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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Unique Device Identification System; Final Rule

Docket No. FDA-2011-N-0090

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Analysis of Impacts

FDA has examined the impacts of the final 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 FDA finds that this final rule is an economically 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. FDA has examined the impacts of this rule as required by the Regulatory Flexibility Act. FDA finds that the potential impact of the final rule on some small entities may be significant. This Regulatory Impact Analysis (RIA) and other sections of the preamble to the final rule constitute the FDA'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 $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. The estimated costs of this final rule will result in a 1-year expenditure that exceeds this amount.

This final rule establishes a system to adequately identify devices through distribution and use. Under this rule, each medical device must be labeled with a unique device identifier (UDI) and the labeler must submit information concerning each device to FDA's Global Unique Device Identification Database (GUDID), unless subject to an exception or alternative. The system established by this rule requires the label and device package of each medical device to include a UDI and requires that each UDI be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology. The UDI is required to be directly marked on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. The rule provides for alternative placement and exceptions in certain circumstances. Medical device records throughout the required device recordkeeping and reporting systems will have to include the UDI. In addition, the final rule establishes accreditation requirements for agencies that may operate a system for the issuance of UDIs and establishes the conditions for when FDA might act as an issuing agency.

A. Summary of Impacts

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: Economic Analysis of the Final Rule," 2013 (Ref. 1). The final ERG report updates the 2012 ERG cost analysis (Ref. 2) used to support FDA's Preliminary Regulatory Impact Analysis of the proposed rule (Ref. 3).

Table 1 of this document presents for each affected sector a summary of the estimated present value and the annualized domestic costs of this final rule over 10 years using discount rates of 7 percent and 3 percent. Over 10 years, the estimated present value of the total domestic

costs is $642.2 million using a 7 percent discount rate and $737.7 million using a 3 percent rate, and the annualized costs are $85.7 million using a 7 percent discount rate and $84.1 million using a 3 percent discount rate.

Table 1.--Summary of the Estimated Domestic Regulatory Costs of the Final Rule (2012 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[1]	$713.2	$620.4	$81.2	$82.6
Issuing Agencies	$1.4	$1.3	$0.2	$0.2
FDA	$23.1	$20.5	$2.7	$2.9
Total Domestic Cost of the Final Rule	$737.7	$642.2	$84.1	$85.7

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

Costs to Domestic Labelers

The majority of the costs of this final rule will 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 is $620.4 million at a 7 percent discount rate and $713.2 million at 3 percent. Over 10 years, the annualized costs for domestic labelers are $82.6 million at a 7 percent discount rate and $81.2 million at 3 percent. The largest components of one-time costs include planning and administration and the costs to integrate the UDI into existing information systems; to install, test, and validate barcode printing software; and to train employees. Other significant components of one-time costs include costs to redesign labels of devices to incorporate a barcode (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) and date format, and to purchase and install equipment needed to print and verify the

UDI on labels. In addition, labelers will incur one-time costs for recordkeeping and reporting requirements, 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.

Costs to Issuing Agencies

Three existing organizations now perform functions similar to those of an issuing agency under the final rule; the estimated present value of costs over 10 years for these three to apply for FDA accreditation and comply with the final reporting requirements is $1.3 million at a 7 percent discount rate and $1.4 million at 3 percent. The annualized costs over 10 years are $0.2 million at both 7 percent and 3 percent discount rates. There may be other qualified organizations that might apply to FDA to become an issuing agency. In such cases, the estimated application preparation, legal, and reporting costs would apply to these 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 is $20.5 million at a 7 percent discount rate and $23.1 million at 3 percent. The annualized costs over 10 years are $2.9 million at 7 percent and $2.7 million at 3 percent.

Costs to Foreign Labelers

Although we excluded foreign costs from our initial regulatory analysis, in our final regulatory impact analysis we include an estimate of the costs to foreign labelers. From FDA device registration and listing data we find that foreign labelers exporting devices to the United States are located in about 90 countries. Because there can be substantial variability in the labor and capital costs labelers face in different countries, we divide foreign labelers into four groups

and apply different assumptions to each group. The present value of the total costs of the final rule for foreign labelers equals about $561 million with a 7 percent discount rate, and equals about $661 million with a 3 percent discount rate. The annualized present value equals about $75 million with both a 7 and 3 percent discount rate.

Uncertainty

We computed uncertainty ranges based on the percentage relationship between the lower and upper bounds surrounding the central estimate of the costs to domestic labelers. The lower bound is about 57 percent lower and the upper bound about 43 percent higher than the central estimate. Applying a similar range of uncertainty to the total costs of the final rule to domestic labelers, issuing agencies, and FDA, over 10 years the total annualized domestic costs range from $48.8 million to $122.5 million at 7 percent and $47.9 million to $120.2 million at 3 percent.

Alternatives

For the final rule, we compare two alternatives to the final rule. We estimate costs for a full coverage UDI requirement that does not allow reduced requirements for class I devices and for devices that FDA has by regulation exempted from the good manufacturing practices (GMP) requirements. The second alternative varies the content of the UDI across all device classes.

Over 10 years at 7 percent, the annualized present value of the highest cost alternative is about $108.0 million. This alternative applies the UDI requirements to class I, II, and III devices, as well as unclassified devices, unless excepted by final § 801.30(a)(3) through (11). Under the lower cost alternative labelers do not incur costs in certain categories such as purchasing and installing printing equipment and software. The annualized present value of this alternative is about $20.3 million.

Summary of Regulatory Flexibility Analysis

FDA conducted a regulatory flexibility analysis of the impact of the final rule on small entities. About 96 percent of domestic labelers are small firms according to Small Business Administration (SBA) size standards (table 20). The average annualized costs of compliance for domestic labelers as a percentage of annual receipts exceed 1 percent for about 32 firms with fewer than 19 employees that label multiple-use devices subject to the direct marking requirements (table 25). These firms represent less than 1 percent of all affected firms in this size category. Without direct marking, the impact on small firms does not exceed 1 percent of average annual receipts (table 24).

Summary of Benefits

The public health benefits from the UDI are related to reductions in medical device-related patient injuries and deaths. The final rule is expected to improve medical device event reporting by providing a standardized, 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 detect problem devices more rapidly. FDA expects that more accurate and prompt identification of problems would lead to a reduced incidence of adverse events. Public health safety alerts, for example, could be more accurate and timely. Similarly, FDA expects that recall actions could more effectively target a problem device. We expect that the increased accuracy of adverse medical device reporting and improved recalls would reduce the total number of adverse medical device events, although we are unable to quantify that reduction.

In addition, a standardized UDI will 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; such benefits (and additional costs) are beyond the scope of this rule.

Table 2.--Economic Data: Costs and Benefits Accounting Statement (2012 dollars)

	Category	Primary Estimate	Low Estimate	High Estimate	Units			
					Year Dollars	Discount Rate	Period Covered	Notes
Benefits	Annualized $millions/year					7%		
	Monetized					3%		
	Annualized					7%		
	Quantified					3%		
	Qualitative	More accurate and prompt identification of device-related adverse events should 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 $millions/year	$85.7	$48.8	$122.5	2012	7%	10 years	Costs to foreign labelers are not included.
	Monetized	$84.1	$47.9	$120.2	2012	3%	10 years	
	Annualized					7%		
	Quantified					3%		
	Qualitative							
Transfers	Federal Annualized $millions/year					7%		
	Monetized					3%		
	From/ To	From:			To:			
	Other Annualized $millions/year					7%		
	Monetized					3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: No effect							
	Small Business: The final rule may have a significant economic impact on a substantial number of small entities that label medical devices.							
	Wages: No effect							
	Growth: No effect							

B. Need for Regulation and Summary of the Final Rule

Section 226(a) of the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) created 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."

Section 614 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144) amended section 519(f) so that it now reads as follows:

Unique Device Identification System

(f) Not later than December 31, 2012, the Secretary shall issue proposed 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 Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.

The final rule implements this provision 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 AIDC technology, 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.

FDA has specified certain categories of devices that are excepted from some or all of the UDI requirements.

This final rule establishes requirements for the UDI that must appear on each label. A UDI consists 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 must include certain information if it appears on the label of the device, including: the lot or batch within which a device was manufactured, the serial number, the expiration date, the date of manufacture, and for human cells, tissues, or cellular and tissue-based products regulated as devices, the distinct identification code required in 21 CFR § 1271.290(c). The final 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. This final rule establishes 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 final rule specifies the data that will have to be submitted to the publicly available GUDID. Users of the GUDID will be able to use the device identifier portion of the UDI to query descriptive data about a specific device.

Section 614 of FDASIA specified timeframes to implement this final rule for devices that are implantable, life-saving, life-supporting and life-sustaining. The final rule requires a more rapid implementation of requirements for such devices.

There currently is an imbalance between the entities that will 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 will incur the costs of

placing a unique identifier on device labels and of providing medical device information to a device database. Distributors, hospitals, group purchasing organizations, 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.[1] The transaction costs of bringing these disparate parties together to create a standardized system are high. 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 final rule, the availability of a standardized UDI system might advance the development of analytic tools and other information technology dependent on device identifiers in health information systems, including database querying and networking.

C. Summary of Comments on the Proposed Regulatory Impact Analysis

In this section we summarize and respond to comments on the economic analysis of the proposed rule, as well as other comments that are relevant to that analysis. For the Preliminary Regulatory Impact Analysis of the proposed rule, see reference 3 to this document.

Benefits

Comment: Some comments stated that the benefits of the proposed rule would be large and would outweigh the costs of the proposed rule. Types of benefits mentioned included cost savings in healthcare, supply chain efficiencies, reduced costs to manufacturers during recalls, and improved track and trace capabilities.

[1] A 1999 Institute of Medicine report, To Err Is Human: Building a Safer Health System, refers to the U.S. health care delivery system as decentralized and fragmented.

Two comments stated that a UDI system would reduce healthcare costs. For example, technology that could identify hard to find devices needed for surgery to replace worn or failing device implants could reduce the need for full revisions in the case of worn components. A second example noted that the Australian joint registry, using device identification, was able to detect problems with metal on metal hips and thus reduce the use of such devices, reduce the number of revision surgeries, and reduce related healthcare costs. One comment noted that certain benefits would not be realized if hospitals and other healthcare facilities are not ready or equipped to adopt and use UDI information and systems.

Response: We acknowledge that hospitals and other healthcare facilities are not required to adopt and use UDI information and systems. However, we noted in the benefits section of Preliminary Regulatory Impact Analysis that the final rule would standardize how medical devices are identified. In turn, standardized identification of medical devices could contribute to future potential public health benefits of initiatives aimed at optimizing the use of automated systems in healthcare. A standardized UDI could serve as an electronic link to device information among existing and future databases related to device use and safety. However, we cannot estimate such future benefits without knowing what those healthcare systems would be. Nonetheless, in the economic analysis of the proposed rule we discuss the potential public health benefits from improved reporting of postmarket medical device adverse events and improved medical device recalls.

Comment: Two comments cited a 1996 estimate that $11 billion is wasted in the healthcare supply chain each year as a result of inefficiencies and errors attributable to the absence or under-utilization of data standards. One comment suggested that the OMB and FDA should incorporate the value of the benefits of a UDI system to patients, providers and the

overall healthcare supply chain. The second comment stated a belief that a UDI system will result in benefits to society equal to or exceeding those estimated for the final rule to require bar code labels on human drug and biological products. The comment stated that investments in a UDI system are fully justified by the benefits already acknowledged in the economic analysis (reduced medical errors and reduced harm due to more efficient device recalls). The comment also noted that manufacturers would realize savings if recalls were more efficient. The comment cited two recent recalls of device implants with costs to manufacturers, including payments for revision surgeries, of $3 billion and $4.7 billion. A third comment referred to an estimate that a UDI system will save manufacturers, distributors and health care providers $16 billion annually. The comment attributed savings to increased efficiency and accuracy of a UDI system, savings created by more efficient recalls and reduced medical errors, but provided no further information or data about the source of this estimate. Another comment stated that the economic analysis could do a better job of considering expected benefits and stated their belief that reduced medical errors, increased patient safety and more efficient product recalls will easily outweigh the costs of implementing the UDI system. The comment stated that healthcare providers would also benefit because a UDI will permit more accurate and efficient inventory management and improved accuracy of invoices and reduced ordering mistakes. Three additional comments noted that the use of AIDC technology in the supply chain would yield business value and cost savings to manufacturers.

Response: In the benefits section of the analysis of the proposed rule, we discuss the potential value of a mandated UDI in FDA investigation and management of national recalls. The final rule does not require the use of UDI in inventory tracking and distribution throughout the supply chain. Therefore, any costs or efficiency gains attributable to inventory tracking are

not a direct effect of this rule (either a cost or savings to the firm). To the extent that costs are incurred by some labelers to integrate the UDI into management systems (see, for example, the costs attributed to larger firms that have integrated enterprise resource planning (ERP) systems described in the section on Costs of the Proposed Rule, Software and Data Integration), adding a capability for inventory management would be a negligible cost incremental to the regulatory costs.

The comments citing efficiency gains from inventory tracking and product distribution apparently confuse the well-known cost savings from product identification in modern business-to-business commerce with the standardized unique production identification required in this final rule. Firms choose to add an inventory management capability if they find that the efficiency savings outweigh the costs. Although these gains can be substantial, they are not contingent on a standardized, FDA-mandated UDI. Indeed, inventory tracking and product distribution systems using various private identifiers are widely used both for medical products and throughout the United States economy. The UDI would replace or augment other identifiers in these systems but cannot be said to be either necessary or sufficient for those systems. The incremental societal benefits from a standardized UDI to be collected in an FDA database will mainly include the public health gains from reductions in medical device-related injuries and deaths, as described in Section G of this document.

Comment: One comment noted that directly marking reusable items would yield benefits related to inventory maintenance, kitting, ensuring personally owned instruments are accounted for, and selecting and ensuring appropriate sterilization method is used.

Response: We agree that directly marking reusable items can yield other benefits.

Cost and Benefit Balance

Comment: A number of comments noted that FDA should weigh the benefits against the costs of the final rule. Comments ranged from general statements without supporting information to specific areas of concern such as the costs for labelers of convenience kits, costs for lower risk class I and class II non-implant devices, costs to the supply chain (including physicians and dental offices), and direct marking.

Response: The final rule implements the requirements of section 519(f) of the FD&C Act which requires the FDA to establish a unique identification system, as amended by section 614 of FDASIA, which requires a specific timeframe for implementation of the requirements for devices that are implantable, life-saving (life-supporting), and life-sustaining. In Section D of the analysis of the proposed rule, we addressed the imbalance between the entities that would incur the cost of establishing a standardized system to identify medical devices and entities that might benefit from the use of such a system. We noted that medical device labelers would incur compliance costs while distributors, hospitals, and other groups could benefit from the availability of a standardized device identifier and database. In Section H, we described the potential public health benefits most likely to occur from the direct actions of the final rule, including improved reporting of postmarket adverse medical device events and improved medical device recalls.

