges direct marking would cause device labelers.

We estimate that 1,222 manufacturers and specification developers that listed either an implant or multiple-use device that might need to be directly marked; 517 establishments with multiple-use devices and 705 establishments with device implants. We assume that 75 percent of labelers of multiple-use devices and 80 percent of implant labelers currently directly mark their devices in some manner, and 20 percent of labelers that currently directly mark devices use barcodes. Of those that do not mark devices, 5 percent of multiple-use device labelers and 15 percent of implant device labelers are assumed to manufacture devices that would be exempt from direct marking (e.g., it is not feasible to mark the device, or direct marking would interfere with the safety and effectiveness of the device).

The proposed rule would require labelers to document the basis for any exception in the design history file, and to notify FDA of the first two exceptions. We estimate the documentation would require about 10 hours per exception. Using an average hourly wage cost of $75, the average cost of an exception would be $750 per exception.

Based on discussions with vendors of direct marking equipment and manufacturers of marked devices summarized in the ERG report, we estimated that about 132 establishments ((517 multiple-use establishments x 0.05) + (705 implant establishments x 0.15)) would incur costs to document exceptions to the direct marking requirement. Furthermore, these establishments would incur annual costs to document exceptions for new products. The number of initial exceptions per establishment is scaled up from one device for the smallest establishments to 50 devices for the largest establishments. In subsequent years, establishments might introduce an average of 0.3 new devices for the smallest establishments, up to an average

of 13 products for the largest establishments. The estimated 1-year costs for 132 establishments to document exceptions to the direct marking requirements would total about $0.5 million; annual costs to document exceptions for new products would be approximately $0.1 million.

Directly Marking Multiple-use and Implanted Devices:

Costs for Establishments that Currently Directly Mark Medical Devices.

Table 11 of this document presents the costs for software upgrades and redesign costs for establishments currently marking implants and multiple-use devices. We estimate that approximately 75 percent of the multiple-use establishments and 80 percent of the implant establishments currently mark their products; 20 percent of these establishments currently use barcodes. Thus, approximately 760 establishments that currently mark devices, but not with barcodes, would incur software and redesign costs ((517 multiple-use establishments x .75 currently marking x .80 not using barcodes) + (705 implant establishments x .80 currently marking x .80 not using barcodes)).

Establishments that currently mark their products, but not with barcodes, would incur software costs of $600 to add barcode capabilities to existing marking systems. This estimate assumes that space limitations would prevent directly marking with a plain text UDI and, therefore, overstates costs. The total cost for software upgrades for direct marking would equal about $0.5 million. Affected establishments would also incur costs to redesign current marks to accommodate the UDI. The redesign is needed to add a UDI, either in plain text or 2-D barcode format, to the existing mark. Redesign costs range from $1,250 per establishment for the smallest establishments to $75,000 for the largest establishments. These redesign costs are assumed the same as the costs to redesign the main packaging label, discussed in the Label

Redesign Cost Section of this document. Total one-time redesign costs would equal about $7.3 million.

In summary, establishments marking multiple-use devices would spend an estimated $3.7 million to upgrade software and redesign marks, and establishments marking implants would spend about $4.1 million to upgrade software and redesign marks. In total, about 760 affected establishments already marking devices, but not using barcodes, would spend about $7.8 million in one-time costs to conform to the direct marking provisions of the proposed rule.

Table 11.--Costs for Software Upgrades and Redesign Costs for Establishments Already Marking Devices (2010 dollars)

Establishment Size	Multiple-Use Item Establishments			Implant Establishments			Total Cost ($ million)
	Number	Assumed Baseline Compliance	Costs [1] ($ million)	Number	Assumed Baseline Compliance	Costs [1] ($ million)	
1-4	94	75%	$0.1	155	80%	$0.2	$0.3
5-9	67	75%	$0.1	108	80%	$0.2	$0.3
10-49	188	75%	$0.6	272	80%	$1.0	$1.6
50-99	58	75%	$0.4	75	80%	$0.5	$0.9
100-249	64	75%	$0.8	56	80%	$0.7	$1.5
250-499	28	75%	$0.8	27	80%	$0.9	$1.7
500+	18	75%	$0.8	13	80%	$0.6	$1.4
Total	517		$3.7	705		$4.1	$7.8

Source: ERG Report, Table 4-9 (Ref. 1).
Note: Numbers may not sum due to rounding.
[1] Software upgrades to print barcodes assumed to cost $600 for the 80 percent of establishments with direct marking equipment not currently applying barcodes. Redesign costs are shown in Table 13 of this document.

Directly Marking Multiple-use and Implanted Devices: Costs for Establishments that Currently Do Not Directly Mark Devices.

Table 12 of this document presents the costs for affected establishments that are not currently marking devices and that would need to purchase and install equipment. The number of affected establishments includes those that do not mark (25 percent of multiple-use establishments and 20 percent of implant establishments). These counts are adjusted to remove the number of establishments expected to file exceptions. The number of affected establishments

that would incur costs to install and operate direct marking equipment equals 138 ((517 multiple-use establishments x .25 currently not marking) - 26 multiple-use establishments filing exceptions) + (705 implant establishments x .20 currently not marking) - 106 implant establishments filing exceptions).

We anticipate that these establishments would likely choose CO2 lasers or yttrium aluminum garnet (YAG) lasers to directly mark devices. Costs would be about $12,000 for a CO2 laser and $55,000 for a YAG laser, plus engineering costs, equaling an estimated 75 percent of capital expenditures, for installation and costs for materials. Capital and installation costs for smaller establishments with one production line that purchase CO2 lasers would be about $21,000 ($12,000 x 1.75 engineering and installation x 1 line). We assume that YAG lasers would be used for all implanted products and in larger establishments. The capital cost for smaller establishments with one production line to purchase and install a YAG laser would be about $96,250 ($55,000 per unit x 1.75 engineering and installation x 1 line); costs are scaled up for larger establishments with greater equipment needs. For example, the largest establishments with 250 or more employees are judged to require 3-4 YAG lasers at $55,000 each, and 1-2 fully automated lasers at $150,000 each plus engineering and installation.

Table 12.--Costs to Install and Operate Direct Marking Equipment among Establishments Not Currently Marking (2010 dollars)

Establishment Size	Number of Lines [1]	Capital Costs Plus Installation [2]		Process Redesign [3]	Establishments Needing Equipment [4]		One Time Costs [5] ($ million)		Total One Time Costs ($ million)	Total Annual Costs [6] ($ million)
		CO2 Lasers	YAGs or High Speed Lasers		Multiple-Use Item	Implant	Multiple-Use Item	Implant		
1-4	1	$21,000	$96,250	$25,000	19	8	$0.5	$1.0	$1.4	$0.1
5-9	1	$21,000	$96,250	$25,000	13	5	$0.3	$0.7	$1.0	$0.1
10-49	1	$21,000	$96,250	$75,000	38	14	$0.9	$2.4	$3.3	$0.3
50-99	1	$21,000	$96,250	$100,000	12	4	$0.3	$0.7	$1.0	$0.1
100-249	2	NA	$192,500	$150,000	13	3	$2.6	$1.0	$3.5	$0.4
250-499	4-6+	NA	$640,938	$200,000	6	1	$3.6	$1.2	$4.8	$0.5
500+	4-6+	NA	$820,313	$250,000	4	1	$3.0	$0.7	$3.7	$0.4
Total					103	35	$11.1	$7.6	$18.7	$1.9

Source: ERG Report, Table 4-10 (Ref. 1).

Note: Numbers may not sum due to rounding.

[1] Assumptions about numbers of production lines from ERG Report, Table 4-7 (Ref. 1).

[2] Costs for the CO^2 laser on a per production line basis; costs for YAGs and high speed lasers are on a per establishment basis. Capital costs include engineering costs assumed at 75% of capital cost. Only smaller operations producing multiple-use items are assumed to use CO2 lasers due to high cost of materials. Costs for establishments with 250 or more employees include costs to install 3-4 YAG lasers at $55,000 each, and 1-2 fully automated lasers at $150,000 each. Implant establishments will only install YAGs or high speed lasers.

[3] Process redesign costs for implants only. Costs will vary widely, and we assume that costs will increase with establishment size, from $25,000 to $250,000 per establishment.

[4] Adjusting for the number of establishments applying for exception and assuming baseline compliance rates of 75 percent for multiple-use device establishments and 80 percent for implant establishments.

[5] One time costs include 40 hours per line to validate operations showing no health and safety issues.

[6] Annual costs assumed at 10 percent of one-time costs.

Process redesign costs for implant manufacturers range from $25,000 for small establishments with one production line to $250,000 for the largest establishments with multiple production lines. Furthermore, establishments that directly mark implants would incur one-time costs of $3,000 per production line (40 hours at $75 per hour) for a manager to validate operations and document that the safety of the devices has not been compromised. We estimated validation costs based on collecting supporting documentation from literature searches of similar devices or materials that have been previously marked without compromising safety. However, because of the complexities of direct marking certain devices, the agency requests comment on how industry would respond to validation requirements, including the cost of testing to demonstrate that direct marking would not interfere with the safety or effectiveness of the device. Moreover, we request comment from small labelers about the cost estimate and their expected response to this requirement. One-time costs of direct marking would be about $11.1 million for multiple-use devices and about $7.6 million for implanted devices, for a total of $18.7 million. Annual maintenance and operating costs would equal about 10 percent of the one-time investment in direct marking equipment, or about $1.9 million.

Costs for Stand-Alone Software Devices.

Stand-alone software devices would be required to have a UDI present on the startup page or in a menu, such as in the help menu under an "About * * *" selection. Because FDA has provided, at a minimum, 3 years between promulgation and implementation, and because software revisions are made frequently, the work to add the UDI in these locations within the software would be integrated into regular revision and update cycles. Most of the time needed to meet this requirement is for planning the implementation of UDI in general, and this has been accounted for in the Administration and Planning Cost Section of this document. Any additional

time needed to add the UDI to the software itself (while the startup page is being edited to contain a new version identifier or revision date) would be a negligible increment to the 30 to 720 hours allotted to the various size establishments to plan for UDI implementation. Although future software revisions would require new UDIs, these changes would be incorporated while other revisions were being made to the software. Moreover, because some software might be sold as a downloadable electronic file rather than as a packaged device, the traditional costs for relabeling (e.g. printing and materials) are somewhat overstated. Therefore, the cost of including a UDI in stand-alone software would be a negligible addition to costs already estimated for those establishments.

Total Costs for Directly Marking Medical Devices.

The one-time total estimated costs to directly mark multiple-use and implanted devices would be $27.0 million, with annual costs for operation and maintenance of about $2.0 million. Incremental costs for direct marking stand-alone software devices are assumed to be a negligible addition to costs already estimated for affected establishments. Because of uncertainty about current compliance and labeler response to the direct marking requirements, we request detailed comments from industry about the industry response and the one-time and annual incremental costs for direct marking medical devices and filing exceptions.

Label Redesign.

The proposed rule would require that, within 1 year, labelers modify the format of dates displayed on device labels. In addition, labelers of devices subject to the UDI requirements would need to add the UDI to device labels according to the implementation schedule described in the preamble of the proposed rule. Because the proposed rule would leave the remaining content of device labels unchanged, labelers may choose to coordinate the label redesign at the

establishment level. As the size of the establishment increases, the number of devices and production lines increases and the required effort increases.

Labels can be permanently attached on the device itself or displayed on the packaging. The cost estimates of the proposed requirement that the UDI be placed on the device label and device package assume that new levels of packaging are not needed. For example, shelf packs of class I devices containing identical multiples that are not individually packaged and labeled would only need to add the UDI to the shelf pack itself. However, device packages that contain other device packages would need different UDIs on the inner and outer device packages.

For the purpose of this analysis, we assume that no device labels have dates presented in the precise format that would be required by the proposed rule. Although labelers would have 1 year to redesign device labels, to avoid the cost of two label redesigns labelers would likely redesign their device labels to add sufficient space for the UDI in human-readable and AIDC format at the same time as they modify the date format. Labelers would print the UDI on the redesigned label at the date specified in their implementation plan. Although the number of labelers that include dates on their device labels is unknown, we conservatively anticipate that most device labels have some type of date printed on the label (e.g., expiration date or date of manufacture). Consequently, we estimate that labelers would incur one-time label redesign costs in the first year.

Table 13 of this document presents the estimated one-time costs to redesign device labels. As noted in the ERG report, these costs are estimated to range from $1,250 for establishments with 1 to 4 employees to $75,000 for establishments with more than 500 employees. For about 4,900 labelers that would redesign device labels in the first year, the total one-time costs would equal approximately $43.0 million. However, we note that these estimates

have a high degree of uncertainty (see the Uncertainty Section G). Consequently, we request detailed comment from industry on this estimate. In addition, we request comment from industry on whether the 1-year effective date for complying with date formats is sufficient or whether this requirement should coincide with the phase-in periods for the label to bear a UDI.

Table 13.--One-Time Cost to Redesign and Modify Device Labels [1] (2010 dollars)

Employment Size	Number of Establishments	Costs Per Establishment	Total One-Time Costs ($ million)
1-4	1,211	$1,250	$1.5
5-9	777	$2,500	$1.9
10-49	1,725	$5,000	$8.6
50-99	472	$10,000	$4.7
100-249	396	$20,000	$7.9
250-499	195	$50,000	$9.7
500+	113	$75,000	$8.5
Total	4,889		$43.0

Source: ERG Report, Table 4-11 (Ref. 1).
Note: Numbers may not sum due to rounding.
[1] Because no labelers are assumed to present label information in the precise format that would be required by the proposed rule, all labelers of non-excepted devices would need to redesign labels. We assumed that labelers of excepted devices would not incur costs to redesign labels. Labelers of devices sold at retail and labelers that currently use variable barcodes that would only be changing date formats.

Supplemental labels, larger labels, and new label printing technologies would increase the cost to produce device labels displaying the UDI. Using U.S. Census data on the value of materials consumed, we estimate that materials for labels, such as paper and ink, represent about 0.2 percent of all material costs, or $58.1 million annually. The increase in materials cost for affected device labels is estimated at 10 percent, or about $5.8 million annually.

Small establishments that choose to add manually a supplemental label would incur costs to affix the supplemental label. An estimated 38 establishments with fewer than 10 employees (2 percent of the 1,883 establishments in this size category) would each spend about $2,625 annually to add the supplemental label to their devices (125 hours x $21 per hour). For all of these labelers, annual incremental labor costs would be about $0.1 million ($2,625 per establishment x 38 establishments).

Finally, labelers would incur costs for the increased amount of time needed to coordinate print jobs with outside printing contractors. Both labelers and printing contractors would spend additional time to ensure proper printing of the variable portion of the UDI. Similar to other labeling costs, the time needed to coordinate label printing increases with the size of the establishment. An estimated 271 establishments would continue to use outside contractors to print labels with the UDI. We estimate that the total time needed to coordinate with an outside printer would be 50 hours for establishments with 1 to 9 employees, 100 hours for establishments with 10 to 49 employees, 200 hours for establishments with 50 to 99 employees, 800 hours for establishments with 100 to 249 employees, 1,200 hours for establishments with 250 to 499 employees and 2,400 hours for establishments with 500 or more employees With a wage cost of $75 per hour, the annual cost for 271 affected establishments to coordinate outside printing would equal about $2.6 million (50 hours x $75 per hour x 151 establishments +100 hours x $75 per hour x 86 establishments + 200 hours x $75 per hour x 18 establishments + 800 hours x $75 per hour x 11 establishments + 1,200 hours x $75 per hour x 5 establishments + 2,400 hours x $75 per hour x 0 establishments).