For the final rule, the FDA has made changes to the proposed rule in response to comments addressing some burdensome provisions of the proposed rule. These changes include removing the requirement for direct marking of implants, revising the requirement for date format so that it is consistent with international standards, and allowing an exception of 3 additional years after the compliance dates for finished devices manufactured and labeled prior to the compliance date. Moreover, FDA retains the exception for the UDI of class I devices to

include a production identifier, and retains the exception for class I devices that are exempted from the good manufacturing practice requirements to bear a UDI.

Comment: One comment stated the analysis of the proposed rule disproportionately focuses on costs to labelers without factoring in substantial cost savings to patients, consumers, health care providers and manufacturers. The comment stated the analysis must also reflect the significant public health benefits and cost savings created by more efficient recalls and reduced medical errors. The comment stated that patients and consumers will experience cost savings as a result of improved access to information which will enable them to make better healthcare decisions and avoid medical costs related to flawed devices or failure to seek prompt medical attention when flaws in devices they rely on are identified.

Response: In Section H of the Preliminary Regulatory Impact Analysis, we describe the potential public health benefits most likely to occur from the direct actions of the final rule, including improved reporting of postmarket adverse medical device events and improved medical device recalls. We have insufficient information to quantify future public health gains from potential initiatives aimed at optimizing the use of automated systems in healthcare, and cannot estimate those future benefits at this time. Nor can we assess the independent contribution of a mandated UDI to the effectiveness of those future systems. Nonetheless, we provided an illustrative break-even analysis to determine the level of effectiveness that would cover the total costs of the proposed rule.

Costs

Comment: Comments referred to specific cost items including the need to purchase new printers and scanners on certain production lines to print and verify the UDI on device labels and

packaging; or generally referred to implementation costs and costs of new procedures, maintenance costs and costs associated with downstream transactions.

One firm estimated a cost of over $100,000 for printing and verification equipment. A second firm estimated the total cost to implement the required processes to meet the proposed rule requirements including updates to printing systems with more advanced computer system technology, equipment installation, validation and training would be $10 million for their U.S. facilities with an estimated cost of $150,000 per packaging line. A third firm estimated that if their current printers were not capable of printing barcodes, it would cost about $350,000 to upgrade.

Response: We cannot comment on the individual estimates provided in the comments because there is not sufficient information documenting the estimates, such as the nature and number of production lines, the way that cost components were grouped, or whether upgrades will be needed. Our cost assumptions for equipment investments for UDI requirements are presented in Table 10 of the Preliminary Regulatory Impact Analysis. We described a range of possible compliance strategies that manufacturers might choose to follow depending on firm size and manufacturing capabilities. We then estimated average per establishment investment costs for printers, scanners, applicators, verifiers and engineering overhead. The cost to add equipment ranged from about $450 for small establishments with manual lines to about $120,000 for establishments with 6 or more fully automated production lines. In addition, we estimated on-going operating and maintenance costs at 10 percent of equipment costs plus labor. Our costs for software validation and for training are presented separately in table 14 of the analysis of the proposed rule.

For the final rule, we reviewed the underlying cost assumptions and labor rates for all cost categories. The producer price index for printing equipment indicates that prices have declined slightly. Our final estimate of printing equipment costs and of the average costs per production line remains unchanged. We increased our estimates of software costs slightly based on the producer price index. We also increased our estimate of planning and implementation costs to account for shorter implementation times required by FDASIA and the hours needed for participation by more managers to plan and implement the rule, and to develop or revise standard operating procedures (SOPs).

Costs Not Addressed

Comment: One firm stated their belief that FDA did not account for costs related to label inventory, participating with issuing agencies (AIDC technology subscriptions), SPL software, label redesign, gathering data elements and submitting to the GUDID, and computer system updates.

Response: In Section F of the Preliminary Regulatory Impact Analysis, we provided estimates of the cost of planning and implementing the new requirements, label inventory, AIDC technology subscriptions, SPL software, label redesign, updating computer systems for both simple and complex ERP systems and preparation of GUDID submissions.

Cost if UDI is serialized

Comment: One firm that is a contract manufacturer was concerned that customers would require devices to be serialized. They estimated the cost for computer upgrades to track UDIs with serial numbers would be $200,000.

Response: Serialization is not required by this final rule. Should customers require devices to be serialized, that is a cost of doing business and might be passed on to the specification developer. This final rule is not expected to affect the use of serialization.

Costs Related to Issuing Agencies

Comment: One comment asked if issuing agencies would charge manufacturers for UDIs and said the costs were not addressed in the analysis of impacts. Another comment from an issuing agency noted that their service is cost-effective for assigning UDIs.

Response: In the analysis of the proposed rule, we estimated the costs of participating with an issuing agency using publicly available information from an issuing agency. We estimated one-time costs per firm would range from $500 for the smallest firms with fewer than 20 employees to $20,000 for firms with 500 or more employees (see table 9 of the Preliminary Regulatory Impact Analysis (PRIA)). We noted that 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. We asked for comment on these estimates and on labelers' current experience with participation fees, including any recurring fees, charged by existing organizations. We did not receive any specific comments that would alter our estimate. Therefore, this estimated cost remains unchanged for the final rule.

Comment: Some comments stated that FDA over-estimated the costs to labelers, to the extent that the existing standards and unique identification numbers offered by potential issuing agencies already meet the standards proposed by FDA. The comments state that some labelers have voluntarily implemented a UDI system and their costs should not be included as costs of the proposed rule.

Response: The FDA provided estimates of the level of voluntary compliance with labeling requirements of the proposed rule and did not assign incremental costs to labelers already compliant with specific proposed requirements. Our baseline compliance assumptions are described in sections 4.2 and 4.3 of the May 2012 ERG report. (Ref. 2) We note, however, that baseline conditions, including any voluntary actions to purchase and use unique identifier numbers from potential issuing agencies would not encompass the full requirements of the rule. For example, the final rule requires a UDI that includes the production identifier on many device labels and packages. We acknowledge that the assumed level of baseline compliance is based on somewhat dated survey data from an industry organization, and that the current level of compliance has likely increased. Therefore, our estimates of cost of compliance may be overstated. However, none of the comments provided data to support using a different level of baseline compliance. We conclude that our estimates of compliance, which include estimates of uncertainty, are reasonable.

Cost Underestimated

Comment: One comment stated the burden associated with the proposed conforming amendments to subparts 21 CFR 820 is likely underestimated. The comment stated that companies will have to amend existing automated processes and databases, such as compliant management processes, to include a field for UDIs and reporting capabilities by UDI. All related procedures would need to be updated as well.

Response: In the analysis of the proposed rule we incorporated the costs of complying with conforming amendments into the costs estimated for information technology (IT) changes. (See the Preliminary Regulatory Impact Analysis, Section F. Software and Data Integration.) The one-time costs would include purchasing software packages, costs to install, test and

integrate the software into existing IT systems where necessary, software validation and employee training. Once IT systems are changed to address all of the needs of the conforming amendments, we estimate that most of the reporting needs are automated, or require only one additional piece of information to be extracted while inspecting a label for other required information. Thus, the incremental burden related to the UDI and conforming amendments would be minimal.

Comment: One comment stated FDA may have underestimated the cost of implementing and maintaining a UDI system. Some provisions of the proposed rule would increase costs for industry by necessitating packaging material changes to ensure that in-line printing requirements can be met. For many low cost Class II products, packaging already comprises 30-35 percent of the overall device cost. In other cases, the proposed rule could affect the manufacturing productivity of large product volume manufacturers resulting in product shortages or the need for additional production lines. "The addition of product cost without a measurable public health benefit is a luxury that the US healthcare system cannot afford. Therefore, FDA must allow for practical alternate placement of UDI and AIDC markings."

Response: The comment did not provide specific information to support the concern that costs for implementing and maintaining a UDI system might be understated. In the economic analysis of the proposed rule, we estimated costs for printing equipment (see table 10) and labor time to operate equipment and verify barcodes. Our estimates include instances where firms may need to install in-line printing equipment on high speed production lines. We estimated annual costs to initial labelers of about $5.8 million for label material changes (see label redesign costs). Although the FDA has accounted for the costs associated with possible compliance solutions, it is possible that on some lines, a solution might not be immediate. We have

accounted for additional labor time to operate equipment and to verify barcodes. We did not account for scenarios where lines are operated at full speed and capacity 24 hours a day because it is unlikely to occur. With respect to allowing for practical alternative placement, section 801.55 of the final rule (801.35 of the proposed rule) provides a process for requesting an exception from or alternative to the requirement for a device to bear a unique identifier. Also, under section 801.30(a)(3) we extend the exception for a label to bear a UDI from class I to all classes of devices, except implants. This exception applies to individual single-use devices (SUDs), all of a single version or model that are distributed together in a single device package and are not intended for individual sale. The final rule therefore extends the general exception for individual single-use devices that are distributed together in a single device package and which are not intended for individual commercial distribution or sale to all device classes except for any implantable device.

Comment: One comment stated FDA underestimated the effort required by manufacturers to make the appropriate labeling changes to all products affected by the proposed rule. The comment specifically mentioned a change control system as part of the Quality Systems Regulation. The firm noted that some firms have thousands of labels that require change and that FDA should allow more time to ensure the accuracy of the required labeling changes.

Response: In the economic analysis of the proposed rule, we estimated the costs for planning and implementation of the proposed requirements, which included revisions to SOPs, and the costs for redesigning device labels. For the final rule, we increase the estimated planning and implementation costs for establishments that label class III devices and for establishments that label life-supporting or life-sustaining devices that are not class III to account for the costs of

managing a large volume of device labels within the shortened implementation timeframes established by statute in FDASIA. See table 6. In addition, in response to comments, we increased cost estimates in certain categories as shown in table 7.

Comment: Several comments stated that the economic impact of the proposed rule appears to overlook major potential costs. The comments referred to one or more of the following costs: (1) hospital, clinic, physician and other healthcare provider costs including IT cost and infrastructure, and costs to read and use multiple AIDC technologies; (2) OUS (outside the United States) labelers; (3) diminished access to products to perform UDI assessments and labeling; (4) the time and effort needed to maintain UDI data; (5) cost paid to issuing agencies; (6) time and cost (on both industry and FDA) of any new submissions; (7) the time and cost for GUDID data analysis; (8) the cost on all stakeholders if finished goods must be reprocessed and (9) the time and effort needed to analyze UDI information and respond to inquiries.

Response: (1) The final rule does not require hospitals and other healthcare providers to use the UDI or develop infrastructure, therefore, we did not estimate either costs or benefits.
(2) For the final rule, we estimate costs for foreign (outside United States) labelers. See Section J of this document.
(3) We cannot respond to this comment because we did not receive sufficient explanation.
(4) We have increased our estimates of the time and effort to maintain the UDI database. See our response to comments on recordkeeping, including the GUDID.
(5) We have accounted for the costs of participating with accredited bodies (Table 9 of the Preliminary Regulatory Impact Analysis) and the time and effort for labelers to maintain UDI databases.

(6) The comment did not specify which submissions it believes FDA omitted. In the economic analysis of the proposed rule, we estimated costs to labelers for submitting exceptions from directly marking medical devices. For the final rule we retain estimates except for implanted devices which are not required to be directly marked. In addition, we include additional costs for filing any other exceptions from or alternatives to a UDI requirement. These additional costs are estimated in the costs for planning and administration. The net increased FDA review costs are captured by the costs associated with setting up and operating the database. The database is expected to increase the cost-effectiveness of data review.

(7) We estimated costs for the GUDID in the Preliminary Regulatory Impact Analysis.

(8) The cost analysis includes costs for reprocessors.

(9) This is out of scope.

Comment: Two comments identified the following categories of increased costs that would affect their firms: the modification of manufacturing processes, the development and testing of new manufacturing processes; development and validation of new data collection tools that communicate with the GUDID; costs for marking, inventory control and inspection of devices; and ongoing burdens of maintaining an accurate system of device tracking, marking, inspection and recordkeeping.

Response: The analysis of impacts for the proposed rule accounted for the cost of developing and installing a UDI capability. Cost elements included administration and plan development, participating in a UDI system operated by an issuing agency, purchasing equipment, direct marking, label redesign, software and data integration, and recordkeeping and reporting including costs for the GUDID and related ongoing operating and maintenance costs.

Comment: Some comments asked FDA to consider the costs to healthcare practitioners, such as the cost to insert UDIs into electronic health records, and the implementation costs for hospitals and other care providers.

Response: The final rule does not require healthcare providers to use a UDI. Decisions to invest in health information systems that would use a UDI would be made independently of this final rule. Nonetheless, the availability of a standardized UDI system could advance development of analytic tools and other information technology that would use a UDI.

Comment: Some comments made general statements that costs were underestimated, the costs are significant, or certain provisions of the rule would substantially increase burdens without clear benefit, but did not provide sufficient information to respond to the statements.

Response: The FDA has no response to these general statements but we note that we have responded to comments that cited specific reasons that costs might be underestimated.

Direct Marking

Comment: Some comments expressed concern about the cost of direct marking. Two comments submitted their own estimates of the cost of direct marking. One cost estimate represented results of an industry survey that covered the cost of purchasing additional machinery to mark devices directly; implementing processes associated with the marking; software systems associated with linking the device packaging with the UDI; quality system validation associated with direct marking including testing to ensure continued safety and effectiveness; regulatory submissions for re-approval of the product; and reworking and redistributing finished goods inventory. The comment stated the cost could be substantially higher than the FDA estimate if 801.50 [devices that must be directly marked] remains unchanged and the criteria for 801.20 [the label of a device to bear a UDI] is defined as when a

device is placed into interstate commerce. The comment requested that the final rule remove the requirement to directly mark devices that are implanted. If the FDA does not remove the requirement to directly mark implants, the comment states that FDA should specify types of implants that are intrinsically unable to be directly marked and read by scanner or humans, or devices that cannot be directly marked for a number of other reasons, including size limitations of the marking area. The comment requested that devices already subject to tracking requirements be exempted from the 801.50 requirement to directly mark devices.

The second comment challenged FDA's assumptions about the percent of firms that directly mark implantable devices and the efforts needed to validate that direct marking does not compromise safety and effectiveness. The comment also questioned the value of the requirement to directly mark devices compared to the industry burden. The comment submitted cost estimates for directly marking implantable devices specific to their firm.

Response: The FDA has decided to withdraw the proposed requirement to directly mark implanted devices. Therefore, the comments on direct marking of implants are not further considered.

Comment: One comment asked whether the direct marking of reusable surgical instruments would cause confusion at the user level with barcode systems already implemented at some hospitals for tracking purposes.

Response: The use of UDI in these settings is outside the scope of this rule. FDA acknowledges, however, the barcodes currently in some facilities are not compatible with UDI, and then these entities could bear some transition costs in converting to a UDI-based system.

Price Effects

Comment: Several comments stated that the costs of regulation would likely be passed on or transferred to purchasers of medical devices (end users such as hospitals and patients, insurance companies and consumers). One comment stated that the direct marking of reusable surgical instruments would increase the cost of affected instruments and noted that they do not have the resources or the technology to mark their own instruments. Another comment stated that inconsistent implementation of AIDC, such as allowing for use of multiple technologies, would result in increased costs to customers. A distributor of medical products estimated costs of $5,000 to $7,000 for each item label change and on-going costs of from $100 to $1,000 for regular changes to the UDI would be passed on to the consumer and would be prohibitively expensive for class I devices.

Response: Nearly all of the costs of this final rule, both one-time costs and the recurring annual costs, are fixed costs. The likelihood that these costs will lead to price increases to purchasers mainly depends on the size of those fixed costs relative to revenues and the market response. In some instances, some of the costs will be passed on in the form of price increases, loss of consumer surplus associated with products that are no longer available, or both. As shown in the Final Regulatory Flexibility Analysis, for most sectors, the annualized costs are small relative to the average annual receipts, indicating that price increases should be small if they occur at all. We note, however, that price increases are more likely for products and market sectors dominated by small businesses.

If a distributor also relabels devices, they are required to comply with UDI. We cannot comment on the distributor's cost estimate because the comment did not provide sufficient detail.

Medical Gases and Medical Gas Devices

Comment: One comment estimated the cost of the proposed rule would be $100 million for the compressed gas industry to implement UDI in terms of additional labeling and registration requirements, and maintenance cost associated with managing GUDID changes. The comment stated the proposed rule appears to be inconsistent with E.O. 13563 Improving Regulation and Regulatory Review.

Response: Filled medical gas containers and closures are regulated as integral parts of a medical gas and are regulated as a prescription drug and generally do not have to bear a UDI. Other gas containers may be regulated as medical devices. We have included these medical devices in our analysis of impacts which includes the costs for labeling, registration, and submission and maintenance related to the GUDID.

GUDID and GMDN

Comment: We received many comments about whether data for excepted devices will be submitted to the GUDID. Some comments asked for clarification about excepted class I devices. Other comments insisted that users need to have the ability to look up any device data in the GUDID, regardless of whether it is an excepted device.

Response: Labelers of devices excepted from the UDI requirements need not submit data to the GUDID. In the final rule, labelers must submit data on all class I devices except those covered by certain general exceptions. For our final analysis, we now include the costs for labelers of these class I devices to submit data to the GUDID, as discussed in the Recordkeeping and Reporting section of this document.

Comment: One comment stated it will be burdensome to submit data to the GUDID when the medical device contains software.

Response: In this case, software is a component of the device. The GUDID reporting burdens for devices that contain software would not be any more burdensome that for any other type of device.

Comment: We received many comments on the GUDID. Although most comments did not give any details about the effort expected to access and use the GUDID, the comments provide insight into the challenges that labelers will face to initially submit data to the GUDID. Many comments expressed general concerns about the number and types of device attributes in the GUDID and many comments supported the proposed list of attributes. Some comments mentioned the costs to convert data into SPL and who would be responsible to manage and validate the data.

Response: We update our estimate of the cost to FDA to create, implement and maintain the GUDID based on accrued and estimated expenses. Based on comments and a better understanding of required data elements and the effort required to use the GUDID, we revise our estimate of the one-time effort needed by labelers to gather, submit and validate data to initially populate the GUDID, and to update existing data or add new GUDID data on a recurring basis. Moreover, we increased our estimate of the frequency that labelers will need to convert data to an SPL document. See tables 10 and 11 of this document.

Comment: Multiple comments claimed that the GMDN system was difficult to use and would be costly for labelers already using other nomenclatures.

Response: FDA plans to provide a feature in the GUDID data entry process that will allow labelers to search for and select the appropriate GMDN nomenclature, which will then be linked to the appropriate GMDN code. We include the costs to understand and use this feature in our estimate of the GUDID costs.

Date Format

Comment: We received several comments on the date format requirement in the proposed rule. The bulk of these comments objected to the use of a non-harmonized date format because it was unnecessarily burdensome and confusing. Some comments specifically stated that the proposed date format conflicted with European date formats. Such a format would require device labelers to maintain two versions of their devices, one for the American market and another for the rest of the world. Some comments stated a non-harmonized date format would increase translation costs for labelers involved in global markets.

Response: The FDA has modified this requirement for the final rule and requires that labelers use a particular date format that is consistent with international usage and international standards.

Comment: We received comments stating that the 1-year implementation period for the date format was too short and would create inefficiencies.

Response: The FDA has modified the compliance date for this requirement. Labelers can modify the date format at the same time they implement the UDI requirements. In the case of devices excepted from the UDI requirements, labelers have 5 years to adopt the new date format.

Comment: We received two comments that we understated the costs of the hardware and software needed to print the date format. See the Label Redesign section of this document.

Response: In response to comments, we have added the cost of date stamp dies for certain labelers.

Impact on Small Business

Comment: Some comments on specific issues such as the date format or direct marking of some devices noted that small businesses would be especially hard hit by these provisions.

Response: Most requirements addressed in these comments have been revised such that small businesses will not be excessively impacted by the final rule. As discussed in the final regulatory flexibility analysis, direct marking of multiple-use devices may create a substantial burden for some small labelers, with average annualized costs exceeding 1 percent of average annual receipts. See table 25 of this document.

Comment: One comment from a small durable medical equipment manufacturer stated that requiring the UDI on class I devices would be burdensome and suggested that the rule include an exemption for durable medical equipment because all of these devices are distributed to end users through direct sales from a hospital or other facility or through retail sales.

Response: The comment provides no details about the potential magnitude of the burden if class I devices were subject to the UDI requirements. Similar to the proposed rule, the final rule excepts all class I devices from the production identifier requirement. Even with this exception, labelers of class I devices will incur planning and administration costs, costs to manage and maintain UDI data, costs to gather and submit device data to the GUDID, and costs to redesign labels to comply with the final date format requirement, if necessary. As discussed in section I of this document, the average annualized costs for domestic labelers only handling class I devices will not exceed 1 percent of the average annual receipts for all small businesses.

Comment: One comment requested that FDA provide information to small businesses on how to comply with the UDI requirements instead of fee-based webinars. The comment stated that labeling and identification systems are expensive to replace.

Response: The FDA will publish a Small Business Compliance Guide for small business on how to implement the UDI requirements. We have included the costs for labelers to read and understand the rule in our cost analysis.

D. Medical Device Manufacturing Profile Update

The profile of the domestic medical device industry stands as presented in the analysis of the proposed rule. In the analysis of the final rule, we distribute labelers by class of device and by implantable, life-supporting or life sustaining devices as shown in table 3a. We use the list of devices identified in the proposed rule amendment as implantable, life-saving and life-sustaining for this purpose (FR69394 Ref. 12).

Table 3a.—Number of Domestic Establishments by Class of Device Labeled[1]

Type of Labeler	Any Class III (May Have Implantable, Life-supporting or life-saving	Class I & II Only (With Implantable, Life-supporting or life-saving)	Class I & II Only (No Implantable, Life-supporting or life-saving)	Class I Only (No Implantable, Life-supporting or life-saving)	Total
Domestic					
Manufacturer	359	536	2,193	1,813	4,901
Reprocessor	-	1	12	8	21
Specification Developer	64	161	475	646	1,346
Subtotal	**423**	**698**	**2,680**	**2,467**	**6,267**
Repackager Relabeler	21	59	402	828	1,310
All Labelers	**444**	**757**	**3,082**	**3,295**	**7,578**

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

[1] An establishment is only counted once.

Note: For domestic establishments, one class I Repackager or Relabeler was moved to class I and II implantable, life-supporting or life-saving devices.

In table 3b, we distribute the establishment counts from table 3a according to establishment size and the estimated level of impact on these establishments. The impact of the final rule will depend on the type of device and whether the device is subject to any exceptions to the final rule. For example, the rule excepts the UDI of class I devices from the requirement to include a production identifier--the variable portion of the UDI--and allows labelers of these devices to use a UPC for the UDI. This exception reduces the impact. Of the estimated 7,578

establishments identified in table 3a, 3,487 establishments will label devices with a UDI that includes the production identifier and 2,163 establishments will label devices with a UDI that does not include the production identifier. An estimated 1,670 establishments only handle devices excepted from the final rule, including 549 establishments that only handle GMP-exempt devices. We expect negligible impacts on these establishments.

Table 3b.—Estimated Number of Domestic Establishments by Level of Impact and Employment Size

	1-4 Employees	5-9 Employees	10-49 Employees	50-99 Employees	100-249 Employees	250-499 Employees	500+ Employees	**Total**
Excepted: Initial Labelers [1]	1,243	301	151	41	35	17	10	**1,799**
Excepted: Repackager & Relabeler[2]	73	21	27	5	3	1	0	**129**
UDI without production identifier: Initial Labelers	355	221	528	144	121	60	35	**1,463**
UDI without production identifier: Repackager & Relabeler	394	114	145	25	15	5	2	**700**
UDI with production identifier: Initial Labelers[3]	754	493	1,046	286	240	118	68	**3,006**
UDI with production identifier: Repackager & Relabeler	270	78	100	17	10	4	2	**481**
Total [4]	**3,089**	**1,228**	**1,997**	**519**	**424**	**205**	**117**	**7,578**

Numbers may not sum due to rounding.

[1] Includes 420 establishments labeling GMP-exempt class I devices excepted under section 801.30(a)(2); includes 1,141 establishments with fewer than 5 employees and 238 establishments with fewer than 10 employees that label devices excepted under sections 801.30(a)(3) through (11).

[2] Includes only establishments labeling GMP-exempt class I devices excepted under section 801.30(a)(2).

[3] Includes 108 establishments with 50 or more employees that now use variable barcodes.

[4] We assume that the 1,379 initial labeler establishments excepted under sections 801.30(a)(3) through (11) would be excluded from any alternative. The full UDI alternative and the alternative for the UDI without a production identifier include 6,199 establishments. With the full UDI alternative, 108 initial labeler establishments with 50 or more employees now use variable barcodes and incur lower planning and administration costs, and would incur no equipment or software costs. For more details about the alternatives, see Section H of this document. With the alternative for the UDI without a production identifier, 474 initial labeler establishments and 84 repackager and relabeler establishments now use UDI compliant barcodes.

E. Costs of the Final Rule

Costs to Domestic Labelers

The final rule requires 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 consists 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 is 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, the date of manufacture, and for human cells, tissues, or cellular and tissue-based products regulated as devices, the distinct identification code required in 21 CFR § 1271.290(c). The UDI will identify the device throughout its distribution and use. Labelers of class I devices are not required to include production identifier(s) in their UDIs. Labels of class I devices that FDA has exempted from GMP regulations are not required to bear a UDI. Other specific categories of devices, listed in § 801.30 (a), are not required to bear a UDI. The UDI must also appear directly on some devices. The final rule requires the submission of product information about each device required to bear a UDI to an FDA database.

We summarize below the regulatory changes from the proposed rule that lead to changes in the estimated costs:

- We have incorporated FDASIA implementation timeframes for implantable, life-supporting or life-sustaining devices that are classified in class I or II or that have not been classified.

- After careful consideration of the comments, we have removed the exception from the requirement for the label of the device to bear a unique device identifier that applied to non-prescription devices purchased at retail establishments. Such devices will be subject to all labeling and GUDID reporting requirements, and a Universal Product Code (UPC) may serve as the unique device identifier for a class I device or device package.
- We have revised the date format requirement to be consistent with international standards. In addition, the date format requirements will go into effect at the same time as other UDI labeling requirements.
- We have removed the requirement for manufacturers of implanted devices to permanently mark devices with a UDI. Magnetic resonance imaging (MRI) compatibility has been added to the GUDID data requirements, if applicable.
- FDA will provide GMDN nomenclature to labelers at no cost.

In addition, FDA made a number of changes to the final rule that indicate a no cost assumption or negligible changes in cost are warranted. We list some of these because they drew numerous comments about potential impacts:

- We have expanded the exception (for the label to bear a UDI) for individual single-use devices that are distributed together in a single device package which bears a UDI and which are not intended for individual commercial distribution or sale to include all such single-use devices, except implantable devices. This exception was limited to class I single-use devices in the proposed rule.

- We have provided a 3-year exception from the requirement for the label of a device to bear a unique device identifier for a finished device that was manufactured and labeled prior to the applicable compliance date.

We continue to use the cost analysis presented in the RIA for the proposed rule as the base for our final cost analysis. We have, however, revised some cost categories and methods for estimating cost in response to changes to the final rule or in response to comments. Such changes are described in the relevant cost sections.

Costs are adjusted to 2012 dollars with the following clarifications:

- We have not adjusted equipment prices, such as for scanners, printers and verifiers, although these prices have declined slightly.
- We have not changed costs for registering with an issuing agency. The costs for registering with HIBCC have not changed.
- We have not adjusted wage rates even though wages for the categories used have declined very slightly over the time period.
- We used the producer price index to review and update as needed certain cost categories such as label material costs, direct marking lasers and related software, and software costs. In cases where the producer price index went down slightly, we declined to make cost adjustments.

In tables 4 and 5 we summarize and compare the one-time and annual costs of the proposed and final rule. For ease of comparison across cost categories, we lump these costs into a single first year and a single annual total; the final rule, however, will be phased in over 7 years, so the one-time and annual costs will begin in different years for different classes of devices.

Table 4-- Summary of the Total One Time Costs of the Proposed and Final Rule—All Labelers (2012 dollars)

	Proposed Rule ($ million)	**Final Rule ($ million)**	**Difference in Cost (Final - Proposed Rule) ($ million)**
Labeling and Database Requirements			
Administration and planning	$37.1	$86.4	$49.3
Registration costs	$2.0	$2.0	$0
Equipment and other investments	$47.5	$47.5	$0
Incremental label cost	NA	NA	NA
Label redesign cost	$47.6	$47.7	$0.1
Software (with training)	$128.7	$131.5	$2.7
Recordkeeping & Reporting	$2.9	$26.5	$23.7
Total Labeling and Database Requirements	$266.0	$341.7	$75.8
Direct Marking			
Implants	$12.0	$0	($12.0)
Multiple-use Devices	$14.9	$14.9	$0
Total Direct Marking	$27.0	$14.9	($12.0)
Total All Cost Elements	$292.8	$356.6	$63.8

Source: FDA PRIA, table 17 (Ref. 3) and ERG Report, Table 4-47 (Ref. 1)

Table 5-- Summary of the Total Annual Costs of the Proposed and Final Rule—All Labelers (2012 dollars)

	Proposed Rule ($ million)	**Final Rule ($ million)**	**Difference in Cost (Final - Proposed Rule) ($ million)**
Labeling and Database Requirements			
Administration and planning	NA	NA	NA
Registration costs	NA	NA	NA
Equipment and other investments	$22.6	$22.6	$0
Incremental label cost	$7.6	$8.4	$0.8
Label redesign cost	NA	NA	NA
Software (with training)	$14.2	$14.7	$0.5
Recordkeeping & Reporting	$0.4	$8.4	$8.0
Total Labeling and Database Requirements	$44.7	$54.1	$9.4
Direct Marking			
Implants	$0.8	$0	($0.8)
Multiple-use Devices	$1.1	$1.1	$0
Total Direct Marking	$2.0	$1.1	($0.8)
Total All Cost Elements	$46.7	$55.2	$8.5

Source: FDA PRIA, table 17 (Ref. 3) and ERG Report Table 4-47 (Ref. 1)

As shown in tables 4 and 5 above, the following categories of one-time and annual costs remain unchanged from the proposed rule:

Registration costs: The cost to participate in a UDI system operated by FDA-accredited issuing agencies remains at $2.0 million for all affected labelers. There are no annual costs for this requirement.