The total annual incremental costs to redesign and modify device labels to add the UDI and change the date format would equal about $8.5 million: $5.8 million for additional materials, $0.1 million for additional time to apply supplemental labels, and $2.6 million for additional time to coordinate printing. Because of uncertainty about labeler response and possible current compliance, we request comment from industry about the one-time and annual incremental costs for redesigned medical device labels.

Software and Data Integration.

The proposed rule would require integration of the UDI into existing information systems and installation of barcode printing software. Because information technology performs many functions in an organization, medical device firms with multiple establishments would coordinate decisions on information technology systems at the firm level rather than at the establishment level. Firms would need to add UDI barcodes to device labels, to incorporate the UDI into device related records and correspondence with FDA, and to manage the device data required for submission to the GUDID. The one-time investment in software and related measures include the costs to do the following: (1) Purchase the software packages or software licenses needed to print barcodes; (2) add the UDI to existing information systems; (3) install, test, and integrate the barcoding software with existing information technology systems; (4) validate that software meets FDA software validation requirements; and (5) train employees.

As of March 2010, there were 5,566 domestic initial labeler firms in the FDA registration and listing database (see Table 6 of this document). When these firms were distributed by type as shown in Table 6, approximately 210 firms were double counted because they owned more than one type of establishments (e.g., a firm could own a manufacturing establishment and a specification development establishment). Adjusting for double counting, we estimated that 1,239 firms exclusively label excepted devices. In addition, an estimated 85 firms have establishments that currently use variable barcodes and an estimated 95 firms have establishments that exclusively label over-the-counter devices sold at retail. These firms have already integrated identifiers and labeled device data into their information systems and have software systems in place that would comply with the proposed rule. Consequently, we anticipate that any regulatory costs for changes to software that would be required by the proposed rule would be negligible for these firms. In contrast, we anticipate that the remaining

3,937 firms (5,566 firms - 210 double-counted firms- 1,239 firms with excepted devices - 180 firms that currently print UDI-compatible identifiers) that do not currently comply with the UDI requirements of the proposed rule would incur one-time and annual costs for investment in information technology and employee training.

An estimated 1,162 small firms operate one manual production line and could readily adapt their information systems. In some cases, firms would manually track barcodes and device information. However, to conform to the software validation requirements of the quality system regulations, we assume that all of these small firms would need to purchase a software package that includes FDA validation tools. Once installed and tested, these firms would require no further validation of their information systems. The one-time costs for small firms with fewer than 5 employees to purchase, install and test software would total about $800, including $200 for the software.

Larger firms with numerous medical devices might need to coordinate multiple production lines and multiple establishments. As firm size increases, the complexity of information management systems increases and firms would require more sophisticated barcode software packages and multiple software licenses. As a result, the costs of software and software licenses increase as the size of the firm increases. The estimated costs of software range from about $7,500 for firms with 5 to 19 employees to $130,000 for firms with 1,000 or more employees.

Integrating device UDIs into existing management information systems requires a certain level of effort to install new software, verify, test and validate that the new software functions as expected, and to make any changes to existing systems. Firms would also need to test and validate any software that would be used to submit device data to the GUDID. Similar to other

costs, the level of effort to integrate UDIs increases as the size of the firm increases. Moreover, adding barcode software to complex management information systems would require additional time to test and validate the software. Some large firms have integrated enterprise resource planning (ERP) systems; a complex computer system that links all of the firm's functions in a standardized enterprise-wide environment to control the flow of information within the organization and control the flow of data with outside sources. Such systems handle asset management, financial and human resources, production, design, sales and marketing. Large firms that have fully integrated ERP systems would require extensive testing and validation to ensure that modifying their systems to accommodate the UDI and the associated device data would have no unforeseen effects on other aspects of the firm's information systems. Because these types of systems are designed to control the flow of information, validation would be of primary importance to the functioning of ERP systems. Consequently, there are considerable cost differences for validation between firms with ERP systems and similar-sized firms without ERP systems. As shown in Table 14 of this document, the one-time costs to purchase, install and integrate, verify and test, and validate software range from $9,500 for firms with 5 to 19 employees to $780,000 for firms with more than 1,000 employees.

Firms would also need to train employees to use the barcoding software. Similar to the investment in software, the number of employees to train increases as the size of the firm increases. For the initial employee training, firms would spend from $100 for the smallest firm (fewer than 5 employees) to train 1 person, to $125,000 for the largest firms (more than 1,000 employees) to train 1,250 people. We consider initial employee training as a one-time cost of the proposed rule.

Including the initial training costs, the total one-time costs for software associated with the UDI range from $900 for firms with fewer than 5 employees to $905,000 for firms with 1,000 or more employees. Table 14 of this document presents a detailed description of the anticipated one-time software-related costs by size of the firm.

Once the software has been installed and shown to function as expected, firms would still need to maintain and validate the software on an annual basis. Furthermore, some on-going training of employees would be needed. These annual costs are shown in table 14 of this document and range from $61 for firms with fewer than 5 employees to $94,650 for firms with 1,000 or more employees.

Table 14.--Per Firm Software Associated Costs for UDI Compliance by Initial Labelers (2010 dollars)

Cost Element	Employment Size by Firm (Number of Employees)						
	1-4 [1]	5-19	20-99 [2]	100-199 [3]	200-499 [4]	500-999 [5]	1000+ [5]
One-Time Costs and Initial Employee Training							
Software	$200	$7,500	$15,000	$30,000	$52,500	$75,000	$130,000
Installation, Integration, Verification & Testing	$600	$1,000	$5,000	$25,000	$45,000	$150,000	$250,000
Validation	$0	$1,000	$2,000	$3,500	$55,000	$250,000	$400,000
Training [6]	$100	$1,000	$5,000	$17,500	$37,500	$75,000	$125,000
Per Firm One-Time Costs	$900	$10,500	$27,000	$76,000	$190,000	$550,000	$905,000
Annual Costs							
Training (25% of initial training)	$25	$250	$1,250	$4,375	$9,375	$18,750	$31,250
Validation (10% of one-time validation)	$0	$100	$200	$350	$5,500	$25,000	$40,000
Software Maintenance Contract (18% of one-time software)	$36	$1,350	$2,700	$5,400	$9,450	$13,500	$23,400
Per Firm Annual Costs	$61	$1,700	$4,150	$10,125	$24,325	$57,250	$94,650

Source: ERG Report, Table 4-13 (Ref. 1).
Note: Numbers may not sum due to rounding.
[1] Establishments have limited production; includes purchase of simple software, simple testing and no validation.
[2] Includes one UDI server, one establishment and one production line.
[3] Requires more testing than firms with 20-99 employees; includes two software licenses.
[4] 75 percent of firms purchase two software licenses; 25 percent of firms have complex ERP systems requiring more expensive software and more time-consuming integration.
[5] Assumes more complex installation requirements associated with ERP systems with more establishments to consider.
[6] Per employee cost of training equals $100.

The industry totals for the one-time and annual costs for software and related costs are shown in table 15 of this document. An estimated 3,937 firms would spend about $174.0 million in one-time costs and about $21.1 million in total annual costs. Because software is a major cost of the proposed rule, we request detailed comment from industry on our estimate and about any pertinent experiences they may have integrating new identifiers into their software systems.

Table 15.--Software Associated Costs for UDI Compliance by Initial Labelers (2010 dollars)

	Employment Size by Firm (Number of Employees)							Total
	1-4	5-19	20-99	100-199	200-499	500-999	1000+	
Number of Firms [1]	1,162	1,403	980	172	96	36	89	3,937
One Time Costs								
Per Firm ($)	$900	$10,500	$27,000	$76,000	$190,000	$550,000	$905,000	
Industry Total ($ mil)	$1.0	$14.7	$26.5	$13.1	$18.2	$20.0	$80.5	$174.0
Annual Costs								
Per Firm ($)	$61	$1,700	$4,150	$10,125	$24,325	$57,250	$94,650	
Industry Total ($ mil)	$0.1	$2.4	$4.1	$1.7	$2.3	$2.1	$8.4	$21.1

Source: ERG Report, Table 4-13 (Ref. 1) and Table 14 of this document.
Note: Numbers may not sum due to rounding.
[1] All firm counts are adjusted to account for: (a) 85 firms printing variable barcodes at this time, (b) 1,334 firms only labeling excepted devices or only labeling over-the-counter devices sold at retail, and (c) 210 firms that were double counted when breaking out firms by establishment types owned (see Section 3 of the ERG Report).

Recordkeeping and Reporting.

In addition to proposing that the UDI be displayed on the labels of medical devices, the proposed rule would require that labelers add the UDI to existing records and to include the UDI in reports and submissions to FDA.[2] For its part, FDA will include the UDI in public health communications, such as public health notifications, recall alerts, cease distribution and notification orders. One aspect of plan development includes the review of SOPs to ensure the requirements of the proposed rule are met. During the review of SOPs, labelers would identify and modify the procedures related to recordkeeping. Furthermore, we expect that integrating the UDI into software systems would include adding the UDI to records. Consequently, the costs of

[2] The UDI must also be included in reports of adverse events. We assume that the incremental time needed to add the UDI to adverse event forms would be negligible.

recordkeeping are largely captured in the administrative, direct marking, and software cost components. We assume that any additional effort would be minimal.

Global Unique Device Identification Database (GUDID)

Labelers of devices required to display a UDI would also need to submit certain data to the GUDID. We anticipate that these costs would be incurred on an establishment basis. Only establishments that exclusively label excepted devices would not be required to submit data to the GUDID. All other labelers would incur some costs to submit required device data to the GUDID.

Much of the required GUDID data is currently included on the device label and thus would be readily accessible to labelers. Most device data would be submitted only once, when the device labeled with the UDI enters commerce. Prior to data submission, however, labelers would need to gather and prepare the data for submission. We anticipate that a manager would perform this task. For small establishments with 1 to 9 employees, it would take a manager about 3 hours and cost about $225 (3 hours x $75 per hour) to prepare the GUDID data. For establishments with 10 to 49 employees, a manager would spend about 6 hours at a cost of about $450 (6 hours x $75 per hour). Because larger establishments with 50 or more employees would likely have incorporated all of the GUDID required data into their management information systems when they integrated the UDI, we expected that the cost to gather UDI data for submission to the GUDID would be negligible for these establishments.

The proposed rule would require that labelers electronically submit UDI data to the GUDID. In most cases, labelers currently submit registration and listing data electronically to the FDA Unified Registration and Listing System (FURLS). Therefore, we anticipate that labelers would have little difficulty with the electronic submission of device data to the GUDID.

Labelers would either enter and validate data submission via a web page, or convert data to the SPL format for uploading and validate the uploaded data. We assume that small labelers will likely use a web-based form to submit data. To submit and validate data, it would cost about $225 for an establishment with 1 to 9 employees (3 hours x $75 per hour) and $300 for an establishments with 10 to 49 employees (4 hours x $75 per hour). Medium and large establishments would incur a cost of about $100 to convert their data to SPL format and incur labor costs of about $338 (4.5 hours x $75 per hour) to upload the SPL file directly to the GUDID and to validate the data.

The one-time costs to gather and submit GUDID data to FDA would equal $2.7 million, or about $0.9 million ($450 per establishment x 1,988 establishments) for very small establishments with 1 to 9 employees, about $1.3 million ($750 per establishment x 1,725 establishments) for small establishments with 10 to 49 employees, and $0.5 million ($438 per establishment x 1,176 establishments) for medium and large establishments. Once submitted, data for a particular version or model would normally remain unchanged. Should changes be necessary, however, both the web page and the SPL format would allow labelers to rapidly edit and resubmit their data. To account for possible minor changes, we estimate that a manager in each of the affected establishments would spend up to one hour annually to modify the GUDID data. These total annual costs would equal about $0.4 million ($75 per hour x 1 hour x 4,889 establishments). We request detailed comment from industry on these cost estimates.

2. Costs for Repackagers and Relabelers

Repackagers and relabelers would incur similar types of compliance costs as initial labelers, but have less complex systems and thus lower per firm and per establishment costs than initial labelers. For these labelers, we assume that the costs for direct marking of devices would

be limited to costs of noting exceptions. Because we assume that no repackagers or relabelers only handle excepted devices, for this analysis we use the establishment and firm counts from tables 5 and 6 of this document (1,310 establishments and 1,212 firms.) Total one-time costs for repackagers and relabelers would be $34.3 million and annual costs would be $5.2 million. Similar to initial labelers, the major one-time cost components for repackagers and relabelers would be $13.1 million for software and training, and $11.3 million for equipment. Other one-time costs include $3.3 million for administration and plan development, $1.6 million to participate in a UDI system operated by an issuing agency, $4.6 million for label redesign, and $0.4 million for recordkeeping and reporting. Annual costs equal $3.1 million for equipment, $1.0 million for incremental label materials, $1.1 million for software including training, and $0.05 million for recordkeeping and reporting. Over 10 years, the total annualized costs would be $10.1 million with a 7 percent discount rate and $9.2 million with a 3 percent discount rate.

3. Efforts to Reduce the Scope and Regulatory Burdens for Certain Low Risk Devices

In this section, we adjust our establishment counts to incorporate the Agency's efforts to reduce the burden for labelers of class I devices and labelers of over-the-counter devices sold at retail. Specifically, labels of class I devices would not be required to bear the variable production identifier portion of the UDI. In addition, labels of a class I device that FDA has by regulation exempted from the GMP requirements and any over-the-counter device sold at retail, including such devices when delivered directly to hospitals and other health care facilities, would not be required to bear a UDI. However, the labels of class II and class III devices still would be required to include variable production information portion of the UDI. Direct marking requirements would remain unchanged.

The overall effect of these provisions is to apply the UDI requirements to fewer devices and labelers. Our initial counts of domestic establishments from FDA's registration and listing data are presented in table 5 of this document. For this section, we estimate the count of establishments that would be subject to reduced compliance costs because they label only class I or unclassified devices. Our estimate of the number of class I establishments includes those establishments that handle unclassified devices. Table 16 presents the number of class II and class III establishments, and the number of class I establishments. We separate the count of class I establishments into establishments that exclusively handle class I devices exempt from GMP requirements, and establishments that handle some non-GMP exempt devices.

Table 16—Distribution of Establishments by Device Type

Type of Labeler	Number of Establishments Labeling Class II and Class III Devices [1]	Number of Establishments Labeling Class I or Unclassified GMP Exempt Devices Only [2]	Number of Establishments Labeling Class I or Unclassified Non-GMP Exempt Devices [3]	Total Number of Establishment
Manufacturer	3,088	399	1,414	4,901
Reprocessor	13	1	7	21
Specification Developer	700	150	496	1,346
Total Initial Labelers	**3,801**	**550**	**1,917**	**6,268**
Repackagers and Relabelers	481	129	700	1,310
All Labelers	**4,282**	**679**	**2,617**	**7,578**

Source: ERG Report, Table 6-23 (Ref. 1)

[1] The UDI is required to include a device identifier and a production identifier.

[2] Devices from these establishments would be covered by general exception 801.30(a)(2); devices would not be required to bear a UDI.