Equipment costs: The one-time costs to purchase and install printers, verifiers, and scanners to add the UDI barcode to device labels is $47.5 million for all labelers. The annual costs to operate verifiers and annual equipment operating costs are $22.6 million for all labelers.

In the following section, we discuss the nature of the change in cost from the proposed rule for the remaining cost categories.

Administration and Plan Development

Public comments stated that FDA underestimated costs for administration and plan development. Several comments stated that planning and implementation would require more effort and involve substantial interactions between multiple departments within the establishment. We have revised costs to account for these comments.

Some comments also requested longer implementation times than allowed by FDASIA. All implantable, life-supporting or life-sustaining devices that are not class III devices now have a 2-year implementation period. We increase planning and administration costs for all labelers of class III devices, and for labelers of implantable, life-supporting or life-sustaining devices that are not class III.

Additional Hours Related to FDASIA Requirements

We have revised our estimate of the number of requests for exceptions for class III establishments and for implantable, life-supporting or life-sustaining devices that are not class III. Table 6 summarizes the estimate of additional hours needed for requesting exceptions and for meeting shortened implementation times due to statutory changes. Depending on establishment size, establishments might submit from 1 (for establishments with fewer than 10 employees) to 60 exceptions (for establishments with more than 500 employees). Using 4 hours per exception, we estimate that from 4 to 240 hours would be required to prepare and submit exceptions. Assuming that 10 percent of establishments submit one or more exceptions, the hourly estimates are then pro-rated over all establishments to estimate the additional number of hours per establishment needed to prepare and submit exceptions.

Table 6.—Additional Hours Estimated for Filing Exceptions and for Shorter Statutory Implementation Period

	Establishment Size						
	1-4	**5-9**	**10-49**	**50-99**	**100-249**	**250-499**	**500+**
Exception Requests							
Number of Requests	1	1	3	6	15	30	60
Total Hours for Requests per Affected Establishment	4	4	12	24	60	120	240
Hours per Establishment [1]	**0.4**	**0.4**	**1.2**	**2.4**	**6**	**12**	**24**
Shortened Implementation Period							
No. of Managers	1	1	1	2	4	6	9
Class III							
Additional Hours Needed	20	40	80	160	320	480	720
Hours per Establishments [2]	1.5	2.9	5.8	11.7	23.3	35.0	52.5
Implantable, Life-Sustaining or Life-Supporting, Not Class III							
Additional Hours Needed	10	20	40	80	160	240	360
Hours Per Establishments [3]	1.2	2.5	5.0	9.9	19.8	29.8	44.7

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

[1] Assumes 10 percent of establishments file exceptions.

[2] Pro-rated all establishments by 7.3 percent to account for the share of affected establishments with class III devices.

[3] Pro-rated all establishments by 12.4 percent to account for the share of affected establishments with implantable, life-supporting or life-sustaining devices that are not class III devices.

We revised the cost of implementing the final rule to include additional labor hours to meet 1 and 2 year implementation periods. Labelers of all class III devices and of implantable, life-sustaining and life-supporting devices that are not class III will be affected. We assume that a manager of a class III establishment with 10 – 49 employees may spend 50 percent of their time for 4 weeks, or about 80 hours. We reduce this time to 20 hours for an establishment with 1-4 employees and 40 hours for 5-9 employees. We increase the number to 720 hours for an establishment with 500 or more employees (80 hours x 9 managers). The number of hours allocated to implantable, life-sustaining and life-supporting devices that are not class III is estimated to be 50 percent of class III hourly estimates. As discussed in the footnotes to Table 6, these hours are then pro-rated on a per establishment basis to estimate the per establishment costs of the final rule. Thus, the additional hours per establishment due to FDASIA implementation

times range from 3 hours (1.5 + 1.2) for establishments with 1-4 employees to about 97.2 hours (52.5 + 44.7) for establishments with 500 or more employees.

Additional Hours for Planning and Implementing the Final Rule

For the final rule, we break out each major task and add additional hours for inter-department communication related to planning and implementation of the final rule. The estimate of total additional labor hours for each cost category is shown in table 7.

All affected establishments will need to perform additional tasks, such as reading the rule and guidance documents, revising SOPs, filing requests for exceptions and implementing the rule. For the final rule we revise our estimates of planning and administration costs using assumptions about the number of lead managers for assumed production lines per establishment size and the number of persons that also must interact with the lead manager, such as representatives from IT, graphics and engineering departments. Thus, initial labelers might spend from 30 hours (30 hours x 1 employee for establishments with fewer than 50 employees) to 270 hours (30 hours x 9 employees for establishments with 500 or more employees) to read and understand the rule.

Similarly, we assume that managers spend about 20 hours for establishments with fewer than 10 employees and 40 hours for all other establishment sizes to revise each SOP. Thus, on average labelers spend from 20 (20 hours x 1 SOP for establishments with fewer than 10 employees) to 360 hours (40 hours x 9 SOPs for establishments with 500 or more employees) to revise SOPs.

We also account for additional time needed for communications among planning entities to make sure that UDI implementation is properly executed. The cost categories include hours for production line modifications, label redesign, IT systems and submitting data to the GUDID.

For the two smallest size categories, one manager is likely overseeing all management tasks alone, so no additional communication and coordination time is assumed. For all other categories except for software acquisition, we assume a total of 20 hours per manager. For software we assume 40 hours per manager to allow for the complexities of purchasing decisions and for larger firms to ensure a seamless system for multiple facilities. Once again, the number of managers increases with employment size. The total number of hours per establishment needed for line modifications, label redesign, and GUDID ranges from 40 hours for an establishment with 10 to 49 employees (20 hours x 2 managers) to 340 hours for the largest size establishment (20 hours x 17 lead and non-lead managers).

The total number of hours for planning and administration ranges from 53 to 2,451 per establishment. Using an hourly wage rate of $75, the average cost per establishment ranges from about $4,000 to $184,000 depending on establishment size for initial labelers.

As in the proposed rule, repackagers and relabelers are assumed to require half the time of the initial labeling establishments. The average cost per establishment for repackagers and relabelers ranges from about $2,000 to $92,000.

Table 7.--Hours and Costs per Establishment for Planning and Administration (2012 dollars)

	Employment Size of Establishment						
	1-4	**5-9**	**10-49**	**50-99**	**100-249**	**250-499**	**500+**
Number of Managers (Line and Other)	1	1	1	2	4	6	9
Number of Interactors (IT, Graphics, Line Engr.)	0	0	1	1	3	5	8
Read & Understand (Hours)	30	30	30	60	120	180	270
Revise SOPs (Hours)	20	20	40	80	160	240	360
Planning & Implementation Communications							
Line Modifications (Hours)	0	0	40	60	140	220	340
Label Redesign (Hours)	0	0	40	60	140	220	340
Software and IT Systems (Hours)	0	0	80	120	280	440	680
GUDID (Hours)	0	0	40	60	140	220	340
Additional Hours for Requests for Exceptions (FDASIA)	0.4	0.4	1.2	2.4	6	12	24
Additional Hours for Shortened Implementation (FDASIA)	2.7	5.4	10.8	21.6	43.2	64.8	97.2
Total Hours [1]	53	56	282	464	1,029	1,597	2,451
Total Costs per Establishment - Initial Labeler [2]	**$3,982**	**$4,185**	**$21,150**	**$34,800**	**$77,189**	**$119,759**	**$183,838**
Total Costs per Establishment - Repackager or Relabeler [3]	**$1,991**	**$2,092**	**$10,575**	**$17,400**	**$38,595**	**$59,879**	**$91,919**

Source: ERG Report, Tables 4-2 and 4-26. (Ref. 1)

[1] Totals may not sum due to rounding.

[2] Costs for all hours are calculated using an hourly wage rate for management occupations in NAICS 3391 of $75, including benefits.

[3] Repackagers and relabelers are assumed to need one-half of the planning time as initial labelers at an hourly wage rate of $75.

The following planning and administration costs for establishments that exclusively label excepted devices and for establishments that print UDI compliant identifiers on their labels remain unchanged from the cost estimated for the proposed rule and are summarized in table 8.

- We estimated that establishments that exclusively label excepted devices or class I devices exclusively using UPCs (all of which have fewer than 10 employees) would spend 2.5 hours to read and understand the rule. Using an hourly wage rate of $75, their costs would be about $190 per establishment.

- We estimated that establishments that currently print UDI compliant identifiers on their device labels and packages (none of which have fewer than 10 employees) would spend from 5 to 30 hours to verify that they are in compliance with the rule. Costs of compliance for these establishments range from $375 to $2,250 depending on size.

Table 8.—Costs per Establishment That Remain Unchanged from the Proposed Rule (2012 dollars)

	Employment Size of Establishment				
	1-9	**10-99**	**100-249**	**250-499**	**500+**
Hours per Establishment	2.5	5	10	20	30
Cost per Establishment [1]	$187.50	$375.00	$750.00	$1,500.00	$2,250.00

[1] Costs are calculated using hourly wage rate of $75, including benefits.

The total one-time costs for planning and administration for all labelers is $86.4 million. There are no annual costs.

Direct Marking

In response to comments on the proposed rule, we have removed the requirement to directly mark implanted devices with a UDI. This change results in a reduction from the proposed rule costs of $12.0 million in the first-year and $0.8 million annually.

We use the same methods and assumptions as in the proposed regulatory impact analysis which estimated the costs for direct marking multiple-use devices that must be sterilized before each use. Our estimates of direct marking cost may be too low to the extent that reprocessed devices are included in the final rule.

Our estimate of the first-year ($0.1 million) and annual ($0.03 million) costs for documenting exceptions are likely conservatively estimated, but we did not adjust these costs for the final rule. We judged the producer price index (Semiconductor Equipment) adjustments

were negligible for the costs of lasers to mark multiple-use devices and the associated marking software which allows barcoding to be performed.

Our estimate of the costs for direct marking multiple-use devices is unchanged from the proposed rule at $14.9 million first-year and $1.1 million annually. However, we estimate an uncertainty range of plus or minus 50 percent for our estimate of direct marking costs in the Analysis of the Uncertainty of Cost Section of this document.

Label Redesign

In response to comments, we have revised the requirement for date formats to make them consistent with international standards. Affected labelers will need to redesign device labels to incorporate the date format change and the UDI. For the final analysis, we have made no changes from the analysis of the proposed rule to assumptions used to estimate the first-year costs for label redesign or the annual costs for label materials and printer coordination time. The one-time costs of $47.6 million for all labelers to redesign labels do not change.

However, we have added costs for some establishments that might install date stamp dies or change current date stamp dies. We estimate that about 10 percent of establishments are affected. Costs of a new date stamp die range from $50 to $150. Using an average cost of $150 installed ($100 per die plus 50 percent markup for installation), costs per establishment range from $150 for smaller establishments with 1 production line to $1,200 ($150 x 8 lines) for the largest establishments with 8 production lines. The total one-time costs for all labelers for date stamp dies are about $0.1 million ($0.1 million for initial labelers and $0.02 million for repackagers and relabelers). See ERG tables 4-16 and 4-37. (Ref. 1)

We adjusted the annual costs of labeling materials by the producer price index of NAICS 322121for converted paper products. With the price adjustment, the cost of labeling materials increases from $7.6 million in the proposed rule to $8.4 million.

The total first-year costs for label redesign for all labelers are $47.7 million; annual costs are $8.4 million.

Software

All assumptions and methods for estimating costs for software remain the same as in the analysis of the proposed rule. We used the producer price index for NAICS 54161Technical and Management Consulting Services to adjust the one-time investment costs of software. The annual cost for a software maintenance contract, estimated to cost 18 percent of software costs, also increased because of the producer price index adjustment for software. All other costs remain unchanged.

With these price index adjustments, the total one-time costs for software and related costs increase from $128.7 million in the proposed rule to $131.5 million for all labelers. The total annual costs of for training, validating and maintaining software are $14.7 million, or $0.5 million higher than the proposed rule.

Recordkeeping and Reporting

As explained in detail in the economic analysis of the proposed rule, the cost components for administrative, direct marking, and software capture most of the costs of recordkeeping. The rule requires that labelers submit data to the FDA's GUDID. For the proposed rule, we estimated that small labelers with fewer than 50 employees would use a web-based portal to enter the required data elements to the GUDID while medium and large labelers with 50 or more

employees would upload the required data elements from their information management systems directly to the GUDID in a SPL format. We keep these assumptions for our final analysis. Moreover, as discussed previously, we use the same wage rate of $75 per hour as we used in the analysis of the proposed rule.

Based on comments and a better understanding of how the GUDID will operate, we use the FDA's device listing data to refine our estimate of the average number of UDIs we expect an establishment to generate, and the effort needed to prepare and submit device data to the GUDID and to validate submitted data. Because there are many device models and packaging sizes for a single device listing, we assume that each listing will generate about 10 UDIs. Table 9 shows our findings of the average number of listings for each size of establishment, and the number of UDIs we estimate each establishment will generate.

Table 9.--Average Number of Listings by Employment Size and the Estimated Number of UDIs Generated for Each Employment Size.

	1-4 Employees	5-9 Employees	10-49 Employees	50-99 Employees	100-249 Employees	250-499 Employees	500+ Employees
Listings	1	3	5	20	40	80	250
UDIs	10	30	50	200	400	800	2500

The exact number of data fields included in a data record will depend on the individual labeler. We anticipated that up to 30 fields may be populated in a GUDID record. For one required field, the GMDN code, the FDA will provide a way for labelers to search for the appropriate GMDN code from a list of device nomenclature terms. Although the owner of the GMDN system, The GMDN Agency, normally charges a fee for access to their system, labelers can use the FDA-provided GMDN codes without charge. When we estimated the costs of the proposed rule, we excluded the costs to understand and use the GMDN codes because we were

uncertain whether the GMDN codes would be available to labelers without charge; we also did not know whether the GMDN code would be a required data element of the GUDID. For our final analysis we include the time to understand the GMDN codes and the time to search and select the appropriate code to enter in the GUDID.

We assume that initial labelers will need to look up the GMDN code and allow additional time for this action. Repackagers and relabelers will use the GMDN assigned by the initial labelers and will not incur additional GMDN costs. Based on the FDA's expert opinion, we estimate a one-to-one relationship between listings and GMDN codes. In the first year, we allow from 16 hours to 64 hours of training to learn and understand GMDN codes. We allow from 4 to 16 hours of training in subsequent years to account for employee turnover and refresher training. Table 10 shows the estimated time for GMDN training by size of the initial labeler.

Labelers may have limited proficiency when they first use the GMDN lookup to assign GMDN codes. Therefore, we assume that initial labelers will spend about 3 hours for each listing to decide upon the appropriate GMDN code to enter in the GUDID. After the first three listings, as labelers become more proficient with the GMDN lookup function, it will take about 1.25 hours to look up and assign the appropriate GMDN code for each additional listing.

For the final analysis, we now include the costs for small initial labelers exclusively using UPCs to spend 10 hours to understand the GUDID requirements and to plan how to comply with this requirement. For other labelers, the adjusted hours for planning and administration include this additional burden. We estimate that the 104 affected establishments will incur one-time costs that total about $78,350.

We have also revised our estimate of the level of effort required to add new records and to modify existing records. For initial labelers manually submitting data via the web-based

portal, managers will spend 30 minutes to gather and organize most of the required data elements for each UDI. Repackagers and relabelers can access the GUDID data entered by the initial labeler, reducing the time repackagers and relabelers will need to gather data for submission to the GUDID; we anticipate that repackagers and relabelers will spend about 15 minutes, or about 50 percent of the time we estimate that initial labelers will spend to gather data.

Because the actions are the same for all labelers submitting data to the GUDID by the web-portal, we estimate that all small labelers will spend 20 minutes to enter data in the GUDID web-based portal, and 15 minutes to proofread and validate entered data. Labelers can access data already in the GUDID to update existing data or to automatically populate fields such as their name and address when they add a new UDI. In subsequent years, therefore, we anticipate that labelers will spend about 35 percent of their first year's effort to submit new data to the GUDID or to revise existing data in the GUDID.

We assume that medium and large labelers (i.e., 50 or more listings) submit batch data from their management information systems in the SPL format to the GUDID. In the economic analysis of the proposed rule, we estimated that managers would spend 4 hours validating the uploaded data. We increase that estimate to 8 hours for the final rule and assume that in the first year, establishments will convert their device data to the SPL format twice during the year. In subsequent years, we anticipate that these establishments will convert device data to the SPL format 4 times each year. We estimate a fixed cost of $200 for each SPL conversion, regardless of the number of listings.

Table 10 summarizes the one-time and annual per establishment level of effort and costs to submit data to the GUDID by the employment size of initial labelers; table 11 summarizes the one-time and annual per establishment level of effort and costs for repackagers and relabelers.

Table 10.--One-Time and Annual per Establishment Level of Effort (hours) and Costs for Initial Labelers to Prepare and Submit Data to the GUDID

	1-4 Employees	5-9 Employees	10-49 Employees	50-99 Employees	100-249 Employees	250-500 Employees	500+ Employees
One-Time: GMDN training (hours)	16	16	16	16	32	32	64
One-Time: Gather, Prepare & Organize Data (hours)	5	15	25	NA (a)	NA (a)	NA (a)	NA (a)
One-Time: Look Up GMDN codes (hours)	3	9	12	30	55	105	318
One-Time: Access and Upload Data to GUDID (hours)	3	10	17	0.5	0.5	0.5	0.5
One-Time: Validate Data Submission (hours)	3	8	13	8	8	8	8
One-Time: Total Number of Hours	29.8	57.5	81.7	54.8	95.8	145.8	390.3
One-Time: Cost of SPL Conversions	NA	NA	NA	$200	$200	$200	$200
Total One-Time Per Establishment Costs	**$2,238**	**$4,313**	**$6,125**	**$4,306**	**$7,381**	**$11,131**	**$29,469**
Annual: GMDN training (hours)	4	4	4	4	8	8	16
Annual: Add or Revise GUDID Data (hours)	4.8	14.5	23.0	13.6	22.3	39.8	114.2

Annual: Total Number of Hours	8.8	18.5	27.0	17.6	30.3	47.8	130.2
Annual: Cost of SPL Conversions	NA	NA	NA	$400	$400	$400	$400
Total Annual Per Establishment Costs	**$663**	**$1,389**	**$2,024**	**$1,717**	**$2,673**	**$3,986**	**$10,164**

Table11.-- One-Time and Annual per Establishment Level of Effort (hours) and Costs for Repackagers and Relabelers to Prepare and Submit Data to the GUDID

	1-4 Employees	5-9 Employees	10-4 Employees	50-99 Employees	100-249 Employees	250-500 Employees	500+ Employees
One-Time: Gather, Prepare & Organize Data (hours)	2.5	7.5	12.5	NA (a)	NA (a)	NA (a)	NA (a)
One-Time: Access and Upload Data to GUDID (hours)	2.5	7.5	12.5	8.0	8.0	8.0	8.0
One-Time: Validate Data Submission (hours)	3.3	10.0	16.7	0.5	0.5	0.5	0.5
One-Time: Total Number of Hours	8.3	25.0	41.7	8.5	8.5	8.5	8.5
One-Time: Cost of SPL Conversions	NA	NA	NA	$200	$200	$200	$200
Total One-Time Per Establishment Costs	**$625**	**$1,875**	**$3,125**	**$838**	**$838**	**$838**	**$838**
Annual: Add or Revise GUDID Data (hours)	2.1	6.3	10.4	2.1	2.1	2.1	2.1

Annual: Cost of SPL Conversions	NA	NA	NA	$400	$400	$400	$400
Total Annual Per Establishment Costs	**$156**	**$469**	**$781**	**$559**	**$559**	**$559**	**$559**

We estimate that to comply with the GUDID requirements, industry will spend about a $26.5 million in set-up costs. Moreover, we estimate the annual costs will be about $8.4 million. We note, however, that these totals do not account for differences in compliance dates.

Costs of the Final Rule to Domestic Labelers Using FDA's Final Implementation Schedule

As mentioned above, the costs for domestic industry presented in tables 4 and 5 of this document treat all one-time costs as occurring in the first year. However, the final compliance dates allow labelers up to 7 years to phase in requirements. This section presents costs in the year they will be incurred according to the final implementation schedule. Therefore, this section best describes the total costs of the final rule for labelers.

The compliance dates after publication of a final rule for medical devices to bear a UDI on the label and to submit data to the GUDID database are:

class III devices and devices licensed under the PHS Act, 1 year,

implantable, life-supporting or life-sustaining devices that are not class III, 2 years,

class II devices that are not implantable, life-supporting or life-sustaining devices, 3 years, and

class I devices, including devices that have been exempted from UDI labeling requirements but which are subject to the date format requirements, and other devices not classified into class I, II, or III, 5 years.

The compliance date for devices that must be directly marked is 2 years for life-supporting and life-sustaining devices; direct marking for all other devices must take place 2 years after the compliance date that applies based on the regulatory class of each device.

By linking FDA's product code database, which provides the class of the device for each product code, with the registration and listing data, we created a count of domestic labelers by highest class of device by listing establishment. This allows us to assign one-time and recurring costs (shown in tables 4 and 5 above) 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 8 percent of affected establishments 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 14 percent that label implantable, life-supporting or life-sustaining devices that are not class III comply in year 2 (and may also label class II, I or unclassified devices); 44 percent that label class II devices (and also class I and unclassified devices, but not class III devices) comply in year 3; and the remaining 34 percent that label only class I and unclassified devices comply in year 5. Direct marking costs are assumed to occur in year 7 for multiple-use devices. We also assume that the overall distribution of establishment sizes is valid within each class.

Table 12 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, the total present value of compliance costs to domestic labelers over a 10-year timeframe equals about $620.4 million with a 7 percent

discount rate and about $713.2 million with a 3 percent discount rate. The annualized present value is $82.6 million at a 7 percent discount rate and $81.2 million at 3 percent.

Table 12.—The Impact of the Staggered Compliance Dates on the Regulatory Costs to Domestic Labelers Over a 10-Year Time Horizon (2012 dollars)

Year	Undiscounted Regulatory Costs of Final Rule by Highest Device Class ($ mil)					Present Value with Discount Rate ($ mil) [1]	
	Class III	Life-supporting or Life-saving, not Implantable, not Class III	Class II	Class I [2]	Total Cost by Year	7 %	3 %
1	$39.7				$39.7	$39.7	$39.7
2	$6.1	$67.8			$73.9	$69.0	$71.6
3	$6.1	$10.4	$214.0		$230.4	$201.3	$217.2
4	$6.1	$10.4	$32.7		$49.21	$40.1	$45.0
5	$6.1	$10.4	$32.7	$62.8	$111.9	$85.4	$99.4
6	$6.1	$10.4	$32.7	$6.0	$55.2	$39.4	$47.6
7	$6.1	$10.4	$32.7	$21.5	$70.7	$47.1	$59.2
8	$6.1	$10.4	$32.7	$7.2	$56.3	$35.1	$45.8
9	$6.1	$10.4	$32.7	$7.2	$56.3	$32.8	$44.5
10	$6.1	$10.4	$32.7	$7.2	$56.3	$30.6	$43.2
Total Years 1 to 10					$799.9	$620.4	$713.2
Annualized Total Over 10 Years ($mil)						$82.6	$81.2

Source: ERG Report, Table 4-74 (Ref. 1)

[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 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 multiple-use devices in year 7.

Cost to Issuing Agencies

We estimated in the proposed rule that the one-time costs would be about $0.5 million, and annual costs about $0.1 million for two issuing agencies. For the final rule, we anticipate that three issuing agencies will apply. For three issuing agencies, the estimated total first-year cost is about $0.8 million with annual costs of about $0.1 million. The estimated present value of costs over 10 years for three existing organizations, currently performing functions similar to those of an issuing agency under the final rule, to apply for FDA accreditation and comply with the final reporting requirements is $1.3 million at a 7 percent discount rate and $1.4 million at 3 percent. The annualized costs over 10 years are $0.2 million at both 7 percent and 3 percent discount rates.

Cost to FDA for the GUDID

In the economic analysis of the proposed rule, we estimated the time it would take contractors and FDA personnel to develop and launch the GUDID. Based on the progress to date, we anticipate that the development and pilot testing phases of the project will be completed in 2013. Using the actual payments and obligated funds, we update our estimate of the total one-time costs for contract services to develop and pilot test the GUDID. As noted in table 13, the one-time costs began in 2011. To calculate present value of these costs, we set 2013 as year 0. We anticipate that the one-time costs will equal about $5.8 million, with a total present value of $6.2 million with a 7 percent discount rate and $5.9 million with a 3 percent discount rate. Once launched, we project that the annual costs to operate and maintain the GUDID will remain the same as originally estimated at $1.9 million. The total estimated annualized costs to FDA for the GUDID over 10 years equal $2.9 million with a 7 percent discount rate and $2.7 million with a 3 percent discount rate.

Table 13.-- One-Time Costs to Develop and Launch the GUDID

One-Time Costs to FDA	Cost ($ million)
Primary Contractor Services	$4.0
Subscription Fees and Consulting Services for Search Tool	$0.1
FDA review, revision, and clearance (3FTE)	$0.5
FDA Electronic Submissions Gateway Support for GUDID	$0.1
Planned Enhancements in FY 2013	$1.1
Total One-Time Cost	**$5.8**

Source: FDA. Includes payments and obligated funds from 2011 to 2013.

Summary of Total Domestic Costs of the Final Rule

Table 14 of this document presents for each affected sector a summary of the estimated present value and the annualized domestic costs of this final rule over 10 years using discount rates of 7 percent and 3 percent. Over 10 years, the present value of the domestic costs is $642.2

million using a 7 percent discount rate and $737.7 million using a 3 percent rate, and the annualized costs are $85.7 million using a 7 percent discount rate and $84.1 million using a 3 percent discount rate.

Table 14.--Summary of the Estimated Domestic Regulatory Costs of the Final Rule (2012 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[2]	$713.2	$620.4	$81.2	$82.6
Issuing Agencies	$1.4	$1.3	$0.2	$0.2
FDA	$23.1	$20.5	$2.7	$2.9
Total Domestic Cost of the Final Rule	$737.7	$642.2	$84.1	$85.7

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

F. Analysis of the Uncertainty of Costs

In the previous section, we presented the estimated central tendency of domestic costs without the accompanying uncertainty. This section summarizes the uncertainty estimates for each of the major cost components and for the total domestic costs. We present the uncertainties as percentage deviations from the central tendencies for each major element of costs.

The uncertainty ranges for each cost element are shown in table 15. Label redesign costs are the most uncertain, with 60 percent uncertainty, because it is not known how many establishments might be able to integrate UDI requirements into routine label redesign cycles. The final implementation schedule offers longer lead times for many class II and I establishments and may help reduce label redesign costs for some establishments. However, costs could be higher for establishments with unusual packaging and labeling requirements.

Table 15.-- Uncertainty Ranges for the Major Cost Elements

Cost Element	Level of Uncertainty (plus or minus relative to mean estimate)
Label redesign cost	60%
Equipment and other investments	50%
Software (with training)	50%
Direct marking multiple-use devices	50%
Administration and planning	25%
Incremental label cost	25%
Recordkeeping and Reporting (GUDID)	25%
Registration costs	10%

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

Cost elements judged to be 50 percent uncertain are equipment costs, software, and direct marking. Equipment costs for smaller establishments are reasonably certain, but costs could vary widely for the largest establishments depending on current practices, the packaging configuration, materials, and labeling requirements. Labelers will be able to select among labeling solutions that may be less expensive than we estimated. For directly marked multiple-use devices, the uncertainty is significant due to the lack of information on current marking practices and methods, and the scope of affected devices subject to the direct marking requirements of the final rule.

For the final analysis we have revised our cost estimates for planning and administration in response to comments and also to address costs due to shortened implementation times required by FDASIA. In addition, we require date format requirements to be met when UDI label changes are required, rather than in 1 year as proposed. With these revisions, we reduce our estimate of uncertainty to 25 percent (from 50 percent in the PRIA). Recordkeeping and GUDID costs as well as incremental label costs are considered reasonable estimates with an uncertainty factor of 25 percent. Barcode registration costs are the most certain with a 10

percent uncertainty factor. We use these factors to produce the bounding estimates shown in table 16 of this document.

Table 16--Bounding Estimates Reflecting Uncertainty in the Estimates of the Total Domestic Cost for Initial Labelers [1] (2012 dollars)

Cost Element	First-Year ($ million)	Low ($ million)	High ($ million)	Annual Recurring ($ million)	Low ($ million)	High ($ million)
Administration and planning	$86.4	$64.81	$107.9	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	$8.4	$6.3	$10.5
Label redesign	$47.7	$19.0	$76.4	NA	NA	NA
Software (with training)	$131.5	$65.7	$197.2	$14.7	$7.3	$22.0
Recordkeeping & Reporting (GUDID)	$26.5	$20.0	$33.2	$8.4	$0.3	$10.5
Total Labeling and Database Requirements	**$341.7**	**$195.1**	**$488.2**	**$54.1**	**$31.2**	**$76.9**
Direct marking: Multiple-Use Devices	$14.9	$7.5	$22.4	$1.1	$0.6	$1.7
Total—All Cost Elements	**$356.6**	**$202.6**	**$510.6**	**$55.2**	**$31.8**	**$78.6**

Source: ERG Report, Table 8-2 (Ref. 1).
[1] Cost estimates assume immediate implementation

When we apply uncertainty estimates to the annualized present value of total costs for all domestic labelers, issuing agencies and the FDA shown in table 14 of this document, the annualized present value of total domestic costs of the final rule over 10 years using a 7 percent discount rate ranges from $48.8 million to $122.5 million around the central estimate of $85.7 million. This estimate accounts for the phased-in implementation and represents our best estimate of the total domestic costs of the final rule. Using a 3 percent discount rate over 10 years the annualized present value of total domestic costs of the final rule ranges from $47.9 million to $120.2 million around the central estimate of $84.1 million.