[3] Devices from these establishments would be covered by general exception 801.30(c); the UDI is not required to include a production identifier

We identified 2,467 initial labeler establishments (550 + 1,917) labeling class I devices. Similar to the adjustments described at the beginning of this Cost Section, establishments would be removed from these counts if the device is subject to the general exceptions not specific to the

class I exception. A final adjustment was made to remove the number of establishments that are assumed to already include production information in the UDI[3].

These adjustments reduce the number of initial labeler establishments labeling class I devices from 2,467 to 1,841[4], including 1,430 initial labelers that exclusively handle non-GMP exempt class I devices, and 410 initial labelers that exclusively handle class I devices exempt from the GMP regulations. These labelers would incur a subset of the costs discussed in sections F1 of this document. For example, labelers of class I non-GMP-exempt devices would not incur the costs to implement the production identifier portion of the UDI and labelers of class I GMP-exempt devices would not incur the costs to implement the UDI, but would need to read the rule.

Labelers of class II and class III devices not covered by any of the general exceptions would incur the costs to comply with the full UDI requirements. Compared to the counts shown in table 8, only 2,836 initial labeler establishments (4,677 – 1,841) would need to develop a full UDI implementation plan under the proposed rule. Similarly, only 481 repackager or relabeler establishments (1,310 – 829) would need to develop a full UDI implementation plan under the proposed rule. See section 6.6 of the ERG report for more detail.

4. Cost of the Proposed Rule to Labelers with Simplifying Assumption

Table 17 summarizes the total costs of the proposed rule for all domestic labelers under the assumption of immediate implementation (i.e., assuming no phase-in). We use this simplifying assumption to permit comparisons with the alternatives listed below. The total one-time costs of the proposed rule would be $292.8 million and annual costs would be $46.7 million. The total annualized costs would be $88.4 million per year at a 7 percent discount rate over 10 years and $81.0 million per year at 3 percent.

[3] We did not adjust the counts of repackager and relabeler establishments in sections F2.
[4] Numbers are rounded and may not sum.

Table 17.--Total First-Year, Annual and Annualized Costs of the Proposed Rule for All Labelers [1,2] (2010 dollars)

Cost Element	First-Year ($ million)	Annual ($ million)
Labeling and Database Requirements		
Administration and planning	$37.1	NA
Barcode registration	$2.0	NA
Equipment and other investments	$47.5	$22.6
Incremental label materials and labor	NA	$7.6
Label redesign	$47.6	NA
Software (with training)	$128.7	$14.2
Recordkeeping and Reporting (GUDID)	$2.9	$0.4
Total Labeling and Database Requirements	$266.0	$44.7
Direct Marking		
Implants	$12.0	$0.8
Multiple-use devices	$14.9	$1.1
Total Direct Marking	$27.0	$2.0
Total--All Cost Elements	$292.8	$46.7
	Annualized Costs ($ million)	
First-Year Costs, annualized at 7 percent over 10 years	$41.7	
Total Annualized Costs, with 7 % annualized 1st- Year Costs	$88.4	
First-Year Costs annualized at 3 percent over 10 years	$34.3	
Total Annualized Costs, with 3% annualized 1st-Year Costs	$81.0	

Source: ERG Report, Table 6-41 (Ref. 1)
Note: Numbers may not sum due to rounding.
[1] The GMP-exempt exclusion cost savings is not fully reflected in administration and planning costs. The cost savings shown reflect a cost savings for these establishments for reading and implementing a static barcoding requirement (the administrative and planning time is assumed to be half of that for planning for a variable barcode requirement). However, GMP-exempt establishments are expected to incur costs only to read and determine they are not affected by the proposed rule. This task is less time intensive than a task that includes implementation of static barcoding requirements.
[2] Includes the GUDID cost savings for establishments exclusively handling devices sold at retail that would be excepted under section 801.30(a)(1).

5. Costs of the Proposed Rule to Labelers Under FDA's Proposed Implementation Schedule

The domestic industry costs presented in table 17 of this document treat all one-time costs as occurring in the first year. However, the proposed effective dates would allow industry up to 7 years to phase in requirements. This section presents costs in the year they would be incurred according to the proposed implementation schedule. Therefore, this section best describes the total costs of the proposed rule for labelers.

The effective dates after publication of a final rule for medical devices to bear a UDI on the label are:

Class III devices, one year,

Class II devices, three years, and

Class I devices and devices not classified into class I, II, or III, 5 years.

The effective dates for devices that must be directly marked allow for two additional years, depending on the regulatory class of each device.

By linking FDA's product code database, which provides the class of the devices for each product code, with the registration and listing data, we created a count of domestic labelers by highest class of device. This allows us to assign the one-time and recurring costs (shown in table 17) on the basis of the percentage of establishments with devices in each device class. For this analysis, labelers are only counted once. For example, if a labeler handled class I and class III devices, this labeler is added to the count of establishments with class III devices, but not added to the count of establishments with class I devices.

Using this approach, we find that about 6 percent of affected establishments would come into compliance in the first year--establishments that label class III devices but may also label class II, class I and unclassified devices. Another 51 percent that label class II devices (and also class I and unclassified devices, but not class III devices) would comply in year 3, and the remaining 43 percent that label only class I and unclassified devices comply in year 5. Direct marking costs are assumed to occur in year 3 for implant devices and in year 7 for multiple-use devices. In addition, all labelers would be affected by the 1-year effective date to change date format on device labels and incur the one-time labeling costs in the first year.

Table 18 of this document presents undiscounted regulatory costs for domestic labelers and the present value of these costs over a 10-year time horizon with a 7 percent discount rate and a 3 percent discount rate. As illustrated, total present value of compliance costs to domestic

labelers over a 10-year timeframe would equal about $500 million with a 7 percent discount rate and about $572 million with a 3 percent discount rate.

Table 18.--The Impact of the Staggered Effective Dates on the Regulatory Costs to Domestic Labelers Over a 10-Year Time Horizon (2010 dollars)

	Undiscounted Regulatory Costs of Proposed Rule by Type of Cost ($ mil)						Present Value with Discount Rate ($ mil) [1]
	All Cost Components Except Label Redesign by Highest Device Class			Label Redesign in 1 Year	Total Cost by Year		
Year	Class III [2]	Class II	Class I [3]	All Classes		7%	3%
1	$20.7			$55.2	$75.9	$75.9	$75.9
2	$3.8			$7.6	$11.3	$10.6	$11.0
3	$16.2	$179.2		$7.6	$203.0	$177.3	$191.3
4	$4.6	$32.4		$7.6	$44.6	$36.4	$40.8
5	$4.6	$32.4	$16.8	$7.6	$61.4	$46.9	$54.6
6	$4.6	$32.4	$0.1	$7.6	$44.8	$31.9	$38.6
7	$4.6	$32.4	$15.6	$7.6	$60.3	$40.2	$50.5
8	$4.6	$32.4	$1.3	$7.6	$45.9	$28.6	$37.3
9	$4.6	$32.4	$1.3	$7.6	$45.9	$26.7	$36.2
10	$4.6	$32.4	$1.3	$7.6	$45.9	$25.0	$35.2
Total for Year 1 to Year 10					$639.0	$499.4	$571.5
Annualized Total Over 10 years ($ mil)						$66.5	$65.0

[1] Present values are calculated for each year at the beginning of the period. Present value adjusts for the time value of money with a 7 percent or 3 percent discount rate (i.e., costs incurred in future years have a lower present value than costs incurred in year 1).
[2] Includes the costs for direct marking of implants.
[3] Includes the costs for direct marking of multiple-use devices.

6. Cost to Issuing Agencies

After reviewing the publicly-available material on the websites of two existing organizations currently performing functions similar to those of an issuing agency under the proposed rule, we concluded that these organizations currently have most of the information and policies in place that FDA would be required for FDA accreditation. To become an issuing agency, managers would spend about 80 hours to prepare and submit their initial application to FDA. With an hourly wage of $75 including benefits, the one-time cost of the application would

equal $6,000 for each organization. Assuming that these two existing organizations submit applications, initial one-time application costs total $12,000 ($6,000 per organization x 2 organizations). Application renewals would require about 20 hours and cost $1,500 (20 hours x $75 per hour) for each organization, for a total of $3,000 in recurring application renewal costs.

Because organizations accept significant legal responsibilities when they become issuing agencies for FDA, we assumed that each organization might spend up to $250,000 in the first year for its executive and legal staffs to ensure that the organization and the interests of its existing members would be sufficiently protected. Furthermore, in subsequent years, each issuing agency might incur about 10 percent of its initial costs for on-going executive and legal reviews, or $25,000 annually. For the two existing organizations currently performing functions similar to those of an issuing agency under the proposed rule, one-time review would therefore cost $500,000 and annual review would cost $50,000.

Once an organization becomes an issuing agency for FDA, it would need to inform its members about any requirements specific to FDA and whether and how their system might change to conform to the requirements of the proposed rule. This would take an estimated 80 hours in the first year and cost $6,000 (80 hours x $75 per hour) for each organization, or a total of $12,000.

In addition, to maintain accreditation, an issuing agency would have to submit a list of their labelers directly to FDA. To accomplish this, an issuing agency would likely modify its software system. We estimated that each organization would need about 20 hours for a software engineer to initially automate data collection of the required labeler information and about 12 hours annually for a manager to maintain the list. With an hourly wage rate of $125 including benefits, it would cost about $2,500 (20 hours x $125 per hour) in the first year for a software

engineer to make changes. With an hourly wage rate of $75 including benefits, it would cost about $900 (12 hours x $75 per hour) annually for a manager in each organization to maintain the list of labelers.

The total initial cost for the two existing organizations currently performing functions similar to those of an issuing agency under the proposed rule would equal about $0.5 million ($12,000 to apply with FDA + $5,000 to modify the software system + $12,000 to inform existing members + $500,000 for executive and legal review). Annual costs would equal about $0.1 million ($3,000 to renew the application + $1,800 to maintain the list of labelers + $50,000 for executive and legal review).

In addition to these two organizations, there may be other nonprofit organizations or State government agencies that decide to apply to become an issuing agency. We assume that the costs estimated for the two existing organizations would apply to any other organization that applies to FDA to become an issuing agency.

7. Cost to FDA for the GUDID

We anticipate that contractors and FDA personnel would participate in the development of a separate database for UDI data. The GUDID would accept electronic submission of UDI-related device data, generate standard reports, and allow queries of publicly-available information. As shown in table 19 of this document, FDA estimates that it would take about 15,100 hours of contractor and FDA personnel time to develop and launch the GUDID. With an average hourly wage of $103, the one-time cost to develop and launch the GUDID would equal about $1.6 million (15,100 hours x $103 per hour). Annualized over 10 years, start-up costs for the GUDID equal about $0.2 million with either a 3 percent discount rate or a 7 percent discount rate. Moreover, once the database is operational, FDA expects it will take about 18,100 hours

each year to run and maintain the database at an estimated cost of about $1.9 million annually. Thus, we estimate that, over 10 years, the total annualized cost of the GUDID to FDA would equal about $2.0 million with a 3 percent discount rate and $2.1 million with a 7 percent discount rate.

Table 19.--Level of Effort to Develop the GUDID (2010 dollars)

Type of Activity	Hours	Cost ($ million)
One-Time Effort to Develop and Deploy the GUDID		
Requirements and specifications	2,100	$0.2
Screen and report mockups	1,500	$0.2
Web, database, and form development	2,000	$0.2
Testing and revisions	2,000	$0.2
FDA review, revision, and clearance (3FTE)	5,200	$0.5
Initial outreach/training	500	$0.1
Initial deployment	1,800	$0.2
Total One-Time Start-Up Costs	15,100	$1.6

Source: FDA Estimate.
Note: Numbers may not sum due to rounding.

The ERG report contains a lower estimate, which was built upon the assumption that FDA would add a new UDI module to the existing FURLS (i.e., the FDA Unified Registration and Listing System). We expect, however, that the GUDID would have more features than an add-on module to the existing FURLS.

8. Impact on Foreign Trade

The Executive Order directs us to consider the possible impacts of regulations on the well-being of the American people. Foreign labelers could face regulatory costs similar to the regulatory costs estimated for domestic labelers. However, we lack information to predict how foreign compliance costs might impact the price and availability of medical devices in the United States and affect the well-being of the American people. Therefore, in this section we include a qualitative discussion of foreign trade in medical devices and possible responses of trading partners to the proposed rule.

We used data on the value of imports to the United States and exports from the United States of medical devices to assess the impact of the proposed rule on foreign trade. Annual trade data is available for most of the medical device manufacturing categories affected by the proposed rule, including NAICS codes 339112 (surgical and medical instrument manufacturing), 339113 (surgical appliance and supplies manufacturing), 334510 (electromedical and electrotherapeutic apparatus manufacturing), 334517 (Irradiation apparatus manufacturing), 339115 (ophthalmic goods manufacturing), and 339114 (dental equipment and supplies manufacturing). Table 20 of this document shows that the annual value of trade (imports plus exports) in these medical device manufacturing industries totals more than $60 billion. The export data includes some freight, insurance and other charges that are excluded from the import data.

Table 20.--United States Imports and Exports of Selected Medical Devices, 2007-2009 ($ million) [1]

NAICS CODE	2007		2008		2009	
	Imports	Exports	Imports	Exports	Imports	Exports
339112	$8,694.4	$8,816.7	$9,138.5	$9,979.4	$9,004.1	$10,038.7
339113	$7,072.9	$6,701.2	$9,007.5	$7,397.9	$8,568.4	$7,686.3
334510	$6,727.7	$7,206.9	$7,216.5	$8,070.4	$6,986.3	$8,094.5
334517	$3,574.2	$3,060.6	$3,721.1	$3,343.1	$3,097.2	$3,235.5
339115	$3,198.1	$1,340.1	$3,265.2	$1,396.0	$3,059.7	$1,291.3
339114	$1,187.9	$1,118.1	$1,278.7	$1,214.0	$1,249.2	$1,166.1
Total	$30,455.3	$28,243.6	$33,627.6	$31,400.9	$31,964.9	$31,512.4

Source: United States International Trade Commission, Interactive Tariff and Trade DataWeb; http://dataweb.usitc.gov (Ref. 2).

[1] In current dollars for the year reported.

A breakdown of the 2007-2009 trade data by country shows that almost every country in the world ships medical devices to the United States, with a small number of countries accounting for a large proportion of the value of medical device imports. Nevertheless, imports from about 130 countries account for about 3 percent of the $32.1 billion total average annual value of imports from all countries in the world, or $1.1 billion in import value.

Table 21 of this document shows that the top ten countries for imports of medical devices to the United States account for about 75 percent of the total average annual value of imports. The top 4 countries account for over 50 percent of the value of imports. Mexico has the largest share of imports, accounting for 15 percent of the total average annual imports. Ireland has a 14 percent share of total average annual imports and Germany has a 13 percent share of total average annual imports. China accounts for 10 percent of the value of total average annual imports.

Table 21.--Top Ten Countries Shipping Medical Devices to the United States by Share of Total Average Annual Import Value[1,2]

Country	Value of Imports 2007-2009 ($ billion)	Average Annual Value of Imports ($ billion)	Share of Total Average Annual Imports
World Total	96.2	32.1	100%
Mexico	14.1	4.7	15%
Ireland	13.1	4.4	14%
Germany	12.4	4.2	13%
China	9.8	3.3	10%
Japan	6.1	2.0	6%
Switzerland	4.5	1.5	5%
United Kingdom	3.3	1.1	3%
Italy	2.8	0.9	3%
Malaysia	2.7	0.9	3%
France	2.6	0.9	3%
Total Share of Imports for Top Ten Countries			75%

[1] Source: U.S. Census Bureau, International Trade Statistics. Based on aggregate data for NAICS 339112, 339113, 339114, 339115, 334510. 334517. http://censtats.census.gov/naic3_6/naics3_6.shtml (Ref. 3).
[2] In current dollars for the year reported.