G. Benefits

The final rule will 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. The public health benefits from the UDI would come from reductions in

medical device-related patient injuries and deaths and improved medical device recalls. More accurate and prompt identification of problems would enable more rapid action to reduce the incidence of the adverse events. FDA would also be able to carry out recall actions more efficiently with more effective targeting of the problem device. Standardized date formats on medical device labels would eliminate any possibility of confusion from date formats that might be interpreted in more than one way.

Improved Postmarket Adverse Device Events Reporting and Device Recalls

The final rule is 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 detect problem devices more rapidly. Public health safety alerts, for example, could be more accurate and timely.

In the analysis of the proposed rule we presented data and studies that document the frequency of device-related adverse events including death, injury, hospitalizations and emergency department visits, which showed about 50,000 serious adverse events reported per year, including about 3,000 deaths. Adverse events are associated with all classes of medical devices. For deaths and serious events only, about 21 percent are associated with class III, 38 percent with class II, 26 percent with class I and 15 percent with unclassified devices. We also described the limitations of adverse event reporting and related electronic tracking and monitoring systems. Inaccurate or incomplete device identification in reporting systems impedes FDA's ability to identify problem devices. The reports often lack sufficient detail to identify the device involved with an adverse event; missing information can include manufacturer name, model number, lot number, or date information. Other impediments to identification of the

problem devices 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, FDA's Manufacturer and User Facility Device Experience (MAUDE) database cannot be as efficiently and effectively searched for reports on specific devices. These shortcomings of the MAUDE data can hamper FDA 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.

With the UDI, FDA will be able to immediately identify and validate the device when an adverse event is reported. A UDI with standardized device information will 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 postmarket surveillance would be warranted. Including standardized and uniform reporting data, such as a standardized device identifiers and nomenclature, in FDA's publicly available GUDID would provide important data elements that could be used to allow searches to be performed quickly for similar devices manufactured by multiple companies.

Similarly, incomplete information or poor device identification hampers FDA's ability to quickly and effectively manage device recalls. For example, the same device may be identified

with several different descriptors. Identifying and locating all of the recalled devices, while simultaneously not removing unrecalled devices, 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.

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.

Standardized Date Formats

An additional benefit of standardizing UDI relates to the formatting of dates on device labels. Standardized formats for dates on medical device labels consistent with international practices will eliminate confusion from date formats that might be interpreted in more than one way.

Optimizing the Use of Automated Healthcare Systems

The development of a standardized UDI may contribute to the value of other health information technology initiatives. Health information technology is considered an important tool to improve patient safety. Although decisions to invest in this technology would be made

independently of the final rule, a UDI system may help to facilitate the adoption and use of complementary information technology systems for improving patient safety.

A standardized UDI could be used in device registries, research studies, and by government and 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.

H. Alternatives to the Final Regulation

We expect that potential public health benefits would begin to accrue after the highest risk class III, implantable devices, and life-saving and life-sustaining devices comply with UDI requirements. As the large number of remaining class II and class I devices comply, both costs and benefits would increase although not proportionally. For the final rule, FDA has tried to balance costs and benefits by providing for a phased implementation period over 7 years, and for less stringent requirements for class I devices. We consider this balance of cost and benefit to be the baseline for the alternatives described in this section. These alternatives adjust the stringency of requirements for all devices, the composition of the UDI, and the trade-off of selecting a specific AIDC technology.

The FDA identified and assessed the costs for labelers of the following alternatives to the final rule:

1. Full UDI requirements for unclassified and class I, II, and III devices.
2. A UDI that does not include the production identifier.

3. Require a Specific AIDC technology.

The preamble to the final rule details FDA's rationale for each topic or area of concern addressed by comments. In response to comments, FDA has taken a number of steps to reduce the costs of the final rule. For example, we removed the requirement to directly mark implanted devices, revised the requirement for date format so that it is consistent with international standards, provided for an exception of 3 additional years after the compliance dates for finished devices manufactured and labeled prior to the compliance date. In addition, we retained the exception for class I devices to bear a UDI that includes the production identifier and retained the exception for class I devices that are exempted from the good manufacturing practice requirements from having to bear a UDI.

We have also increased our estimates for some costs as shown in Table 7. We adjust these costs before we estimate costs for alternatives. Tables 4 and 5 summarize changes in the one-time and annual cost categories of the proposed and final rules assuming immediate implementation.

We use the same methods for calculating the costs of the final rule and the first two alternatives. Approximately 6,199 establishments are affected under both alternatives. See footnote 4 of table 3b of this document. Consistent with analysis presented in Section E of this document, we assume for all alternatives that labelers of excepted devices (devices covered by final § 801.30(a)(3) - (11) -- general exceptions) are excepted from the UDI requirements. For the selected alternative, labelers of class I devices are not required to include a production identifier in the UDI and the label of class I devices that are exempt from GMPs are not required to bear a UDI.

The first alternative includes most of the requirements of the final rule, but does not allow for certain reduced requirements for class I devices. The next alternative requires only the device identifier portion of the UDI to be included in the barcode (the production identifier is not required). The barcode would not change through the life of the device and thus, UDI label requirements can be met with a one-time label revision. Because a production identifier is not required and more establishments are in compliance, costs in many of the cost categories do not apply under this option. The requirements for direct marking remain unchanged under both alternatives. We summarize the costs of the first two alternatives in table 19 of this document.

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

Under this alternative, all requirements of the final rule would apply to class II and III devices. However, unlike in the final rule, the label for class I devices would be required to 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.

The costs of this alternative are shown in table 17 of this document. All class I establishments not covered by the general exceptions under § 801.30(a)(3) through (11) incur costs related to complying with a UDI that includes the production identifier and the label of some GMP-exempt devices are required to bear a UDI that includes the production identifier under this alternative (see footnote 4 in table 3b). The primary categories of cost increases are for planning and administration, purchasing and installing printers, verifiers and scanners, and software and related training.

The estimated total one-time costs for all domestic labelers are $501.2 million, with annual costs of $83.4 million. The total present value of this alternative is $811.6 million and the annualized present value is $108.0 million with a 7 percent discount rate over 10 years.

Table 17.--Summary of Total Costs of the Full Requirements Alternative for Affected Domestic Labelers [1] (2012 dollars)

Cost Element	First-Year ($ million)	Annual ($ million)
++Labeling and Database Requirements		
Administration and planning	$132.4	NA
Barcode registration	$2.2	NA
Equipment and other investments	$82.8	$39.6
Direct Marking	$14.9	$1.1
Incremental label materials and labor	NA	$10.4
Label redesign	$47.7	NA
Software (with training)	$192.3	$23.1
Recordkeeping and Reporting (GUDID)	$28.9	$9.2
Total Cost—All Elements	$501.2	$83.4

Source: ERG Report, Table 4-45 (Ref. 1).
Note: Numbers may not sum due to rounding.
[1] Labelers include medical device manufacturers, reprocessors, specification developers, repackagers and relabelers.

2. **A UDI That Does Not Include a Production Identifier**

Under this alternative, we modify the full UDI alternative such that labelers would not be required to include a production identifier. The UDI would include only a device identifier for the specific version or model of a device and the labeler of that device. Existing human-readable production 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 UDI requirements (see footnote 4 in table 3b).

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 UDI to printing a UDI that only includes the device identifier.

A summary of the total costs of this alternative for all labelers is presented in table 18 of this document.

Table 18.--Total First-Year, Annual and Annualized Costs of UDI Implementation for All Domestic Labelers Under the Alternative for a UDI that Does Not Include the Production Identifier[1] (2012 dollars)

Cost Element	First-Year ($ million)	Annual ($ million)
Labeling and Database Requirements		
Administration and planning	$16.4	NA
Barcode registration	$2.2	NA
Equipment and other investments	NA	NA
Direct Marking	$14.9	$1.1
Incremental label materials and labor	NA	$3.5
Label redesign	$47.6	NA
Software (with training)	NA	NA
Recordkeeping and Reporting (GUDID)	$28.9	$9.2
Total--All Cost Elements	$110.1	$13.8

Source: ERG Report, Table 4-46 (Ref. 1).
Note: Numbers may not sum due to rounding.
[1] Labelers include medical device manufacturers, reprocessors, specification developers, repackagers and relabelers.

The total present value of this alternative is $152.4 million and the annualized present value is $20.3 million with a 7 percent discount rate over 10 years.

3. **Require a Specific AIDC technology**

Requiring a specific AIDC technology would be highly prescriptive and might limit future AIDC technologies or innovations. OMB Circular A-4 recommends that agencies select standards that are not prescriptive but allow flexibility in approaches to meeting requirements. Requiring adherence to a particular AIDC technical standard would be detrimental to innovation concerning AIDC technologies, and would, we believe, do long-term harm by slowing the adoption of new technologies.

For the economic analysis of the final rule, we assumed that a machine-readable barcode would be most commonly used by labelers. This form of the UDI is consistent with current barcoding configurations of major barcoding organizations that might apply to FDA as issuing agencies. We assume that the symbologies used to represent the UDI on labels are those that are

currently used for trade purposes (standard linear or 2-D barcodes). This would allow labelers who currently barcode and existing barcoding organizations to maintain nearly all of their current practices. We note that the cost of using linear or 2-D barcodes is not significantly different for labelers. Most scanners read several types of barcodes, although firms with older scanners might need replacements before the routine replacement cycle.

We find there is no compelling reason for labelers to choose less common barcode technologies, but other technologies, such as radio frequency identification (RFID), would require specialized scanners.

This rule does not impose any requirement on the purchaser or end-users of a device, and any investments voluntarily made to use UDIs are outside the scope of this rule. However, any costs associated with not specifying an AIDC technology, such as the costs to acquire multiple readers, would mostly be incurred by these UDI-using entities. If FDA selected a specific AIDC technology, such as 2-D barcodes, this might minimize uncertainty for those organizations that choose to invest in barcode reading technologies independent of this final rule.

We note that any form of UDI could contribute to greater efficiencies among those entities that use UDIs, although one specified AIDC technology might be slightly more efficient in the short run than a non-specified technology. Over time, however, imposing a prescriptive technology might be less efficient if advances in technology cannot easily be accommodated.

Summary of Alternatives

Table 19 of this document summarizes the total present value and annualized present value costs of the final rule and the first two alternatives analyzed above, using a 7 percent discount rate over 10 years. We also show the difference in annualized costs compared with the

previous alternative. Because we do not quantify the benefits of this final rule, we are unable to quantify the differences in benefits across these alternatives.

Table 19.—Summary of Alternative Costs and Annualized Domestic Cost Savings Compared to the Previous Alternative [1,2] (2012 dollars)

Alternative	Present Value, 10 Years, 7 Percent ($ million)	Annualized Present Value, 10 Years, 7 Percent ($ million)	Annualized Cost Savings Compared with Previous Alternative, 10 Years, 7 Percent ($ million)
Full UDI for unclassified and class I, II, and III devices	$811.6	$108.0	NA [3]
Final rule: do not require the production identifier for class I devices; certain class I devices are exempt from UDI	$620.4	$82.6	$25.4
Do not require the production identifier for all device classes	$152.4	$20.3	$62.3

[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 7 percent discount rate over 10 years.
[3] NA means not applicable.

I. Small Business Impact

The Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act, requires a Regulatory Flexibility Analysis unless the agency can certify that the rule would have no significant impact on a substantial number of small entities. This document constitutes our Final Regulatory Flexibility Analysis. FDA finds that the potential impact of the final rule on some small entities may be significant.

Need for the Rule and Objectives of the Rule

The final rule fulfills the statutory requirement to establish a unique device identification system for medical devices that will adequately identify a device through distribution and use. Currently, medical device manufacturers are not required to use a standardized device identifier.

The final rule will require that medical devices be labeled with both a human and machine readable UDI. In the near-term, we anticipate that the 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.

Summary of Issues Raised in Comments on the Initial Regulatory Flexibility Analysis.

Some comments addressed small business impacts of the proposed rule. Although these comments stated that the rule would significantly impact their businesses and other small labelers, none of the comments provided sufficiently detailed information about the potential impacts of the rule or the size of their businesses to revise the assumptions underlying our analysis. As noted in our responses to comments discussed in Section C of this document, the final rule eliminates the direct marking requirement for implants and requires a widely accepted international standard for the date format. Direct marking of implants was the most burdensome provision of the proposed rule for small businesses. According to comments, the proposed date format could have imposed unintended burdens on domestic labelers that export devices to other countries. By addressing these issues, the final rule minimizes the most burdensome impacts on small businesses.

Number of Affected Small Entities

The Small Business Administration defines small medical device manufacturers as those with 500 or fewer employees and small medical device wholesalers as those with 100 or fewer employees. Device manufacturers are included in North American Industry Classification System (NAICS) categories for manufacturing industries; firms that repackage and relabel medical devices are 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 (Surgical & Medical Instrument Manufacturing) 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 20 of this document shows the Small Business Administration's size standards for the NAICS categories of affected labelers.

Table 20.--Size Standards by Industry

Industry NAICS	Description of Industry	Number of Employees
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
42345	Medical, Dental & Hospital Supplies Merchant Wholesalers Industry	100
42346	Ophthalmic Goods Merchant Wholesalers Industry	100

From the FDA's device registration and listing data, we identified 6,569 domestic firms considered labelers for the purposes of the rule, including 5,566 initial labelers (i.e., medical device manufacturers, medical device reprocessors, specification developers) and 1,212 firms that repackage or relabel medical devices. Using data from the Small Business Administration and the U.S. Census Bureau, we distribute our counts of firms from the registration data into employment size categories. We estimate that approximately 30 percent of the initial labelers exclusively handle devices covered by the general exceptions to the final rule, and will only need to read and understand the rule to determine the final rule does not affect them. Of the remaining initial labelers affected by the final rule, about 96 percent fall below the Small Business

Administration's threshold for small business. About 10 percent of repackagers and relabelers exclusively handle GMP-exempt devices, and about 95 percent of the remaining repackagers and relabelers fall below the threshold. See Table 6-1 in the ERG Report (Ref. 1) for more detail. The final rule will impact small firms differently depending on how closely their current practices align with the final requirements. To avoid understating the impact of the final rule on small entities, we concentrate our analysis on domestic firms not currently using identifiers that conform to the UDI requirements, and on domestic firms required to directly mark multiple-use devices.

Description of the Reporting and Recordkeeping Burdens and Personnel Skill Levels

Regardless of size, all firms subject to the UDI requirements of the final rule 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 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 will be needed to conform to the requirements of the final rule. Table 21 of this document describes the reporting and recordkeeping burdens by major cost component.

Table 21.--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--requires from 4 hours to 120 hours in the first year, depending on the size of the firm.	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 14 hours to 115 hours in first year and 5 hours to 40 hour annually in subsequent years.	100%	IT, managerial, technical or clerical staff trained to upload data

Impact of the Rule on Small Entities

Impact on Initial labelers

We use data on average industry receipts to estimate the impact of the final rule on small entities. We have updated our original estimates with industry-specific producer price indices. Table 22 of this document shows the revised average annual receipts for small initial labelers by NAICS code and employment size.