Trade data shows that medical devices from the United States are exported throughout the world. Similar to imports of medical devices, a small number of countries receive the majority of medical devices exports, based on the value of exports. Table 22 of this document shows the top ten countries that purchase U.S. exports of medical devices. These countries account for approximately two-thirds of the total average annual value of medical device exports.

The top countries receiving medical devices from the United States are Japan, the Netherlands and Canada each receiving at least 10 percent of the total average annual value of exports.

Table 22.--Top Ten Countries Receiving Medical Devices from the United States by Share of Total Average Export Value [1,2]

Country	Value of Exports 2007-2009 ($ billion)	Average Annual Value ($ billion)	Share of Total Average Annual Exports
Japan	12.2	4.1	12%
Netherlands	11.0	3.7	10%
Canada	10.4	3.5	10%
Germany	9.0	3.0	9%
Belgium	6.2	2.1	6%
Mexico	5.7	1.9	5%
United Kingdom	4.8	1.6	5%
France	4.1	1.4	4%
Australia	3.7	1.2	3%
China	3.4	1.1	3%
Total Share of Exports for Top Ten Countries			67%

[1] Source: U.S. Census Bureau, International Trade Statistics. Based on aggregate data for NAICS 339112, 339113, 339114, 339115, 334510. 334517.
http://censtats.census.gov/naic3_6/naics3_6.shtml (Ref. 4).
[2] In current dollars for the year reported.

As noted previously in this document, the total value of shipments for all device manufacturing industries equaled about $117 billion in 2007 (table 3 of this document). The data in table 23 of this document shows that imports and exports each represent about one-fourth of the value of domestic production of these medical devices manufacturers. This percentage demonstrates the importance of international trade to the medical device industry.

Foreign producers.

About one-half of the registered establishments that would be considered labelers and affected by the proposed rule are located in countries other than the United States. Table 23 of this document shows a distribution of these approximately 7,100 foreign labeler establishments by the type of labeling activity. This list was generated using the same methodology used to count the number of affected domestic labelers.

Table 23.--Number of Foreign Registered Establishments Considered Labelers under the Proposed Rule[1]

Type of Labeler	Foreign Registrants	Total Registrants	Percentage of Total Registrants
Manufacturers	6,492	11,393	57%
Reprocessors	3	24	13%
Specification Developers	276	1,622	17%
Relabelers and Repackagers	320	1,630	20%
Total	7,091	14,669	48%

[1] Source: ERG Report (Ref. 1).

We lack data on the structure of the foreign medical device industry, the size distribution of foreign establishments and firms, the proportion of foreign output exported to the United States, and the complexity of foreign medical device manufacturing facilities; data that would allow us to predict likely responses of foreign labelers to the proposed rule and likely changes in the cost of imported medical devices. However, the OECD publishes country data on relative comparative advantage (RCA) by type of industry. Economic theory predicts that with international trade, countries will employ resources in industries where they can efficiently produce goods. RCA gives us an indication of the degree of specialization of a particular industry in the global economy. Table 24 of this document presents a list of countries with medical, precision, and optical instrument manufacturing that have RCA values exceeding one; a value that indicates specialization in the industry. This suggests that the medical device industry has developed as an important sector of the economy of these countries. Moreover, along with the United States, table 24 of this document includes some countries such as Mexico, Germany, Ireland, Japan, and the Netherlands that are among our top ten trading partners of medical devices. Although uncertain, the cross trade in medical devices among countries with a specialization in medical device manufacturing suggests that the foreign and domestic medical device industries have developed similar standards and practices.

Table 24.--OECD Measure of Specialization of the Medical, Precision and Optical Instrument Manufacturing Industry by Country

Country	Revealed Comparative Advantage For Manufacturers of Medical, Precision and Optical Instruments (ISIC 33) [1]
Switzerland	4.549
Korea	2.041
United States	1.843
Ireland	1.823
Japan	1.52
Denmark	1.374
Germany	1.277
United Kingdom	1.255
Netherlands	1.151
France	1.073
Mexico	1.066

Source: OECD Micro Trade Indicators (by category of industry, ISIC), data extracted on 28 Jul 2010 19:45 UTC (GMT) from OECD.Stat; www.oecd.org/std/its/tradeindicators (Ref. 4).

[1] The revealed comparative advantage (RCA) measures the intensity of trade specialization of a country and is calculated as the industry's share of exports from a country divided by the industry's share of global exports. A country has not specialized in exports of the industry if the RCA is less than 1; a country has specialized in exports of the industry if the RCA is greater than 1.

The number of foreign labelers expected to be affected by the proposed rule almost equals the number of affected domestic labelers. This might suggest that under the proposed rule, the incremental costs of foreign manufacturing would rise by about the same amount as the incremental costs of U.S domestic manufacturing. Although we lack information on the types and number of medical devices produced by these foreign firms, any disproportionate increase in the cost of production of medical devices between foreign and domestic labelers could affect international trade. Moreover, increases in the cost of production of medical devices in other countries would be expected to increase the cost of imports of medical devices to American consumers, as would be expected with the domestic labelers.

We estimated that the total annualized costs to domestic labelers would be about $66.5 million with a 7 percent discount rate and about $65.0 million with a 3 percent discount rate. There is greater uncertainty in estimating the costs to foreign firms. As we have noted, although much of the medical device trade with the U.S. is concentrated in a few countries, a large number

of countries manufacture some types of medical devices. Because we lack sufficient information to estimate the potential impact of this rule on foreign labelers or the impact on international trade, we request comment from affected industries about their expected compliance costs and responses to the proposed rule.

9. Summary of Total Costs of the Proposed Rule

Table 25 of this document presents, for each affected sector, a summary of the estimated total present value and the annualized domestic costs of this proposed rule over 10 years using discount rates of 7 percent and 3 percent. Over 10 years, the total present value of the domestic costs would be $514.0 million using a 7 percent discount rate and $588.6 million at 3 percent, and the annualized costs would be $68.4 million at a 7 percent discount rate and $66.9 million at 3 percent.

Table 25.--Summary of the Estimated Regulatory Costs of the Proposed Rule [1,2] (2010 dollars)

Affected Sectors	Total Present Value of Cost over 10 years ($ million)		Total Annualized Costs Over 10 Years ($ million)	
	3 Percent	7 Percent	3 Percent	7 Percent
Domestic Labelers	$571.5	$499.4	$65.0	$66.5
Issuing Agencies	$1.0	$0.9	$0.1	$0.1
FDA	$16.1	$13.7	$1.8	$1.8
Imports	Not quantified	Not quantified	Not quantified	Not quantified
Total Domestic Cost of the Proposed Rule	$588.6	$514.0	$66.9	$68.4

[1] Present value and annualized costs calculated at the beginning of the period.
[2] This summary table 25 is identical to table 1 of this document.

Costs to Domestic Labelers.

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. Over 10 years the annualized

costs to domestic labelers would be $66.5 million at a 7 percent discount rate and $65.0 million at 3 percent. The largest components of one-time costs would include the costs to integrate the UDI into existing information systems, to install, test and validate barcode printing software, and to train employees, and to purchase and install equipment needed to print and verify the UDI on labels. In addition, the redesign of all device labels to incorporate the date format within 1 year, the redesign of the UDI barcode format, and the direct marking of certain devices are significant components of one-time costs.

The largest annual cost components include labor, operating, and maintenance costs associated with equipment for printing operations and labor related to software maintenance and training needed to maintain the UDI data and UDI reporting systems.

Costs to Issuing Agencies.

The estimated present value of costs over 10 years for two existing organizations currently performing functions similar to those of an issuing agency under the proposed rule, to apply for FDA accreditation and comply with the proposed reporting requirements would be $0.9 million at a 7 percent discount rate and $1.0 million at 3 percent. The annualized costs over 10 years would be $0.1 million at a 7 percent and 3 percent discount rate. In addition to these two organizations, there may be other nonprofit organizations or State or Federal Government agencies that might apply to FDA to become an issuing agency. In such cases, the estimated application preparation, legal and reporting costs would apply to other organizations.

Costs to FDA to Establish and Maintain the GUDID.

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.

Costs to Foreign Labelers.

We lack sufficient information to quantify the potential impact of the proposed rule on foreign establishments and thus exclude these establishments from our cost estimate. However, we include a qualitative discussion of the potential impact of this rule on trade and the cost of imported products.

G. Analysis of the Uncertainty of Costs

The estimates of compliance cost presented in the Cost Section F of this document are associated with uncertainty, with some cost categories more uncertain than others. This section qualitatively discusses the uncertainty of the cost estimates for each of the major cost components and presents an upper bound and lower bound estimate for each cost component, as well as total cost. The domestic industry costs presented in this uncertainty analysis treat all one-time costs as occurring in the first year and do not incorporate the proposed effective dates, which would allow industry up to 7 years to phase in requirements. The agency welcomes comments on assumptions and on estimates of cost used for this analysis.

The maximum number of domestic firms and establishments expected to be affected is reasonably certain. All affected entities are already required to be registered with FDA. Any that are not registered are out of compliance with FDA's registration and listing requirements. More uncertain is the share of establishments involved in labeling devices for retail outlets only. These uncertainties are handled within bounding estimates made for each cost category. These bounding estimates depend on factors related to the uncertainty in each cost category.

Another uncertainty is how many establishments would only have devices that meet an exception, and thus would be excepted from the UDI requirements. We estimated that 1,141 establishments in the 1-4 employee size group and 238 establishments in the 5-9 employee size

group would meet one of the exceptions listed in 801.30(a)(3) - (12). However, if none of these establishments met an exception, this would add $2.7 million per year to the costs of the rule.

The first cost category, Planning and Administrative Costs, is our best estimate of the time needed for companies to undertake basic compliance preparations, although some entities might spend more or less time. The true overall average across most entities is unlikely to differ too widely (i.e., an order of magnitude) from the estimate. However, the requirement to meet the date format change in 1 year could have an effect on planning and administrative costs for certain establishments. Establishments needing to make this change might need to change the way they assign lot numbers (if their lot numbers are based on the date that appears on the label). The number of establishments this requirement might affect is uncertain, but because of this implementation period, we chose a relatively wide bounding assumption, setting costs between 50 percent lower and 50 percent higher than that estimated in the Cost Section F of this document.

Costs to participate in an accredited UDI system are considered reasonably reliable. A plus or minus 10 percent factor is used to bound the estimate for this cost category.

Somewhat less certain are the cost estimates for equipment. The costs for smaller establishments are reasonably certain, but those for the largest establishments could vary widely if certain types of device packages are being labeled. If establishments must create new levels of packaging and labeling for certain devices, additional equipment for packaging and labeling might need to be purchased than was estimated in the Cost Section F of this document. For example, class II devices that are not labeled separately within another device package (a shelf pack), combination products with a separable device that is not individually labeled, and certain devices intended for more than one use that are currently placed unlabeled within kits could be

affected. We do not have information about the prevalence of such devices or the number of establishments to which this situation might apply.

Alternatively, establishments would be able to judge which of several options (e.g., switching from outside printing to in-house printing) are the least expensive for them in complying with UDI requirements. We did not attempt to judge which options would be chosen on the basis of cost, which could overstate the equipment costs. To account for these uncertainties, we estimated costs using factors of plus or minus 50 percent for equipment costs.

It is possible that few establishments would need additional materials for labels. Because the proposed rule would allow for a shelf pack to be labeled in lieu of requiring each individual item therein to be labeled with a UDI, because 2D barcodes (which are very small) can be used to represent UDI information, and because label redesign should solve many label size issues without the need to expand label area, it is possible that the lower bound of the material costs could be substantially smaller than our estimate.

The approximation of label materials costs (2 percent of all packaging materials costs) and the potential cost increase associated with larger packaging and labeling areas (estimated at 10 percent) are also both uncertain, as is the cost implications of the need to change label designs within 1 year of implementation. This requirement could lead to less cost-effective means of complying, including the possibility for some classes of devices, the need to go through two separate rounds of label redesign to accommodate, first, the date format change, and second the UDI change. The proposed rule requests comments on the value of linking this requirement to the effective date for the UDI requirement for each device class. However, we are not certain of the number of such affected entities and may have overstated the costs under the timing assumption that all affected establishments would redesign labels in the first year. Device

labelers that are currently required to have dates on their labels have a previously established date format and are not affected by the proposed rule requirement. The number of labelers who choose to use a date on their labels is not known, but could be relatively small. All of these uncertainties and assumptions could make estimated costs too low or too high. An uncertainty factor of plus or minus 25 percent has been chosen for this cost category.

Label redesign costs are more speculative, given the range of technical, regulatory, and marketing considerations at play. It is not known how many establishments might be able to integrate UDI requirements into routine label redesign cycles, which could reduce the incremental cost of label redesign. On the other hand, the long lead times offered by the proposed implementation schedule implies that many establishments might be able to do this, although the number who must meet an earlier deadline for date format changes is not known. Alternatively, costs could be much higher at establishments with unusual packaging and labeling issues, including any that are affected by the need to label and package at a new level. We used a plus or minus 60 percent factor to create the upper and lower bound estimate for this cost item.

Software costs are also considered highly speculative. Costs could be overstated because we cannot estimate how much of the integration costs would be performed as a result of complying with the proposed rule and how much would be performed as a result of corporate preferences for integration. The integration would, however, yield benefits in terms of recordkeeping and reporting cost savings, so the lower bound factor reflects the judgment that some integration might be performed to reduce incremental costs of recordkeeping and reporting. We use uncertainty factors of plus or minus 50 percent for this cost item. GUDID costs are considered reasonable estimates, so have been given factors of plus or minus 25 percent.

Direct marking costs range in their certainty. Implant marking costs are considered the most uncertain, due to the paucity of data about the extent to which implants are currently directly marked. Although contacts have indicated that most implants that can be marked (subject to size and material constraints) are directly marked and that health and safety issues should not arise, we recognize that higher costs for marking implants could arise. On the other hand, if all of the implants currently able to be marked are being marked, and those not currently marked would meet the exceptions for direct marking, costs for marking implants could be overstated. Additionally, if "technologically feasible" implies that a plain-text UDI would have to be marked, even if it must be magnified to be read, this could substantially increase costs. If any exceptions would need to be made on the basis of health and safety, which could be a much lengthier process than the exception process considered in the Cost Section F of this document, costs for exceptions would be higher. Also, if FDA were to deny a portion of the exceptions currently estimated to be requested, substantially more establishments would need to install equipment, increasing the equipment and operating costs for directly marking devices. We are also not certain whether additional costs would be incurred as a result of needing to mark devices with plain text so small that it requires magnification to be read. Because of all of these uncertainties, we estimate an uncertainty factor of plus or minus 80 percent.

For multiple-use devices, the uncertainty is significant, again due mainly to the paucity of data on current marking practices and, to a lesser extent than that for implants, the issue of technological feasibility. Therefore, we selected a factor of plus or minus 50 percent to calculate bounding estimates.

These factors produce the bounding estimates shown in table 26 of this document. As table 26 shows, with uncertainty considered (and with no implementation schedule used), we

estimated the annualized compliance cost of the proposed rule to U.S. labelers using a 7 percent discount rate would be $44.5 million per year at the low end and $131.8 million per year at the high end, with the central estimate equal to $88.4 million per year. With a 3 percent discount rate, the low end of annualized cost would be $41.5 million and the high end would be $120.6 million, with the central estimate of annualized costs equal to $81.0 million.

Applying the bounding estimates to table 25 of this document with the phase-in implementation, our best estimate of the total cost of the proposed rule for all domestic labelers, issuing agencies and the FDA, the annualized present value of costs to initial labelers of the proposed rule over 10 years using a 7 percent discount rate would range from $34.9 million to $101.8 million at 7 percent and $34.1 million to $99.7 million at 3 percent.

Table 26--Bounding Estimates Reflecting Uncertainty in the Estimates of the Total Domestic Cost for Initial Labelers [1] (2010 dollars)

Cost Element	First-Year ($ million)	Low ($ million)	High ($ million)	Annual Recurring ($ million)	Low ($ million)	High ($ million)
Labeling and Database Requirements						
Administration and planning	$37.1	$18.5	$55.6	NA	NA	NA
Barcode Registration	$2.0	$1.8	$2.2	NA	NA	NA
Equipment and other investments	$47.5	$23.8	$71.3	$22.6	$11.3	$33.8
Incremental label materials and labor	NA	NA	NA	$7.6	$5.7	$9.5
Label redesign	$47.6	$19.0	$76.2	NA	NA	NA
Software (with training)	$128.7	$64.4	$193.1	$14.2	$7.1	$21.3
Recordkeeping & Reporting (GUDID)	$2.9	$2.2	$3.6	$0.4	$0.3	$0.5
Total Labeling and Database Requirements	$265.9	$129.7	$402.0	$44.7	$24.3	$65.0
Direct Part Marking						
Implants	$12.0	$2.4	$21.7	0.8	$0.2	$1.5
Multiple-Use Devices	$14.9	$7.5	$22.4	$1.1	$0.6	$1.7
Total Direct Part Marking	$27.0	$9.9	$44.0	$2.0	$0.7	$3.2
Total—All Cost Elements	$292.8	$139.6	$446.0	$46.7	$25.1	$68.3
Annualized First-Year Costs (7 percent)[2]	$41.7	$19.9	$63.5			
Annualized First-Year Costs (3 percent)[2]	$34.3	$16.4	$52.3			

	Total Annualized Costs ($ million)		
	Central	Low	High
Total Annualized Costs (7 percent)[2]	$88.4	$44.9	$131.8
Total Annualized Costs (3 percent)[2]	$81.0	$41.4	$120.6

Source: ERG Report, Table 8-3 (Ref. 1).

[1] Cost estimates assume immediate implementation. The GMP-exempt exclusion cost savings is not fully reflected in administration and planning costs. The cost savings shown reflect a cost savings for these establishments for reading and implementing a static barcoding requirement (the administrative and planning time is assumed to be half of that for planning for a variable barcode requirement). However, GMP-exempt establishments are expected to incur costs only to read and determine they are not affected by the proposed rule. This task is less time intensive than a task that includes implementation of static barcoding requirements.

[2] First-year costs are annualized over 10 years.

H. Benefits

The proposed rule would standardize how medical devices are identified and contribute to future potential public health benefits of initiatives aimed at optimizing the use of automated systems in healthcare. We restrict our description to potential public health benefits most likely to occur from the direct actions of the proposed rule. These potential public health benefits would include:

- Improved reporting of postmarket adverse medical device events;
- Improved medical device recalls.

Both postmarket surveillance and recall actions are often hampered by poor product identification. A UDI would not automatically solve these problems--human reporting behavior and other data issues hamper surveillance efforts--but having a UDI could reduce certain costs of product identification and thereby contribute to improved detection of problem medical devices.

As discussed in section I.B of the preamble to the proposed rule (Additional Benefits), the development of a standardized UDI may contribute to the value of other health information technology (HIT) initiatives. HIT is considered an important tool to improve patient safety, and a range of HIT initiatives have begun. The adoption rates for selected HIT initiatives in U.S. hospitals as of 2006 were estimated as follows: electronic medical record = 37 percent; computerized physician order entry = 13.9 percent; bar-coding at medication dispensing = 27.1 percent; and barcoding at medication administration = 4.7 percent. Some researchers attribute financial and cultural barriers to the initially observed slow rates of adoption. (Ref. 5) Although decisions to invest in HIT

would be made independently of the proposed rule, a UDI system may help to facilitate the adoption and use of complementary HIT systems for improving patient safety.

A standardized UDI also could be used in national and National Institutes of Health (NIH) device registries, in NIH studies, by the Center for Medicare and Medicaid Services, and by private healthcare organizations. Such uses would require complementary developments and innovations in the private and public sectors and investment in technologies to use the UDI. Moreover, many of these actions would be developed in future years. Identifying and assessing these potential future benefits and costs, however, is beyond the scope of this analysis. Nonetheless, the creation of a platform to link specific device information to research databases is likely to enhance the value of such databases.

An additional benefit of standardizing UDI relates to the formatting of dates on device labels. A standardized formatting of dates on medical device labels would eliminate any possibility of confusion from date formats that might be interpreted in more than one way. Examples of possible confusion due to inconsistent date formatting are described at II.B.11 of the preamble to the proposed rule. The proposed date format may contribute to more accurate identification of a device by making it possible to distinguish between those devices that have passed an expiration or use-by date and those that have not. More accurate identification would make it easier to both avoid the risks of using "expired" devices and the costs of premature disposal of devices that have not actually reached an expiration or use-by date. We lack sufficient detail to estimate the individual benefits associated with the date format. These benefits would be captured in the global benefits presented below.

1. Improved Reporting of Adverse Medical Device Events

Baseline and Background.

The proposed rule would be expected to improve adverse medical device event reporting by providing a reliable and unique identifier with which to report a problem device. With more reliable identification of devices associated with an adverse medical event, FDA would be able to improve postmarket surveillance of medical devices and to detect problem devices more rapidly.

To describe how the UDI could improve postmarket surveillance of medical devices, we begin with a characterization of the baseline level of adverse medical device events that occur in normal medical practice with current technology, and FDA regulations and databases associated with adverse medical device event reporting. A few studies have estimated the overall frequency of adverse medical device events. Although these studies produce different estimates of the frequency of adverse medical device events and embody much uncertainty, they suggest that a considerable number of medical device-related adverse events occur each year. One study generated a national estimate that in a one-year period, 455,000 visits to emergency departments were for injuries associated with medical devices. Of these, 58,000 patients were hospitalized, although the cause of the injury could not be established (Ref. 6). Samore and others searched patient records at a major tertiary teaching hospital to gather information on the number of adverse device events (Ref. 7). Samore's team examined computer-flagged medical records, telemetry problem checklists, clinical engineering work logs, patient survey results, and other hospital data to identify possible adverse medical device events and to determine whether such techniques could be used to identify events consistently. When

they combined the three detection methods, they estimated the incidence rate for adverse medical device events was 83.7 per 1,000 hospital admissions. Because the study collected data from only one hospital, we cannot apply the rate to the 40 million annual hospital admissions but the results point to a high national incidence of adverse events. Using a national sample of hospital discharge diagnoses for the years 1997-2003, Bright and Shen found 820,000 to 1,100,000 diagnoses per year related to adverse medical device events (Ref. 8).

FDA collects data on adverse medical device events as part of its regulatory responsibilities under FDA's Medical Device Reporting (MDR) requirements. Medical device manufacturers, importers and user facilities must report to FDA all deaths and serious injuries that a medical device has or may have caused or contributed to. In addition, manufacturers and importers must also report to FDA certain device malfunctions. FDA provides a gateway for the electronic reporting of mandatory adverse events (Electronic Medical Device Reporting (eMDR)). In addition, consumers and others who are not required to report by the MDR rule can voluntarily report device problems to MEDWATCH. Healthcare professionals and consumers are encouraged to voluntarily report adverse events involved with medical devices to MEDWATCH.

All adverse medical device event reports received by FDA are entered into FDA's Manufacturer and User Facility Device Experience (MAUDE) database. FDA uses MAUDE to help identify an increase in the number of reports associated with a device or an increase in the severity of adverse events reported for a device. With this information, FDA can further investigate newly identified problems related to medical devices and determine appropriate regulatory responses.

The number of reports of serious outcomes submitted to FDA has increased steadily since 2005. As stated in the preamble to the proposed rule, from 2005 through 2009 FDA received more than 17,700 reports involved a death, and more than 283,000 reports involved an injury. However, there can be more than one report submitted for an adverse event. Table 27 of this document shows the number of adverse events from 2008-2010 by device classification. During this three year period, about 9,000 deaths and 150,000 serious injuries were associated with adverse medical device events. Because we lack information about the total number of marketed devices by device class, we cannot determine the relative risks of a serious adverse event for the different device classes. Nevertheless, this data suggests that adverse events associated with serious harm can occur with all classes of medical devices.

Table 27. -- Number and Share of Adverse Events by Device Class and Event Type (2008-2010)

Device Class	Type of Adverse Event				Total Number of Events	Share of Events by Device Class
	Death	Serious Injury	Malfunction	Other or Missing Outcome		
Class III	1,810	30,501	41,036	2,482	75,829	20%
Class II	3,326	55,987	80,367	4,620	144,300	38%
Class I	2,374	39,033	57,877	3,008	102,292	27%
Unclassified	1,408	22,500	30,091	1,642	55,641	15%
TOTAL	**8,918**	**148,021**	**209,371**	**11,752**	**378,062**	**100%**

Limitations of MAUDE Data.

Ideally, the MAUDE data should provide the FDA, the public, and researchers with electronic search capabilities to track both general and specific measures of medical device-related adverse events. However, analyzing medical device adverse event data and

adequately identifying the suspected medical devices can be hampered or delayed because of inaccurate, incomplete, or inconsistent reports of an event.

For example, some medical device adverse event reports do not contain enough information to identify the device involved with the adverse event, including manufacturer name, model number, lot number, or date information. An informal review of fatality reports (totaling 556 reports) in the MAUDE database that occurred during a 2-month period in 2006 revealed that 25 percent of the fatality reports were missing some portion of manufacturer, model, and lot or date information. Moreover, at least 23 of these fatality reports were associated with implanted devices and ventilators that lacked model numbers, lot numbers or both. In some specific episodes where FDA staff was initially unable to determine the device models or lots implicated in adverse events, the medical devices were eventually recalled.

Other impediments to identifying a suspected device include: changes to model numbers and brands made by distributors; interchangeable use of catalog numbers and model numbers; and punctuation, abbreviation, and spelling of manufacturer names or brand names.

Inaccurate and incomplete reporting of device identifiers causes FDA to devote substantial resources finding and verifying the information necessary to identify these devices before the adverse event data can be used. Moreover, without a uniform identifier, the MAUDE database cannot be efficiently and effectively searched for reports on specific devices. These shortcomings of the MAUDE data can hamper agency efforts to assess subtle or complex patterns in the adverse event histories. Under these

conditions, FDA requires more time to identify patterns in device failure than needed if devices could be readily and unambiguously identified.

How the UDI Requirements Can Improve the Current Situation.

Near-Term Improvements.

The lack of an unambiguous device identifier limits the current usefulness of the MAUDE data. With the UDI, FDA would be able to immediately identify and validate the device when an adverse event is reported. It would also make the device easily searchable throughout the system, regardless of variants of manufacturer names, model, or catalog numbers, or descriptors used to identify the device. A UDI could improve FDA's ability to compile additional evidence on similar device types and reduce the time needed to realize that a wider search for data on the device in question or enhanced postmarketing surveillance would be warranted. Including data such as product codes or GMDN in FDA's publicly available GUDID would provide an important data element that could be used to allow searches to be performed quickly for similar devices manufactured by multiple companies.

Future Improvements.

With the MAUDE data alone, the Agency is unable to compare failure frequencies across similar devices or alternative treatments to assist in determining if the problem is with the device itself (rather than just with a particular lot or lots). Once medical devices are identified with a UDI, there is the potential to increase the amount of data available on medical devices and to improve postmarket surveillance. Linking MAUDE data to other databases could increase the ability to use MAUDE to assess causality. With widespread use, many diverse databases could be linked by the UDI.

Using linked data from many sources would allow for more robust data analysis of device problems and outcomes and would allow FDA to perform independent postmarket surveillance. This linking, however, would require that commercial and public databases incorporate and use the UDI and make that data available for postmarket surveillance.

Commercial and public databases containing UDI-linked device use could be used by FDA to estimate exposure. With exposure estimates, the agency would be able to more accurately and quickly determine if adverse event reports indicated a public health problem. Causality is always difficult to determine in human activities, but the ability to link product databases by the UDI could make more causal inferences possible. For example, if a disproportionate number of adverse event reports come in for a particular device model relative to similar models of the same device, the agency could check the gross numbers of adverse events against use to determine if the larger number reflects simply greater exposure or if it reflects greater risk.

2. Improved Efficiency in Removing Recalled Devices from Use

Baseline and Background.

Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health. In most cases, companies voluntarily recall medical devices when problems arise. FDA oversees recalls to ensure that the actions the company takes are adequate to protect the public health. During a medical device recall, FDA works with the recalling firm to obtain information about the product, the problem, the recall strategy, and planned steps to prevent the problem from happening again; conducts audits to make sure the recall efforts are appropriate and

effective; and makes sure the company takes necessary actions to prevent the problem from happening again.

FDA classifies medical device recalls into three categories, representing the potential risk to public health: class I, class II, and class III. This classification process usually takes place after the company has issued its recall.

- Class I recall: high risk
- Class II recall: less serious risk
- Class III recall: low risk

A class I recall is the most serious. In a class I recall, there is a reasonable chance that the product will cause serious health problems or death; the company whose product is being recalled notifies its distributors or vendors and directs them to notify the intended recipients of the device, including other vendors, hospitals, nursing homes, outpatient treatment facilities, doctors, or individual patients. The notification usually contains the name of the device being recalled, identifying lot or serial numbers, the reason for the recall, and instructions about how to correct, avoid, or minimize the problem. FDA may also issue a press release or public health notice during a class I recall.

A class II recall usually represents a less serious risk than a class I recall. In a class II recall, there is either a possibility that the device will cause temporary or reversible health problems, or there is a remote chance that the device will cause serious health problems; the company notifies its distributors or vendors and sometimes asks them to notify the intended recipients of the device. FDA generally does not issue a press release or expect the company to issue a press release for class II recalls, unless there is a specific need to do so (for example, if the device could affect the health of a large number

of people, if patients need more information, or if the recalling company could not reach every intended recipient).

A class III recall represents a less-serious risk than a class II recall. In a class III recall, there is little chance that using or being exposed to the device will cause health problems. Because the product violates the law, there is still a need to take an action to address the problem. In a class III recall, the company notifies distributors or vendors. FDA would not issue a press release, and it would not expect the company to issue a press release.

Table 28 of this document shows the estimated number of FDA recall actions that occurred from 2005 through 2009, broken down by recall class and device class. As illustrated, the majority of recall actions were class II recalls of class II devices (2,076 of 3,446.) However, similar to the data on adverse events, we lack sufficient information about the total number of marketed devices by device class to conclude anything from this data about the relative risk of recall by device class.