Table 22.—Initial Labeler Average Annual Receipts by Size of Firm ($1,000 in 2012 Dollars)

Type of Labeler [1]	0-4 Employees	5-19 Employees	20-499 Employees
NACIS 325413	992.3	3,854.9	31,593.7
NAICS 334510	492.5	1,980.9	19,963.1
NAICS 334517	608.8	2,344.0	19,029.1
NAICS 339112	455.2	1,773.6	16,339.0
NAICS 339113	390.9	1,730.3	14,586.1
NAICS 339114	431.6	1,359.9	21,165.2
NAICS 339115	1,830.3	1,733.4	9,046.6
Reprocessors [2]	455.2	1,773.6	16,339.0
Specification Developers [3]	633.2	1,847.4	17,542.6

Source: ERG Report, Table 5-3 (Ref. 1), based on estimated receipts reported for 2007 (SBA, 2007) updated to 2012 dollars with the NAICS-appropriate producer price index.
[1] NAICS codes for medical device manufacturing firms.
[2] Equal to the average annual receipts for NAICS 339112.
[3] Updated with the producer price index for NAICS 325413.

Most small firms with only excepted devices will incur the one-time costs to read the rule. Firms with fewer than 10 employees account for over 80 percent of these firms. We estimate that firms with fewer than 10 employees will spend about 2.5 hours at a cost of less than $200. Some small firms of excepted devices will also need to revise their device labeling to conform to the new date format. When annualized over 10 years, the per firm cost to redesign device labels range from about $180 to $7,200 with a 7 percent discount rate, and range from $150 to $5,900 with a 3 percent discount rate.

Firms that currently include identifiers that conform to the UDI requirements (e.g., include a UPC on the label of class I devices, include conforming barcodes that include a production identifier on class II and class III devices) will primarily incur one-time planning and administration costs for the GUDID, one-time costs to revise labeling to accommodate the date format, one-time costs to submit data to the GUDID, and annual costs, as needed, to submit new data to the GUDID and to update data already submitted to the GUDID. Annualizing over 10 years, the average per firm cost for these firms ranges from about $1,800 to $14,600 with a 7

percent discount rate, and range from about $1,500 to $12,000 with a 3 percent discount rate. These average annualized costs for this group of small firms will not exceed 1 percent of average annual receipts for any size or industry group.

For the small firms most impacted by the final rule, we aggregate per firm costs for initial labelers of Class II or Class III devices not currently using identifiers that conform to the UDI requirements, and for initial labelers required to directly mark multiple-use devices. Table 23 of this document shows a breakdown by employment size for small firms of the total annualized costs over 10 years with 7 percent discount rates.

Table 23.--Annualized Costs for Affected Initial Labelers by Size (2012 dollars)

	0-4 Employees	5-19 Employees	20-499 Employees
Full UDI without Direct Marking	$2,471	$13,569	$41,348
Full UDI with Direct Marking	$8,288	$19,386	$94,394

Source: ERG Report, Table 5-4 (Ref. 1).

As shown in table 24, the annualized cost for small initial labelers not required to directly mark devices does not exceed 1 percent of the average annual receipts. Comparing the burden for different firm sizes, we find that the greatest burden falls on firms with 5-19 employees. Moreover, within this firm size, dental equipment and supplies manufacturers in NAICS 339114 incur the largest relative burden.

Table 24.--Relative Burden of the Final Rule Without Direct Marking[1]

	0-4 Employees	5-19 Employees	20-499 Employees
NAICS 325413	0.2%	0.4%	0.1%
NAICS 334510	0.5%	0.7%	0.2%
NAICS 334517	0.4%	0.6%	0.2%
NAICS 339113	0.6%	0.8%	0.3%
NAICS 339114	0.6%	1.0%	0.2%
NAICS 339115	0.1%	0.8%	0.5%
Reprocessors	NA	0.8%	0.3%
Specification Developers	0.4%	0.7%	0.2%

Source: ERG Report, Table 5-5 (Ref. 1).

[1] We calculate burden as the annualized costs as a percentage of average annual receipts. Excludes firms in NAICS 339112, 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 UDI compatible barcodes. Costs are annualized over 10 years with a 7 percent discount rate. We use average per firm receipts from table 22 of this document.

The final rule will create the greatest burden on small firms required to directly mark devices. Because the types of devices affected by the direct marking requirement generally fall into NAICS code 339112, Surgical & Medical Instrument Manufacturing, we compare the impact of the final rule on this industry with and without the costs for direct marking. According to listing data, we estimate that about 100 firms will be affected by this requirement, of which over 80 percent (85 firms) have employment under the 500-employee threshold. As shown in table 25, 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; 19 of these firms have fewer than 5 employees. Moreover, the first year costs for equipment needed to directly mark multiple-use devices equal about $24,000 for firms with fewer than 10 employees. The one-time cost of this equipment represents about 5.3 percent of the average annual receipts for firms with fewer than 5 employees and represents about 1.4 percent of the average annual receipts for firms with 5 to 19 employees. However, these firms represent less than 1 percent of the estimated 3,550 firms with fewer than 20 employees.

Table 25.--Relative Burden of the Final Rule by Employment Size on Small Surgical & Medical Instrument Manufacturers (NAICS 339112) [1]

	0-4 Employees	5-19 Employees	20-499 Employees
Without direct marking	0.5%	0.8%	0.3%
With direct marking	1.8%	1.1%	0.6%

Source: ERG Report, Tables 5-5 and 5-6 (Ref. 1).
[1] We calculate burden as average annualized costs as a percentage of the average annual receipts.

Impact on Repackagers and Relabelers

We assume that the final rule will require that all repackagers and relabelers incur the full costs to comply with the UDI requirements, but will not incur costs for direct marking. As discussed in our initial regulatory flexibility analysis, none of these labelers will incur costs that exceed 1 percent of average annual receipts.

Alternatives Considered

We analyze the costs of two alternatives to the final rule in Section H of this document. The costs and cost savings for the alternatives are summarized in Table 19 of this document. Because approximately 96 percent of all affected labelers are small entities according to the Small Business Administration's size standards, the impact on small firms is essentially the same as for the industry as a whole.

J. Foreign Impacts

Costs for Foreign Labelers

Number of Foreign Labelers

From the FDA's device registration and listing database, we identified the foreign labeler establishments that export devices to the United States. When tallied by type of labeler, we find there were 7,091 foreign registrants in March 2010. When ranked by the number of product

listings, the top 20 countries exporting devices to the United States account for about 90 percent of foreign registrants and foreign listings.

As a proxy for determining which importer countries are likely to have manufacturing processes similar to the United States, we note that FDA device export requirements for domestic manufacturers recognize the marketing authorization of certain countries, called Tier 1 countries. Composed primarily of economically developed countries, Tier 1 countries include: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, the European Union (EU), and the European Economic Area (the EU plus Norway, Iceland and Liechtenstein). For our analysis, we divide exporting countries into two groups: Tier 1 countries and non-Tier 1 countries.

Because the UDI requirements of the final rule differ for class I devices than for other devices, we sort foreign establishments into two groups: labelers that only handles class I devices, and all other labelers. According to the listing data, about 55 percent of all foreign establishments handle only class I devices.

Table 26 shows a breakdown of foreign labelers by country tier and device class. The distribution of labelers is roughly equal between Tier 1 and non-Tier 1 countries. However, non-Tier 1 countries have almost 50 percent more establishments only labeling class I devices than Tier 1 countries.

Table 26.—Number of Foreign Labeling Establishments by Country Tier and Class of Device

	Number of Establishments in Tier 1 Countries	Percent in Tier 1 Countries	Number of Establishments in Non-Tier 1 Countries	Percent in Non-Tier 1 Countries	Total Number of Foreign Establishments	Percent of Total
Class I Devices Only	1,585	44%	2,336	67%	3,921	55%
Not Class I only Devices	2,043	56%	1,127	33%	3,170	45%
Total	**3,628**	**100%**	**3,463**	**100%**	**7,091**	**100%**

Source: ERG Report, Table 3-7 (Ref. 1)

Assumptions Used in the Analysis of the Costs to Foreign Establishments

The UDI requirements for foreign and domestic labelers are equivalent; class I devices require a UDI that does not include the production identifier and class II and class III devices require a UDI that includes the production identifier. In contrast to our analysis for domestic labelers, we assume that none of the foreign establishments exclusively label excepted devices and thus include all foreign establishments in our analysis.

We use a similar approach for the analysis of the individual cost components of foreign labelers as we used for our analysis of domestic labelers. As the complexity of the labeling operation increases, the cost to comply with the final rule increases; for domestic labelers, we use employment size as a measure of the complexity of the labeling operation. However, a foreign establishment may produce many other device types for its own domestic market or for other non-U.S. markets where the UDI system is not required. Consequently, assigning costs to establishments on the basis of employment size could distort the costs of the final rule for foreign labelers. As a proxy for employment size, we use the number of listings for an establishment. We assume a similar level of effort for domestic and foreign establishments that have the same number of listings. We first map the number of listings for each domestic establishment to the employment size of the domestic establishment. This gives us groupings based on the number of

listings that align with the domestic employment size of any establishment. We then use the number of device listings in the FDA's registration and listing database to assign each foreign establishment to a listing group equivalent to the domestic employment sizes. With this approach, we can use our per-establishment estimates of the required level of effort to develop our foreign cost estimate. In contrast to the domestic analysis, we don't separate out costs by type of labeler (initial labelers or repackagers and relabelers), an assumption that may somewhat overstate costs.

The potential range of production methods employed in the countries exporting devices to the United States complicates the cost analysis. As previously discussed, the FDA designates some countries as Tier 1 countries because they have a regulatory structure similar to the United States. Moreover, the Tier 1 group includes mostly developed countries, suggesting capital to labor ratios similar to those found in the United States. We expect to find differences in capital to labor ratios and wages between Tier 1 countries and non-Tier 1 countries. To account for these differences, we assume that in non-Tier 1 countries establishments with 25 or fewer listings (roughly equivalent to domestic firms with fewer than 100 employees) will use manual production lines, manual recordkeeping systems, and submit data to the GUDID through the web portal. However larger labelers in non-Tier 1 countries will use automated production lines and software systems similar to domestic labelers and labelers in Tier 1 countries.

To capture differences in wages, we take the top 20 countries that export devices to the United States to calculate the weighted average of the per-capita GDP adjusted for purchasing power parity, weighted by the percentage of listings in each country tier (Table 4-49, Ref.1). We find that the purchasing power parity adjusted per-capita GDP for Tier 1 countries averages about 77 percent of the purchasing power parity adjusted per-capita GDP for the United States;

the purchasing power parity adjusted per-capita GDP for non-Tier 1 countries averages about 28 percent of the purchasing power parity adjusted per-capita GDP for the United States. Although not all countries exporting devices to the United States have been included in this analysis, the overall share of device listings among establishments in the top 20 countries represents 90 percent of the total number of foreign listings. Thus, we expect that the countries excluded from our calculation will have relatively little influence on these percentages. We use these percentages to adjust labor costs for each group.

Because capital goods may be purchased in the global marketplace, we assume that all labelers will face the same costs for materials, equipment, and software. To the extent that some labelers can purchase the capital goods at lower costs from their domestic sources, this approach will overstate costs. However, we lack sufficient information to adjust these estimates, but discuss further in the section on uncertainty. See the ERG Report (Ref. 1) for more information about the foreign costs estimates.

Costs for Labelers Located in Tier 1 Countries

As discussed previously, we use the FDA's device registration and listing data to divide foreign labelers into groups by location, number of listings and class of listed devices. Table 27 shows a breakdown of labelers located in Tier 1 countries by device class group and listing group. Of the 3,628 foreign labelers in Tier 1 countries, 1,585 establishments, or approximately 44 percent, list only class I devices.

Table 27.--Number of Labelers Located in Tier 1 Countries, by Device Group and Listing Group

	1 Listing	2-3 Listings	4-10 Listings	11-25 Listings	26-50 Listings	51-100 Listings	101+ Listings	**Total**
Class I Devices Only	648	508	296	77	37	11	8	**1,585**
Not Class I Devices Only	394	531	568	316	127	63	44	**2,043**
Total	**1,042**	**1,039**	**864**	**393**	**164**	**74**	**52**	**3,628**

Source: ERG Report, Tables 4-50 and 4-52 (Ref. 1).

Table 28 shows the average per-establishment one-time costs for foreign labelers located in Tier 1 countries. As noted previously, we adjust wages in Tier 1 countries to be about 77 percent of wages in the United States. Thus, foreign labelers will incur lower costs than domestic labelers for labor intensive actions such as planning and administration, label design, and GUDID. Other cost elements that include a labor component are lower for foreign labelers than domestic labelers. Depending on the number of devices labeled for export to the United States and whether the labeler exclusively handles class I devices, first-year costs vary from about $4,300 to about $87,000 for class I only labelers and from about $7,400 to about $714,000 for all other labelers. Table 29 shows the average per-establishment annual costs for these labelers. Annual costs vary from about $560 to about $45,000 for labelers of class I devices and vary from about $3,500 to about $272,000 for all other labelers.

Table 28.--Estimated Average Per-Establishment One Time Costs for Labelers in Tier 1 Countries ($)

		1 Listing	2-3 Listings	4-10 Listings	11-25 Listings	26-50 Listings	51-100 Listings	101+ Listings
All Establish-ments	*Barcode Registration*	500	500	500	0	0	0	0
	Label Design & Date Stamp	978	1,940	3,865	7,715	15,445	38,575	57,870
	GUDID	1,723	3,321	4,716	3,316	5,684	8,571	22,691
Class I only	*Planning and Administration*	1,120	1,120	2,899	2,968	4,909	5,255	5,948
Not Class I only	*Planning and Administration*	3,066	3,222	16,285	26,796	59,436	92,214	141,556
	Equipment	374	374	21,104	21,104	21,913	35,108	45,279
	Software	748	10,575	25,770	25,770	68,480	163,167	446,149
Total for Class I only		**4,321**	**6,881**	**11,980**	**13,999**	**26,037**	**52,401**	**86,509**
Total for Not Class I only		**7,389**	**19,932**	**72,241**	**84,701**	**170,958**	**337,636**	**713,544**

Source: ERG Report, Tables 4-50 and 4-52 (Ref. 1).

Table 29.--Estimated Average Per-Establishment Annual Costs for Labelers in Tier 1 Countries ($)

Tier I Countries		1 Listing	2-3 Listings	4-10 Listings	11-25 Listings	26-50 Listings	51-100 Listings	101+ Listings
All Establish-ments	*GUDID*	511	1,070	1,558	1,014	1,751	2,761	7,518
Class I only	*Label Materials*	47	47	254	999	3,621	5,886	37,555
Not Class I only	*Equipment*	37	37	7,415	7,415	12,843	24,833	40,092
	Label Materials	2,934	2,934	6,029	12,549	49,821	75,186	176,155
	Software	57	1,757	4,092	4,092	9,589	21,766	48,159
Total for Class I only		**557**	**1,116**	**1,812**	**2,013**	**5,372**	**8,647**	**45,074**
Total for Not Class I only		**3,538**	**5,798**	**19,094**	**25,070**	**74,004**	**124,546**	**271,925**

Source: ERG Report, Tables 4-50 and 4-52 (Ref. 1).

Costs for Labelers Located in Non-Tier 1 Countries

Table 30 shows a breakdown of foreign labelers located in non-tier 1 countries by device group and listing group. In non-Tier 1 countries, 2,336 labelers only handle class I devices, accounting for about two-thirds of all of the labelers in non-Tier 1 countries.