Table 28.--Medical Device Recall Actions by Recall and Device Class (2005-2009)

	Recall Class [1]					
	I		II		III	
	Recalls by Device Class		Recalls by Device Class		Recalls by Device Class	
Device Class	Number	Share	Number	Share	Number	Share
III	36	29%	256	9%	51	10%
II	84	68%	2,076	74%	350	69%
I	4	3%	483	17%	106	21%
Total by Recall Class	124	100%	2,815	100%	507	100%

[1] Sixty three unclassified recalls during this period have been excluded.

Describing the Problem with Medical Device Recalls.

Many of the problems described with respect to adverse medical device event reporting also affect device recalls. With incomplete information or poor device identification recalls are often incomplete or misdirected. Indeed, the same device may be identified with several different descriptors. Identifying and locating all of the recalled devices, while simultaneously not removing devices without problems, presents many challenges, even when a single product is involved. When a recall action involves many versions or types of a product, the problems of incomplete data are multiplied. With a large number of products involved in a single recall action, product removal could be slow and possibly incomplete, which suggests that potentially hazardous devices occasionally remain in use beyond their recall. Incompletely or slowly executed recalls of potentially hazardous devices could lead to patient deaths or injuries: the longer a defective or problem recalled device remains in use, the more likely it is to cause a serious problem.

Although class I recalls generate the most thorough and careful recall efforts, even these recalls can be hampered by incomplete product identification. For example, an incomplete class I recall involved a brand of bronchoscope that was difficult to sterilize completely due to a design defect. Because of a failure in communication at one large hospital, the recalled bronchoscopes continued to be used after the recall, resulting in a pattern of infections among the affected patients.

How the UDI Requirements Can Improve the Situation.

Near-Term Improvements.

Increasing the speed and effectiveness of medical device recalls would reduce adverse events associated with those recalled devices. Although the threat posed by

incomplete withdrawals of recalled devices exists, current databases are inadequate to estimate the numbers of patient injuries or deaths or injuries that might be averted with more effective FDA management of device recalls. For example, in the case of the incomplete class I recall of the bronchoscope, had a UDI system been incorporated in the hospital's materials management system, while not sufficient to prevent the episode, it might have helped the hospital to identify the recalled bronchoscopes more quickly and completely remove them from service sooner, thereby reducing the numbers of patients potentially exposed to infection.

Future Improvements.

A device identifier, combined with a system that can capture the device identifiers in patient records, would also have facilitated the search for at-risk patients (assuming that electronic health systems were in place) by providing a computer searchable number in the record, possibly preventing active infections or more quickly identifying infections needing treatment. A comprehensively implemented UDI-based system would facilitate more thorough and complete FDA dissemination of information about the specific devices being recalled and FDA oversight of the recall action.

3. Reduced Device Related Medical Errors and UDI

Another potential benefit of the required UDI system would be reduced medical errors from human and mechanical problems with medical devices. FDA's MAUDEdatabase captures reports of device related medical errors. However, the limitations of the MAUDE database described above prevent us from estimating the frequency of reported medical errors associated with devices. Table 27 includes reports of device related medical errors, but the frequency is not explicitly or easily enumerated.

Furthermore, medication errors, a subset of medical errors, may also be attributed to medical devices. Although not nationally representative, an insight into the frequency of device related medication errors comes from the 2007 IOM report on preventing medication errors. The IOM report cites a study of medication errors by major cause which attributes 4 percent of medication errors to devices (Ref. 9). Because we lack data on the frequency of device related medical errors, the agency is requesting that commenters provide specific data or anecdotal information on the nature and frequency of device related medical errors including device-related medication errors.

Establishing a link between an FDA-mandated UDI system and a reduction in medical errors is more complicated. The UDI and the GUDID would allow users to electronically access specific product identification and information printed on the device label. Although the final regulation would not require other entities to electronically capture and use this information in automated systems, there is a clear intent for the UDI to serve as a key that would link the GUDID with other complementary systems in use now or that might be developed to reduce medical errors and improve patient safety. Hospitals and other health-care facilities will choose to make investments in the new technology and methods if they expect it to be a cost-effective method to reduce errors involving medical devices. To the extent that the FDA-requirement for a UDI increases the perceived cost-effectiveness of scanner-based device use and thereby increases the use of scanner-based treatment delivery, it could lead to reduced medical errors. The identification technology, however, would not be the decisive consideration. Other studies indicate that health-care facilities base the technology adoption decision on cost and effectiveness.

As we point out in the discussion of adverse event reporting, medical errors may be noticed sooner and preventive measures taken when adverse event reports are collected in a central database (or linked databases under standardization). The adverse medical device event that appears random to individual users can more readily be identified as a design, performance, or user error when combined with like events and analyzed using a unique identifier.

Putting a standardized unique device identifier on a device label is one step in creating systems that could reduce device related medical errors. Changes in technology and user practices are also required. The proposed rule would create a platform that would enhance the value of the new electronic health technologies and thereby might encourage their development. But the decision to invest and adopt the new technologies would be made independently of the proposed rule.

4. The Public Health Implications of Better Device Analyses by FDA

The public health benefits from the UDI would come from related reductions in medical device-related patient injuries and deaths. More accurate and prompt identification of problems would enable more rapid action to reduce the incidence of the adverse events. Public health safety alerts, for example, could be more accurate and timely. FDA would be able to carry out recall actions more efficiently with more effective targeting of the problem device.

The proposed rule would standardize how medical devices are identified. A standardized UDI could serve as an electronic key to link device information among existing and future databases related to device use and safety. Thus, a UDI for medical devices could contribute to potential public health benefits of initiatives aimed at

optimizing the use of automated systems in healthcare, but we cannot estimate those future benefits without knowing what those healthcare systems would be.

Because we have insufficient information to quantify the public health gains from this proposed rule, we carry out an illustrative break-even analysis to determine the level of effectiveness that would cover the total costs of the proposed rule. The total present value of the costs of the proposed rule over 10 years would be about $515 million using a 7 percent discount rate and about $590 million using a 3 percent discount rate. The average number of deaths associated with (although not necessarily caused by) reported adverse medical device events was 2,973 per year from 2008 through 2010 (table 27 of this document). We exclude all non-fatal adverse events from the calculations because those events include a wide a variety of outcomes and are dominated by the value of averted fatal events. The current estimated value of a statistical life used in FDA analyses is $7.9 million (Ref. 10). Using 10-year averages and assuming that benefits begin in year 3, we find that less than a 0.5 percent decline in the average annual reported number of deaths (about 14 averted deaths per year using a 7 percent discount rate and 13 averted deaths per year using a 3 percent discount rate) would produce monetary benefits approximately equal to the total present value of the costs of the proposed rule. Because reported adverse device events represent a fraction of the number of actual adverse device events, the percentage breakeven decline as a fraction of all adverse device events would be smaller than 0.5 percent.

In summary, the UDI should benefit FDA's adverse medical device event reporting and surveillance efforts, and improve recall operations. Despite some difficulties and incompleteness that are likely to remain in FDA's data, the enhancement

could lead to earlier, more definitive, or more frequent identification of problem devices. The increased effectiveness of surveillance and the more effective management of recalls should reduce the total number of adverse medical device events, although we are unable to quantify that reduction.

I. Alternatives to the Proposed Regulation

The agency identified and assessed the costs for labelers of the following alternatives to the proposed rule:

1. Full UDI requirements for unclassified and class I, II, and III devices.

2. A requirement for labeling only.

3 Apply UDI requirements only to class II and class III devices.

4. A UDI that includes only static information (variable information such as lot or batch, serial number, and date, would not be required).

5. Apply UDI requirements only to class III devices.

The costs of these alternatives are summarized in table 37 of this document. Consistent with analysis presented in the Cost Section F of this document, we assume for all alternatives that labelers of excepted devices (devices covered by proposed 801.30(a)(3) - (12) general exceptions) would be excepted from the UDI requirements, and some small labelers, assumed to exclusively distribute over-the-counter devices to retail outlets. The proposed rule includes an implementation of seven years before all requirements must be implemented. Because the implementation schedule could differ across the alternatives considered, to simplify and to present a more robust comparison of costs, in this section we assume immediate implementation. This means that all upfront costs and annual costs are assumed to occur beginning in the first year for all alternatives

and for the proposed rule. The best estimate of costs of the proposed rule to initial labelers with the phased-in implementation schedule is shown in table 18.

The first alternative includes most of the requirements of the proposed rule, but does not allow for certain reduced requirements for class 1 devices. The costs for the next four alternatives allow the labeling and database requirements to vary and differences in costs are compared to the highest cost alternative.

1. Full UDI Requirements for Unclassified and Class I, II, and III Devices

Under this alternative, all requirements of the proposed would rule apply to class II and III devices. However, the label for class I devices would be required to also bear the production identifier portion of its UDI and class I devices that FDA has exempted from GMP regulations would not be included under a general exception. Direct marking is unchanged.

The costs of this alternative are shown in table 29 of this document. Because some class I labelers would be required to include variable information in the device identifier portion of the UDI and the label of some GMP-exempt devices would be required to bear a UDI under this alternative, one-time costs related to planning and administration would be increased by $9.5 million compared with the proposed rule (table 17). In addition, the one-time costs for barcode registration and for recordkeeping would be increased slightly, $0.1 million for barcode registration and $0.3 million for recordkeeping. Annual costs associated with equipment and software would be increased by $17.0 million and $8.0 million, with incremental label materials ($1.9 million) and recordkeeping and reporting to GUDID increased somewhat ($0.04 million). Because all device labelers are assumed subject to the date format requirements, we do not assume

changes to the cost due to label redesign. However, class I device labelers may spend about $1.9 million more annually in label material costs because the variable identifier portion of the UDI may require more space than the fixed identifier only. Costs for directly marking devices remain unchanged. The following paragraphs discuss more fully the two largest categories of cost increases: equipment and software.

Under this alternative, all class I establishments not covered by the general exceptions under 801.30(a)(3) - (12) would incur costs related to complying with the variable barcode requirement. The costs would be dependent on the labeler's current printing capabilities and their compliance response which might include using outside contractors to print labels that incorporate variable information, modifying current in-house label printing systems, or purchasing and installing equipment that would incorporate the frequent changes needed to include the variable information. For the approximately 1,840 class I initial labelers, the one-time increase in costs would equal $28.2 million, and the annual cost increase would equal $14.4 million. For the 830 repackagers and relabelers, the increase in costs would be $7.1 million in one-time and $2.7 annually.

Similarly, we assume that wider use of variable identifiers will require additional software and data integration costs. This may include costs related to purchasing and installing software or modifying existing device tracking systems, and software validation and training. To calculate the cost increase for software, we assumed that each class I firm operates only one establishment. This assumption may overestimate the number of affected firms and thus overestimate the cost increase. The one-time increase in costs would equal $52.4 million, and the annual increase in cost would be $7.1 million

for 1,840 initial labelers. The 830 affected repackagers and relabelers would have an increase in one-time costs of $5.9 million, and $0.9 annually.

Total one-time costs for all domestic labelers would be $396.3 million, with annual costs of $73.6 million. The total annualized costs would be $130.1 million with a 7 percent discount rate and $120.1 million per year over 10 years with a 3 percent discount rate.

Table 29.--Summary of Total Costs of the Full Requirements Alternative for Affected Domestic Labelers (2010 dollars)

Cost Element	First-Year ($ million)	Annual ($ million)
Labeling and Database Requirements		
Administration and planning	$46.5	NA
Barcode registration	$2.2	NA
Equipment and other investments	$82.8	$39.6
Incremental label materials and labor	NA	$9.5
Label redesign	$47.6	NA
Software (with training)	$187.1	$22.2
Recordkeeping and Reporting (GUDID)	$3.1	$0.4
Total Labeling and Database Requirements	$369.3	$71.6
Direct Marking		
Implants	$12.0	$0.8
Multiple-use devices	$14.9	$1.1
Total Direct Marking	$27.0	$2.0
Total Cost--All Elements	$396.3	$73.6
	Annualized Costs ($ million)	
Annualized First-Year Costs [1]	$56.4	
Total Annualized Costs [1]	$130.1	
Annualized First-Year Costs [2]	$46.5	
Total Annualized Costs [2]	$120.1	

Source: ERG Report, Table 4-25 (Ref. 1).
Note: Numbers may not sum due to rounding.
[1] First-year costs are annualized at 7 percent over 10 years.
[2] First year costs are annualized at 3 percent over 10 years.

2. A Requirement for Labeling Only

We also assessed the alternative of only requiring a unique device identifier to appear on the label of a medical device. This alternative would not include the

requirements for direct marking of devices and for filing related exceptions, and would not require device identifying information to be submitted to a GUDID.

The largest reduction in costs compared to the first alternative would be from not requiring direct marking. One-time costs of $27.0 million for implants and multiple-use devices, and $2.0 million in annual costs, would be avoided. Also, there would be reduced costs of about $3.1 million in one-time costs, and $0.4 million annually related to the GUDID. Although not included in the summary cost comparisons of alternatives, FDA would not incur one-time costs of about $1.6 million and annual costs of $1.9 million to set up and maintain the GUDID.

Total one-time industry costs of this alternative to only require a UDI on medical device labels would be $366.2 million and annual costs would be $71.2 million. (See table 30 of this document.) The total annualized costs of this alternative would be $123.4 million per year, using a discount rate of 7 percent over 10 years, and $114.2 million per year at 3 percent over 10 years. Under this scenario, all firms would have annual compliance costs of less than 1 percent of revenues.

Table 30.--Total First-Year, Annual and Annualized Costs of UDI Implementation for All Labelers Under the Labeling Only Alternative [1] (2010 dollars)

Cost Element	First-Year ($ million)	Annual ($ million)
Labeling and Database Requirements		
Administration and planning	$46.5	NA
Barcode registration	$2.2	NA
Equipment and other investments	$82.8	$39.6
Incremental label materials and labor	NA	$9.5
Label redesign	$47.6	NA
Software (with training)	$187.1	$22.2
Total--All Cost Elements	$366.2	$71.2
	Annualized Costs ($ million)	
Annualized First-Year Costs [2]	$52.1	
Total Annualized Costs [2]	$123.4	
Annualized First-Year Costs [3]	$42.9	
Total Annualized Costs [3]	$114.2	

Source: ERG Report, Table 6-2 (Ref. 1).
Note: Numbers may not sum due to rounding.
[1] Labelers include medical device manufacturers, reprocessors, specification developers, repackagers and relabelers.
[2] First-year costs are annualized at 7 percent over 10 years.
[3] First year costs are annualized at 3 percent over 10 years.

3. Apply UDI Requirements Only to Class II and Class III Devices

Under this alternative, FDA would require labelers of class II and class III devices to meet the UDI labeling and GUDID requirements, and all classes of devices would be directly marked. Labelers of class I devices and unclassified devices would be exempt from the general UDI labeling and database reporting provisions. If labelers of unclassified devices were required to comply, this would slightly increase the estimate of the total number of affected labelers and the costs of this alternative.

We used FDA's Registration and Listing database to match product codes to class identifiers in FDA's product codes database. Class II and class III devices were identified, and the counts of firms and establishments by type of labeling activity were recalculated for this subset of labelers. Table 31 shows the revised count of domestic class II and class III labeling establishments and firms by employment size. The total

number of affected labeler establishments under this alternative would be 4,282, compared with 7,578 labeler establishments identified in tables 4 and 5 of this document.

Table 31.--Number of Affected Domestic Establishments by Employment Size and Type of Labeling Activity Under a Class II and Class III UDI Alternative [1,2]

Type of Labeler	Employment Size									
Initial Labelers	1-4	5-9	10-19	20-49	50-99	100-249	250-499	500-999	1000 or more	Total
Manufacturers	1,027	500	438	440	264	233	117	43	26	3,088
Single-Use Device Reprocessors[3]	0	3	0	2	2	2	4	0	0	13
Specification Developers	376	109	96	76	26	13	3	1	1	700
	Employment Size									
Non-Manufacturing Labelers	1-4	5-9	10-49		50-99	100-249	250-499	500 or more		Total
Repackagers and Relabelers	270	78	100		17	10	4	2		481

[1] Source: ERG Report, Tables 6-3, 6-4, and 6-6 (Ref. 1).
[2] Numbers may not add due to rounding.
[3] All counts of reprocessors by size remain the same as those in table 5 of this document, except that we assume that the reprocessors in the 5-9 employment size group are the likeliest to be currently reprocessing class I devices. Therefore, all but three of these reprocessors are removed from the analysis to match the total number of establishments reprocessing class II and class III devices.

The number of affected domestic firms that manufacture class II and class III devices by size and type of labeling activity is shown in table 32 of this document. The number of labeling firms affected by this alternative is 3,673, compared with 6,778 firms identified in table 6 of this document. We adjust these counts of affected establishments and firms for exceptions and baseline compliance. We use the same methods for calculating costs for class II and III establishments as described in the Cost Section F of this document.

Table 32.--Number of Affected Domestic Firms by Size and Type of Labeling Activity Under a Class II and Class III UDI Alternative [1,2]

Type of Labeler	Employment Size							
Initial Labelers	1-4	5-19	20-99	100-199	200-499	500-999	1,000 or more	Total
Manufacturer	877	791	526	114	88	38	122	2,556
Single-Use Device Reprocessors	0	3	3	2	2	1	0	11
Specification Developer	393	179	73	9	6	2	5	668
	Employment Size							
Non-manufacturing Labelers	1-4	5-19	20-499		500 or more			Total
Repackagers and Relabelers	263	115	52		9			438

[1] Source: ERG Report, Tables 6-5, and 6-7 (Ref. 1).
[2] Numbers may not add due to rounding.

The domestic costs of the alternative to apply the provisions of the proposed rule to only class II and class III devices and direct marking to all device classes are shown in table 33 of this document. One-time costs to all labelers to comply with only the labeling and database requirements would be $212.0 million and annual costs would be $44.4 million. One-time and annual costs related to direct marking are unchanged at $27.0 million and $2.0 million. The total one-time costs of this alternative would be $238.9 million and annual costs would be $46.4 million.

Table 33.--Total First-Year, Annual and Annualized Costs of UDI Implementation for All Labelers Under the Class II and Class III Alternative [1] (2010 dollars)

Cost Element	First-Year ($ million)	Annual ($ million)
Labeling and Database Requirements		
Administration and planning	$27.8	NA
Barcode registration	$0.9	NA
Equipment and other investments	$48.2	$23.7
Incremental label materials and labor	NA	$7.9
Label redesign	$28.4	NA
Software (with training)	$104.9	$12.6
Recordkeeping and Reporting (GUDID)	$1.8	$0.2
Total Labeling and Database Requirements	$212.0	$44.4
Direct Marking		
Implants	$12.0	$0.8
Multiple-use devices	$14.9	$1.1
Total Direct Marking	$27.0	$2.0
Total--All Cost Elements	$238.9	$46.4
	Annualized Costs ($ million)	
Annualized First-Year Costs [2]	$34.0	
Total Annualized Costs [2]	$80.4	
Annualized First-Year Costs [3]	$28.0	
Total Annualized Costs [3]	$74.4	

Source: ERG Report, Table 6-8 (Ref. 1)
Note: Numbers may not sum due to rounding.
[1] Labelers include medical device manufacturers, reprocessors, specification developers, repackagers and relabelers of class II and class III devices.
[2] First-year costs are annualized at 7 percent over 10 years.
[3] First-year costs are annualized at 3 percent over 10 years.

The total annualized costs of this alternative would be $80.4 million per year using a 7 percent discount rate over 10 years, and $74.4 million per year at 3 percent. Impacts per firm would remain the same as for the proposed rule, because this alternative would not affect per-establishment costs or the need for direct marking.

4. A Unique Device Identifier That Includes Only Static Information

Under this alternative, we modify the full UDI alternative such that labelers would not be required to include variable information in the UDIs. The UDI would include only the fixed portion that could be used to access data that identifies the specific version or model of a device and the labeler of that device. Existing human-readable variable information would continue to appear on medical device labels (e.g., the lot,

batch, serial number, expiration date or date of manufacture), consistent with most current practices. Under this alternative, more establishments would already comply with the requirements because of existing use of static barcodes. We estimate that 2/3 of the manufacturers with 50 or more employees use at least static barcoding. Those that do not barcode static information are mostly small establishments. About 5 percent, of all manufacturers with fewer than 50 employees are assumed to use a static barcode. No reprocessors or specification developers are assumed to label with static barcodes.

Manufacturers would continue to use current printing procedures and would not need to purchase additional printing equipment. In addition, because variable information would not be contained within the barcode, firms would be able to use their current systems of tracking lot, batch or serial numbers and no new software to integrate variable information into existing systems or related training would be needed. Planning and administrative costs would be reduced primarily because less time is needed to develop plans for those labelers going from not printing any barcode to printing a static barcode.

The one-time costs to register for barcodes, and one-time label redesign costs would remain unchanged from the full requirement alternative. Certain annual costs for supplemental labels and coordination with outside printers would be avoided. One-time and annual costs for direct marking and GUDID would not change.

For repackagers and relabelers, this alternative would provide some reductions in cost to repackagers and relabelers because the requirements to add a static barcode are simpler to plan and carry out.

A summary of the total costs of requiring static information in the UDI for all labelers is presented in table 34 of this document. The one-time costs for labeling and database requirements of a static barcode alternative would be $87.2 million and annual costs would be $3.4 million. The most significant reductions in the costs compared with the full requirements alternative would be about $82.8 million in one-time costs and $39.6 million in annual costs for equipment and other investments, and $187.1 million in one-time costs and $22.2 million annually for software and training. Costs for direct marking would remain at $27.0 million in one-time costs and $2.0 million in annual costs.

Table 34.--Total First-Year, Annual and Annualized Costs of UDI Implementation for All Domestic Labelers Under the Static Barcode Alternative [1] (2010 dollars)

Cost Element	First-Year ($ million)	Annual ($ million)
Labeling and Database Requirements		
Administration and planning	$34.3	NA
Barcode registration	$2.2	NA
Equipment and other investments	NA	NA
Incremental label materials and labor	NA	$3.0
Label redesign	$47.6	NA
Software (with training)	NA	NA
Recordkeeping and Reporting (GUDID)	$3.1	$0.4
Total Labeling and Database Requirements	$87.2	$ 3.4
Direct Marking		
Total Direct Marking	$27.0	$2.0
Total--All Cost Elements	$114.2	$5.4
	Annualized Costs ($ million)	
Annualized First-Year Costs [2]	$16.3	
Total Annualized Costs [2]	$21.7	
Annualized First-Year Costs [3]	$13.4	
Total Annualized Costs [3]	$18.8	

Source: ERG Report, Table 6-18 (Ref. 1).
Note: Numbers may not sum due to rounding.
[1] Labelers include medical device manufacturers, reprocessors, specification developers, repackagers and relabelers.
[2] First-year costs are annualized at 7 percent over 10 years.
[3] First year costs are annualized at 3 percent over 10 years.

The total one-time costs of this alternative would be $114.2 million and annual costs would be $5.4 million. The annualized costs would be $21.7 million per year at a 7 percent discount rate over 10 years, and $18.8 million per year at 3 percent.

5. Apply UDI requirements only to Class III devices.

Under this alternative FDA would require only labelers of class III devices to meet the UDI labeling and GUDID requirements, and only class III devices would be directly marked. The general approach and the underlying assumptions used for preparing this estimate are not comparable to the methods used to estimate alternatives 1 through 4 due to the very limited subset of firms and devices that would be covered by the class III only alternative. Therefore, this estimate is intended only to provide a rough estimate of the costs. The simplifying assumptions are discussed in more detail below. The uncertainty surrounding this estimate is broader than the uncertainty discussed for the other alternatives.

To analyze this alternative, we used the Registration & Listing database to match product codes to class identifiers in FDA's product codes database. Those devices that were identified as class III devices were captured in the analysis, and counts of establishments by type (manufacturer, reprocessor, specification developer, and R/R) were recalculated for this subset of class III-only labelers. We assume for purposes of this estimate that one firm operates one establishment. This assumption possibly overstates firm-level costs estimated for the software cost component because the assumption overestimates the number of firms that would be affected. We then assumed that the distribution by size and NAICS for both firms and facilities would be the same as used for all affected entities. For this analysis, however, we assumed no class III devices are

over-the-counter devices sold at retail, so there was no adjustment made for such exceptions. We also assumed that only 1 percent of multiple-use device establishments label class III devices.

Table 35 presents the revised count of domestic class III labeling establishments by employment size. The total estimated number of affected labeler establishments and firms by employment size for this alternative based on the methodology described in the preceding paragraph would be 444, compared with 7,578 labeler establishments and 6,778 labeler firms affected for all devices.

Table 35.--Number of Affected Domestic Establishments by Employment Size and Type of Labeling Activity Under a Class III UDI Only Alternative [1,2] (2010 dollars)

Type of Labeler	Employment Size									
Initial Labelers	1-4	5-9	10-19	20-49	50-99	100-249	250-499	500-999	1000 or more	Total
Manufacturers	119	58	51	51	31	27	14	5	3	359
Single-Use Device Reprocessors	0	0	0	0	0	0	0	0	0	0
Specification Developers	34	10	9	7	2	1	0	0	0	64
	Employment Size									
Non-Manufacturing Labelers	1-4	5-9	10-49		50-99	100-249	250-499	500 or more		Total
Repackagers and Relabelers	12	3	4		1	0	0	0		21

[1] Source: ERG Report, Tables 6-9, 6-10 ,6-11 and 6-12 (Ref. 1).
[2] Numbers may not add due to rounding. Although the total number of establishments and firms are assumed to be equal, employment size categories for establishments vary somewhat from employment size categories for firms; categories are more aggregated at the firm level.

We generally used the same methods for calculating costs as described in the Cost Section F of this document. The analysis continues to assume the percentages of establishments currently barcoding with variable barcodes remain the same under this alternative.

For the direct marking cost estimate, we determined that very few multiple-use devices would be classified as class III (many are surgical instruments that are class I

devices). We estimated that only 1 percent of multiple-use device establishments would be affected by the direct marking requirement. To keep the number of affected direct marking facilities from exceeding the number of total class III establishments, we also assumed that 40 percent of implant manufacturers and 20 percent of specification writers would label class III implants. The combination of these assumptions results in an estimated 84 percent of all establishments handling class III devices needing to also mark their devices.

The domestic costs of the alternative to apply the provisions of the proposed rule, including direct marking, to only class III devices are shown in table 36 of this document. One-time costs to labelers to comply only with the labeling and database requirements would be $33.6 million and annual costs would be $5.8 million. One-time and annual costs for direct marking would be $4.7 million and $0.3 million. The total annualized cost estimated for this alternative would be $11.6 million per year using a 7 percent discount rate over 10 years and $10.6 million using 3 percent. Although narrowing the scope of devices covered would reduce the compliance costs to industry substantially, a unique device identifier would not be required for the majority of medical devices (class II and I) that are associated with serious adverse events and with recalls. See tables 27 and 28.

Table 36.--Total First-Year, Annual and Annualized Costs of UDI Implementation for All Domestic Labelers Under the Class III Only Alternative [1] (2010 dollars)

Cost Element	First-Year ($ million)	Annual ($ million)
Labeling and Database Requirements		
Administration and planning	$3.1	NA
Barcode registration	$0.07	NA
Equipment and other investments	$5.1	$2.6
Incremental label materials and labor	NA	$0.6
Label redesign	$3.1	NA
Software (with training)	$22.1	$2.6
Recordkeeping and Reporting (GUDID)	$0.2	$0.03
Total Labeling and Database Requirements	$33.6	$5.8
Direct Marking		
Implants	$4.5	$0.3
Multiple-use devices	$0.1	$0.01
Total Direct Marking	$4.7	$0.3
Total--All Cost Elements	$38.3	$6.1
	Annualized Costs ($ million)	
First-Year Costs, annualized at 7 percent over 10 years	$5.4	
Total Annualized Costs, with 7 % annualized 1st- Year Costs	$11.6	
First-Year Costs annualized at 3 percent over 10 years	$4.5	
Total Annualized Costs, with 3% annualized 1st-Year Costs	$10.6	

Source: ERG Report, Table 6-14 (Ref. 1)
Note: Numbers may not sum due to rounding.
[1] Labelers include medical device manufacturers, reprocessors, specification developers, repackagers and relabelers of class III devices.

6. Summary of Alternatives

Table 37 of this document summarizes the one-time and annual costs of the proposed rule and of alternatives 1 through five, assuming immediate implementation. Using a 3 and 7 percent discount rate over 10 years, the total annualized cost of each alternative and the difference in annualized costs compared with the previous alternative are also presented.

Table 37.--Summary of Alternatives and Annualized Domestic Cost Savings Compared to the Previous Alternative[1, 2, 3] (2010 dollars)

Alternative	First Year Cost ($ million)	Annual Cost ($ million)	Total Annualized Cost ($ million)[1]		Annualized Cost Savings Compared with Previous Alternative ($ million)	
			3 percent	7 percent	3 percent	7 percent
Full UDI for unclassified and class I, II, and III devices	$396.3	$73.6	$120.1	$130.1	NA[4]	NA[4]
Require UDI labeling change only	$366.2	$71.2	$114.2	$123.4	$5.9	$6.7
Proposed rule-with immediate implementation: do not require variable barcode for class I devices; certain class I devices are exempt from UDI[5]	**$292.8**	**$46.7**	**$85.8**	**$88.4**	**$28.4**	**$35.0**
Exempt class I devices from UDI[5]	$238.9	$46.4	$74.4	$80.4	$11.4	$8.0
Require only static barcode information on device labels	$114.2	$5.4	$18.8	$21.7	$55.6	$58.7
Require full UDI for class III only	$38.3	$6.1	$11.6	$11.3	$7.2	$10.4

[1] The costs shown do not include costs to issuing agencies or the costs to FDA to develop a database.
[2] Annualized costs are calculated using a 3 and 7 percent discount rate over 10 years.
[3] All costs are estimated under an immediate implementation assumption, including the costs for the proposed rule; see table 18 for the costs of the proposed rule with the proposed implementation schedule.
[4] NA means not applicable.
[5] The costs of the proposed rule used for comparison in this are higher than the actual costs (see table 18), which are reduced through a phased in implementation of the upfront and annual costs. This estimate assumes unclassified devices also would be exempt.

J. Small Business Impact

The Regulatory Flexibility Act requires a Regulatory Flexibility Analysis (RFA) unless the agency can certify that the rule would have no significant impact on a substantial number of small entities. Because the potential impact of the proposed rule on some small entities may be significant, this document constitutes our Initial Regulatory Flexibility Analysis (IRFA).

1. Need for the Rule and Objectives of the Rule

The proposed rule would fulfill the statutory requirement to establish a unique device identification system for medical devices that would adequately identify a device through distribution and use. Currently, medical device manufacturers are not required to use a standardized device identifier. The proposed rule would standardize how medical devices are identified by requiring that medical devices be labeled with a UDI that is both human and machine readable. In the near-term, we anticipate that UDI will help to improve the efficiency of recalls of medical devices and to improve medical device adverse event reporting. In the future, standardized device identifiers would contribute to the success of other initiatives aimed at optimizing the use of automated systems in healthcare.

2. Number of Affected Small Entities

The proposed rule would affect labelers of medical devices. As discussed previously in this document, 6,569 domestic firms would be considered labelers for the purposes of this rule, including medical device manufacturers, medical device reprocessors, specification developers, and firms that repackage or relabel medical devices. Small firms that only handle devices covered by the general exceptions from the proposed UDI requirements, including the GMP exempt class I labelers, would not be affected by the UDI requirements of the proposed rule. We anticipate that the potential impact of the rule on excepted firms would be minimal compared to the impact on small firms that would be required to add the UDI to device labels. To avoid understating the impact of the proposed rule on small entities, we concentrate our analysis on domestic firms that would need to conform to the UDI requirements.

The SBA considers as small, medical device manufacturers with 500 or fewer employees and medical device wholesalers with 100 or fewer employees. Device manufacturers would be included in NAICS categories for manufacturing industries; firms that repackage and relabel medical devices would be included in NAICS categories for the merchant wholesale industry. Because no NAICS category exists for medical device reprocessors, we use the size standard for NAICS 339112 to determine the number of small reprocessors. Similarly, no NAICS category exists for medical device specification developers. To determine the number of small specification developers, we use the size standard for the medical device manufacturing industry (NAICS 3391). Table 38 of this document shows the SBA size standards for the NAICS categories of affected labelers.

Table 38.--Size Standards by Type of Labeler and NAICS

Type of Labeler	NAICS	Description of Industry	SBA Size Standard (Number of Employees)
Manufacturers	325413	In vitro diagnostic substances manufacturing	500
	334510	Electromedical & electrotherapeutic apparatus manufacturing	500
	334517	Irradiation apparatus manufacturing	500
	339112	Surgical & medical instrument manufacturing	500
	339113	Surgical appliance & supplies manufacturing	500
	339114	Dental equipment & supplies manufacturing	500
	339115	Ophthalmic goods manufacturing	500
Repackaging & Relabeling	42345	Medical, Dental and Hospital Supplies Merchant Wholesalers Industry	100
	42346	Ophthalmic Goods Merchant Wholesalers Industry	100

An estimated 1,873 small firms would meet the criteria for the general exceptions (including the GMP exempt class I exception) from all UDI requirements of the proposed rule. Table 39 of this document shows that of the estimated 4,693 domestic non-excepted firms, 96 percent fall below the SBA size standard for small firms. For device manufacturing, the percentage of small firms ranges from 88 percent for in vitro

diagnostic substances manufacturing to 98 percent for dental equipment and supplies manufacturing. The percentage of small firms for the other types of labelers equals 96 percent for reprocessors, 95 percent for firms that repackage and relabel devices, and 99 percent for specification developers.

Table 39.--Number and Percentage of Affected Small Firms by Type of Labeler

Type of Labeler	Employment Size			Number of Firms		Percent of Small Firms
	1-4	5-19	20-499	Small	Total	
Initial Labeling Firms	1,060	1,339	1,051	3,451	3,612	96%
	Employment Size					
	1-4	5-19	20-99			
Repackaging & Relabeling Firms	654	297	81	1,032	1,082	95%
Total	1,714	1,636	1,132	4,483	4,693	96%

Source: ERG Report, Table 7-5 (Ref. 11).
Numbers may not sum due to rounding.

3. Description of the Reporting and Recordkeeping Burdens and Personnel Skill Levels

Regardless of size, all firms subject to the UDI requirements of the proposed rule would need to perform several actions, some of which include reporting and recordkeeping. Because medical device labelers routinely prepare and submit reports to FDA, none of these actions would require new skills. Moreover, all labelers have personnel who can prepare labels with the UDI and operate label printing or marking equipment. Consequently, no new skills would be needed to conform to the requirements of the proposed rule. Table 40 of this document describes the reporting and recordkeeping burdens by major cost component.

Table 40.--Potential Reporting and Recordkeeping Burdens on Small Labeler Firms

Cost Component	Actions involving reporting or recordkeeping	Percentage of Small Firms	Professional Skill Level
Administration and Planning	Create new or modify existing SOPs--accounts for about 25 percent of cost component.	100%	Managerial
Barcode Registration	Complete registration form--a minor part of this component	10%	Managerial
Equipment	Record outcome of the verification tests and necessary remedial actions	100%	Quality Control Inspector
Direct Marking	Document exceptions require 10 hours per exception Verify safety by preparing summary of literature reviews	3% with exceptions 3% verify safety	Managerial
Software	Document testing, verification and validation Except for smallest firms, automates UDI-related recordkeeping and report generation	100%	Inspector or quality assurance; IT, accounting or clerical staff for reports
GUDID	Primary reporting and recordkeeping requirement. Automated or web-based entry minimizes the time needed for these actions. Requires from 3 to 4.5 hours in first year and 1 hour annually in subsequent years.	100%	IT, managerial, technical or clerical staff trained to upload data

4. Impact of the Rule on Small Entities

We use U.S. Census data on average industry receipts to estimate the impact of the proposed rule on small entities. Table 41 of this document shows the average annual receipts for small firms by NAICS and employment size. For this analysis, the average annual receipts for NAICS 339112 serves as a proxy for average annual receipts of reprocessing firms and the device manufacturing industry average annual receipts serves as a proxy for average annual receipts for specification developers. The average annual receipts of firms in NAICS 42345 and 42346 serves as a proxy for the average annual receipts for firms that repackage and relabel medical devices.

Table 41.--Average Annual Receipts by Type and Size of Firm (2007 Dollars)

Type of Labeler [1]	Per Firm Average Annual Receipts ($1,000) by Employment Size		
	0-4 Employees	5-19 Employees	20-499 Employees
NACIS 325413	$890.4	$3,459.3	$28,350.9
NAICS 334510	$520.4	$2,093.2	$21,094.8
NAICS 334517	$594.1	$2,287.7	$18,572.2
NAICS 339112	$443.0	$1,726.1	$15,901.6
NAICS 339113	$365.8	$1,619.2	$13,649.7
NAICS 339114	$330.7	$1,042.1	$16,218.1
NAICS 339115	$1,643.6	$1,556.6	$8,124.2
Reprocessors [2]	$443.0	$1,726.1	$15,901.6
Specification Developers [3]	$568.2	$1,657.8	$15,742.1
	0-4 Employees	5-19 Employees	20-99 Employees
Repackaging and Relabeler Firms[4]	$807.5	$2,804.2	$14,287.5

Source: ERG Report, Tables 5-4 and 5-9 (Ref. 1), based on estimated receipts reported for 2007 (SBA, 2007).
[1] NAICS codes for medical device manufacturing firms.
[2] Estimated to equal annual receipts for NAICS 339112.
[3] Estimated to equal average receipts for the medical device manufacturing industry.
[4] Estimated to equal the average of annual receipts for NAICS 42345 and 42346.

To estimate the magnitude of the potential burden of the proposed rule on small firms, we calculate the average annualized costs of the rule as a percentage of average annual receipts. The detailed cost estimates discussed previously were adjusted from an establishment basis to a firm basis and aggregated by firm size. Table 42 of this document shows a breakdown by employment size for small firms of the total annualized costs over 10 years with 3 percent and 7 percent discount rates. Firms that directly mark devices would have higher annualized costs than similar-sized firms that would not need to directly mark devices; firms directly marking implants would have the highest annualized costs of all types of small firms. Furthermore, we only include the costs for labelers required to include the variable information portion of the UDI. The average annualized costs for labelers of class I devices excepted from including production information would be substantially lower than the average annualized costs for labelers required to include the production information. Consequently, our estimate of the

potential burden of the proposed rule for labelers with no devices requiring direct marking significantly overestimates the burden for labelers of class I devices.

Table 42.--Annualized Domestic Costs of the Proposed Rule for Small Firms by Type and Size (2010 dollars)

Type of Small Firm	Annualized Per Firm Costs by Employment Size					
	3 percent			7 percent		
	1-4	5-19	20-499	1-4	5-19	20-499
Initial Labelers with No Direct Marking that Include Variable Information	$1,199	$9,576	$31,369	$1,333	$10,345	$33,782
Initial Labelers with Direct Marking of Implants	$28,190	$36,567	$101,659	$31,449	$40,461	$111,327
Initial Labelers with Direct Marking of Multiple-Use Devices	$6,413	$14,790	$74,736	$7,150	$16,162	$81,147
	1-4	5-19	20-99	1-4	5-19	20-99
Firms that Repackage and Relabel Devices	$969	$5,464	$23,997 [1]	$1,072	$5,958	$25,835 [1]

Source: ERG Report, Tables 5-5 and 5-9 (Ref. 1).
[1] Annualized costs for firms with 20-199 employees.

Tables 43 and 44 of this document illustrate the burden of the proposed rule on small firms that would not be expected to directly mark devices. We estimate the relative burden of the proposed rule on different size firms as annualized costs as a percentage of average annual receipts. As shown in tables 43 and 44 of this document, the burden for firms not directly marking devices would not exceed 1 percent of average annual receipts with 3 percent and 7 percent discount rates, with the burden estimated to be the largest for small firms in NAICS 339114 that employ between 5 and 19 employees.

Table 43.--Relative Burden of the Proposed Rule by Industry Sectors Not Needing to Directly Mark Devices[1]

Industry Sector	Annualized Costs as a Percentage of Average Annual Receipts					
	3 percent			7 percent		
	1-4	5-19	20-499	1-4	5-19	20-499
NAICS 325413	0.1%	0.3%	0.1%	0.1%	0.3%	0.1%
NAICS 334510	0.2%	0.5%	0.1%	0.3%	0.5%	0.2%
NAICS 334517	0.2%	0.4%	0.2%	0.2%	0.5%	0.2%
NAICS 339114	0.4%	0.9%	0.2%	0.4%	1.0%	0.2%
NAICS 339115	0.1%	0.6%	0.4%	0.1%	0.7%	0.4%
Reprocessors	NA	0.6%	0.2%	NA	0.6%	0.2%
Specification Developers	0.2%	0.6%	0.2%	0.2%	0.6%	0.2%
	1-4	5-19	20-99	1-4	5-19	20-99
Repackage and Relabel	0.1%	0.2%	0.2%[2]	0.1%	0.2%	0.2%[2]

Source: Tables 41 and 42 of this document.

[1] Excludes firms with devices that will require direct marking, firms labeling excepted devices and class I devices exempt from GMP regulations, and firms that currently use variable barcodes. As noted, costs are annualized over 10 years with a 3 percent or 7 percent discount rate. Average per firm revenues from table 41 of this document.

[2] Based on per-firm costs for the 20-199 employment size; this likely overstates the impact of the proposed rule on these small entities.

We anticipate that the proposed rule would create the greatest burden on small firms required to directly mark devices. These firms would normally be included in NAICS 339112 and NAICS 339113. Table 44 of this document shows that the burden on firms in these industries that have no devices that require direct marking ranges from 0.2 to 0.6 percent of average annual receipts using both 3 percent and 7 percent discount rates. By contrast, an estimated 32 small firms with 1 to 19 employees would incur annualized costs to directly mark devices that exceed 1 percent of average annual receipts. Firms required to directly mark implants would have a greater burden than firms required to directly mark multiple-use devices. For the firms with 1 to 4 employees that directly mark implants (e.g., 8 firms), annualized costs would be about 7.7 percent of average annual receipts with a 3 percent discount rate and about 8.6 percent with a 7 percent discount rate, but for the firms that directly mark multiple-use devices (e.g., 19 firms) annualized costs would only be 1.4 percent of average annual receipts with a 3 percent discount rate and 1.6 percent with a 7 percent discount rate. The one-time cost of

equipment needed to directly mark implant devices represents 34 percent of the average annual receipts and the one-time cost of equipment needed to directly mark multiple-use devices represents 5 percent of the average annual receipts. For firms with 5 to 19 employees, annualized costs as a percentage of average annual receipts would total 2.3 percent with a 3 percent discount rate and 2.5 percent with a 7 percent discount rate for firms with direct marking of implants (e.g., 5 firms), and only 0.9 percent with both 3 percent and 7 percent discount rates for firms with direct marking of multiple-use devices (e.g., 13 firms). The one-time cost of equipment needed to directly mark implant devices represents 8 percent of the average annual receipts and the one-time cost of equipment needed to directly mark multiple-use devices represents 1 percent of the average annual receipts. For more detail on the burden of the proposed rule on small firms, see section 5 and section 7 of the ERG report.

Average annualized costs exceed 1 percent of average annual receipts for about 0.7 percent of all affected small labelers. For about 7 percent of the firms with fewer than 20 employees that manufacture surgical and medical instrument (NAICS 339112), average annualized costs as a percent of average annual receipts would exceed 1 percent. The burden for about 2 percent of the firms with fewer than 20 employees that manufacture surgical appliance and supplies (NAICS 339113) would exceed 2.3 percent. Because of our uncertainty about the burden of the direct marking requirements on small firms, we request detailed comment from small firms about our estimates of the potential impact of the proposed rule and how they expect to respond to the direct marking requirements. For more detail on the burden of the proposed rule on small firms, see section 5 and section 7 of the ERG report.

Table 44.--Relative Burden of the Proposed Rule by Employment Size and Industry Sector on Small Entities Required to Directly Mark Devices

Affected Industry by Type of Devices that Require Direct Marking	Employment Size		
	1-4	5-19	20-499
	Number of Affected Firms[1]		
NAICS 339112 - Surgical and medical instrument manufacturing			
Multiple-use items require direct marking	19	13	53
No devices require direct marking	57	201	226
NAICS 339113 - Surgical appliance and supplies manufacturing			
Implants require direct marking	8	5	17
No devices require direct marking	133	382	401
	Annualized Per Firm Costs as Percent of Average Annual Receipts[2]		
NAICS 339112 - Surgical and medical instrument manufacturing			
Multiple-use items require direct marking	1.6%	0.9%	0.5%
No devices require direct marking	0.3%	0.6%	0.2%
NAICS 339113 - Surgical appliance and supplies manufacturing			
Implants require direct marking	8.6%	2.5%	0.8%
No devices require direct marking	0.4%	0.6%	0.2%
	Annualized Per Firm Costs as Percent of Average Annual Receipts [3]		
NAICS 339112 - Surgical and medical instrument manufacturing			
Multiple-use items require direct marking	1.4%	0.9%	0.5%
No devices require direct marking	0.3%	0.6%	0.2%
NAICS 339113 - Surgical appliance and supplies manufacturing			
Implants require direct marking	7.7%	2.3%	0.7%
No devices require direct marking	0.3%	0.6%	0.2%

Source: Tables 41 and 42 of this document.

[1] Firms are counted once (i.e., firms with devices requiring direct marking are excluded from the count of firms with no devices requiring direct marking).

[2] Costs annualized at 7 percent over 10 years.

[3] Costs annualized at 3 percent over 10 years.

5. Alternatives Considered

We analyze the costs of several alternatives to the proposed rule in the Alternatives Section I of this document. The costs and cost savings for the alternatives are summarized in table 37. Because approximately 96 percent of the affected labelers are small entities according to the SBA size standards, the impact on small firms would be the essentially same as for the industry as a whole.

II. References

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