Table 30.--Number of Labelers Located in Non-Tier 1 Countries, by Type and Number of Device Listings

	1 Listing	2-3 Listings	4-10 Listings	11-25 Listings	26-50 Listings	51-100 Listings	101+ Listings	**Total**
Class I Devices Only	617	787	605	224	78	19	6	**2,336**
Not Class I Devices Only	182	230	370	201	84	42	18	**1,127**
Total	**799**	**1,017**	**975**	**425**	**162**	**61**	**24**	**3,463**

Source: ERG Report, Tables 4-56 and 4-58 (Ref. 1).

The average per-establishment one-time costs for foreign labelers located in non-Tier 1 countries are shown in table 31. Similar to our approach for Tier 1 countries, we assume that wages in non-Tier 1 countries equal about 28 percent of wages in the United States, based on the average purchasing power parity adjusted per capita GDP for non-Tier 1 countries in the top 20 countries exporting devices to the United States.

To capture the differences between non-Tier 1 economies and Tier 1 economies, we modify some of our assumptions about the level of effort required to comply with the requirements of the final rule. In contrast to labelers in Tier 1 countries, we assume that all of the labelers in the non-Tier 1 countries will need to register with an approved issuing agency. To the extent that some foreign labelers already register with an issuing agency, this assumption will overstate these costs. In addition, we assume that labelers with 25 or fewer listings will operate manual productions lines, have manual information systems and manually process any UDI data, including using the web portal to enter data to the GUDID. Similar to our analysis of the number of records that labelers will submit to the GUDID, we assume 10 UDIs for each listing.

For labelers of class I devices only, first-year costs range from about $1,900 to about $41,500. First-year costs range from about $3,200 to about $340,000 for all other labelers in non-Tier 1 countries. Annual costs for labelers in non-Tier 1 countries are shown in table 32. These costs vary from about $230 to $40,300 for labelers of class I devices only, and vary from about $1,400 to about $134,000 for all other labelers.

Table 31.--Estimated Average Per-Establishment First Year Costs for Labelers in Non-Tier 1 Countries ($)

Non-Tier I Countries		1 Listing	2-3 Listings	4-10 Listings	11-25 Listings	26-50 Listings	51-100 Listings	101+ Listings
All Establishments	*Barcode Registration*	500	500	500	2,000	2,000	2,000	10,000
	Label Design & Date Stamp	365	715	1,415	2,815	5,645	14,075	21,120
	GUDID	627	1,208	1,715	5,521	2,067	3,117	8,251
Class I only	*Planning and Administration*	407	407	1,054	1,079	1,785	1,911	2,163
Not Class I only	*Planning and Administration*	1,115	1,172	5,922	9,744	21,613	33,533	51,475
	Equipment	290	290	725	1,304	16,965	27,180	35,055
	Software	315	945	1,575	6,300	45,940	95,792	213,399
Total for Class I only		**1,899**	**2,830**	**4,684**	**11,416**	**11,497**	**21,103**	**41,534**
Total for Not Class I only		**3,211**	**4,829**	**11,851**	**27,684**	**94,230**	**175,697**	**339,299**

Source: ERG Report, Tables 4-56 and 4-58 (Ref. 1).

Table 32.--Estimated Average Per-Establishment Annual Costs for Labelers in Non-Tier 1 Countries ($)

Non-Tier I Countries		1 Listing	2-3 Listings	4-10 Listings	11-25 Listings	26-50 Listings	51-100 Listings	101+ Listings
All Establishments	*GUDID*	186	389	567	1,899	637	1,004	2,734
Class I only	*Label Materials*	47	47	254	999	3,621	5,886	37,555
Not Class I only	*Equipment*	26	26	66	119	5,441	10,265	16,172
	Label Materials	1,097	1,097	2,354	5,199	20,421	31,086	87,955
	Software	79	236	394	1,575	7,274	14,478	26,722
Total for Class I only		**232**	**436**	**820**	**2,898**	**4,258**	**6,890**	**40,289**
Total for Not Class I only		**1,388**	**1,748**	**3,380**	**8,792**	**33,773**	**56,833**	**133,583**

Source: ERG Report, Tables 4-56 and 4-58 (Ref. 1).

Costs for Labelers Located in in Tier 1 and Non-Tier 1 Countries for Direct Marking

Direct marking costs apply to a subset of establishments in both Tier 1 and non-Tier 1 countries. Labelers with multiple use devices subject to the direct marking requirement will incur the additional costs of this requirement regardless of other classes of devices labeled at those establishments. Except for the wage adjustment, all assumptions and cost estimates remain the same as we used to estimate the domestic costs for direct marking. FDA data suggests that 350 establishments in Tier 1 countries and 318 establishments in non-Tier 1 countries list

multiple use devices subject to the direct marking requirements of the final rule. We estimate that the total one-time cost of direct marking, including applying for exceptions, marking the devices, upgrading existing equipment or purchasing new equipment equals about $11.0 million for Tier 1 labelers, and about $7.1 million for non-Tier 1 labelers. We estimate annual costs of about $0.8 million for Tier 1 labelers and of about $0.4 million for non-Tier 1 labelers.

Total Costs to Foreign Establishments

Table 33 shows the total first-year and annual costs for foreign labelers to comply with the requirements of the final rule. We estimate total one-time costs of about $230 million and total annual costs of about $70 million. With estimated one-time costs of $180 million and estimated annual costs of $56 million, labelers located in Tier 1 countries account for about 80 percent of estimated total foreign costs.

Table 33.--Total One Time and Annual Costs for Foreign Labelers by Type of Cost and County Tier

	Tier 1 First-Year Costs ($ mil)	Tier 1 Annual Costs ($ mil)	Non-Tier 1 First-Year Costs ($ mil)	Non-Tier 1 Annual Costs ($ mil)	Total First-Year Costs ($ mil)	Total Annual Costs ($ mil)
Administration and planning	42.9	0.0	10.4	0.0	53.3	0.0
Barcode registration costs	1.5	0.0	2.9	0.0	4.4	0.0
Direct marking	11.0	0.8	7.1	0.4	18.1	1.2
Equipment and other investments	26.0	11.5	3.8	1.2	29.8	12.8
Incremental label materials cost	NA	29.6	NA	8.0	NA	37.7
Label redesign and date stamp cost	17.8	NA	5.9	NA	23.7	NA
Software (with training)	67.3	9.3	13.8	2.2	81.1	11.5
GUDID	13.4	4.3	6.5	2.1	19.8	6.4
Total	**179.9**	**55.5**	**50.5**	**14.0**	**230.4**	**69.5**

Taking into account the staggered compliance dates, over 10 years the present value of the total costs to foreign labelers equals $561.3 million with a 7 percent discount rate and equals $661.4 million with a 3 percent discount rate. The annualized present value of the total costs over 10 years equals $74.7 million with a 7 percent discount rate and $75.3 million with a 3 percent discount rate.

Table 34.--Impact of the Staggered Compliance Dates on the Regulatory Costs to Foreign Labelers Over a 10-Year Time Horizon (2012 dollars)

Year	Cost for Class III Device Labelers ($ mil)	Cost for LS/LS Device Labelers ($ mil)	Cost for Class II Device Labelers ($ mil)	Cost for Class I Device Labelers ($ mil)	Total Cost for All Labelers ($ mil)	Present Value with 7 % Discount Rate ($ mil)	Present Value with 3 % Discount Rate ($ mil)
1	$13.2				$13.2	$13.2	$13.2
2	$3.8	$36.3			$40.1	$37.4	$38.9
3	$3.8	$10.5	$171.2		$185.5	$162.0	$174.8
4	$3.8	$10.5	$49.5		$63.8	$52.0	$58.3
5	$3.8	$10.5	$49.5	$25.8	$89.5	$68.3	$79.6
6	$3.8	$10.5	$49.5	$4.6	$68.4	$48.7	$59.0
7	$3.8	$10.5	$49.5	$23.3	$87.1	$58.0	$72.9
8	$3.8	$10.5	$49.5	$5.8	$69.5	$43.3	$56.5
9	$3.8	$10.5	$49.5	$5.8	$69.5	$40.5	$54.9
10	$3.8	$10.5	$49.5	$5.8	$69.5	$37.8	$53.3
Total ($ mil)	**$47.4**	**$120.1**	**$517.5**	**$71.1**	**$756.0**	**$561.3**	**$661.4**
Annualized Present Value ($ mil)						**$74.7**	**$75.3**

Source: ERG Report, Table 4-76 (Ref. 1).

Uncertainty of Estimated Foreign Costs

Similar to our analysis for the domestic industry, we present a potential range of costs for foreign labelers based on ranges of uncertainty for each cost element. We judged that the percentage ranges used for the domestic analysis, however, do not sufficiently capture the foreign uncertainty. The foreign data contain more uncertainty than the domestic data.

Furthermore, the response of foreign labelers to the final rule is more uncertain than the response of domestic labelers. We therefore have increased our estimate of the percentage of uncertainty from those estimates used in our analysis of domestic uncertainty. Only two of the cost elements, registration costs and incremental label costs, are judged to have less than a 50 percent uncertainty. The most uncertain cost elements are software, with 75 percent uncertainty, and equipment costs, with 70 percent uncertainty, because the costs to comply with the final UDI requirements will vary greatly depending on the sophistication of a labeler's production line and the level of automation in the establishment. Other cost elements judged to be more than 50 percent uncertain include label redesign, and direct marking of multiple-use devices.

Table 35.--Uncertainty Ranges for the Major Cost Elements

Cost Element	**Level of Uncertainty (plus or minus relative to mean estimated cost)**
Software (with training)	75%
Equipment and other investments	70%
Label redesign cost	65%
Multiple-Use Devices	60%
Administration and planning	50%
Recordkeeping & Reporting (GUDID)	50%
Incremental label cost	30%
Registration costs	25%

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

Using the total first-year and annual costs shown in table 33 and the uncertainty values in table 35, we calculate the possible range of costs for foreign labelers. As shown in table 36, for foreign labelers the one-time costs may range from $86.5 million to $374.2 million, and annual costs may range from $38.7 million to $100.3 million.

Table 36.--Lower and Upper Bound Estimates of First-Year and Annual Costs for Foreign Labelers ($ million)

	Lower Bound First-Year Cost	Estimated First-Year Cost	Upper Bound First-Year Costs	Lower Bound Annual Costs	Estimated Annual Costs	Upper Bound Annual Costs
Administration and planning	26.7	53.3	80.0	NA	NA	NA
Registration costs	3.3	4.4	5.5	NA	NA	NA
Equipment and other investments	9.0	29.8	50.7	3.8	12.8	21.7
Incremental label cost	NA	NA	NA	28.2	37.7	47.1
Label redesign cost	8.3	23.7	39.1	NA	NA	NA
Software (with training)	20.3	81.1	142.0	2.9	11.5	20.1
Recordkeeping & Reporting (GUDID)	9.9	19.8	29.8	3.2	6.4	9.6
Total Labeling and Database Requirements	77.4	212.2	347.0	38.2	68.4	98.4
Total Direct Marking	9.1	18.1	27.2	0.6	1.2	1.8
Total	**86.5**	**230.4**	**374.2**	**38.7**	**69.5**	**100.3**

Source: ERG Report, Table 8-4 (Ref. 1).

Although we cannot identify all of the uncertainty, we expect that these ranges capture much of the potential differences in individual cost components. A vast number of countries export devices to the United States. Our analysis may not capture all of the challenges labelers in different countries may face when complying with the requirements of the final rule. By using different assumptions to estimate compliance costs for the four groups of foreign labelers (i.e., Tier 1-Class I only, Tier 1-Not Class I only, Non-Tier 1-Class I only, Non-Tier 1-Not Class I only) we address some of the potential variability in foreign costs. Using this approach, however, we implicitly assume less wage variation within a tier than between the two tiers. We also lack information about the capital costs that labelers face in their individual countries and whether this varies within tiers.

To assign costs, we used number of listings as a proxy for size. This approach may distort the compliance options available to certain labelers. Foreign labelers that we consider small and to which we assign costs based on manual production lines may in fact be large

multinational companies doing business in other parts of the world. In this case, our estimates may understate the costs for these labelers to comply with the final rule.

We lack information about current practices and have assumed that no foreign labelers currently comply with the requirements of the final rule. This assumption may lead us to overstate costs. Foreign labelers, especially those that export to the United States, may include UPCs on their exported class I devices now. To the extent that this occurs, we may overestimate foreign costs.

Possible Impact on International Trade

The final regulation will affect domestic and foreign labelers of medical devices. However the diversity of medical devices presents challenges to determine what effect the final rule will have on international trade. 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, but present a brief qualitative discussion of possible responses to the final regulation.

Annual trade data is available for most of the medical device manufacturing categories affected by the final rule. As seen in tables 37 and 38, the trade data show a dynamic global market in medical devices, with many countries both importing medical devices from and exporting medical devices to the United States. Domestic exports from 2010 to 2012 averaged about $36 billion per year, with exports to the top 15 countries accounting for about 78 percent of all medical device exports from the United States. Japan and the Netherlands alone account for almost one-quarter of the average annual value of exports for this period.

Table 37.—Value of Domestic Exports from 2010 to 2012 by Share of Export Value [1, 2]

Country	Total Exports ($ billion)	Average Annual Exports ($ billion)	Share of Average Annual Exports
World Total	106.6	35.5	100%
Japan	13.8	4.6	13%
Netherlands	11.0	3.7	10%
Canada	8.9	3.0	8%
Germany	8.4	2.8	8%
China	5.9	2.0	6%
Belgium	6.5	2.2	6%
Mexico	5.4	1.8	5%
Australia	4.1	1.4	4%
France	3.8	1.3	4%
United Kingdom	3.5	1.2	3%
Brazil	2.7	0.9	3%
Switzerland	2.6	0.9	2%
Korea	2.3	0.8	2%
Singapore	2.0	0.7	2%
Sweden	2.1	0.7	2%

[1] Source: USITC Interactive Tariff and Trade DataWeb. Based on tariff and trade data from the U.S. Department of Commerce and the U.S. International Trade Commission aggregated for NAICS 339112, 339113, 339114, 339115, 334510. 334517. http://dataweb.usitc.gov/

[2] "Free alongside ship" value of domestic exports in current dollars for the year reported.

Foreign imports into the United States averaged about $39 billion per year. Ranking countries by the import value to the United States, we find that the top 15 importing countries account for about 85 percent of the total average annual value of imports. Mexico is the top importer of medical devices to the United States. Along with China, Ireland and Germany, the top 4 importing countries account for over 50 percent of the value of imports.

Table 38—Value of Imports from 2010 to 2012 by Share of Import Value [1, 2]

Country	Total Imports ($ billion)	Average Annual Imports ($ billion)	Share of Average Annual Imports
World Total	118.1	39.4	100%
Mexico	17.6	5.9	15%
China	14.7	4.9	12%
Ireland	15.5	5.2	13%
Germany	13.8	4.6	12%
Japan	7.1	2.4	6%
Switzerland	6.6	2.2	6%
Malaysia	4.3	1.4	4%
United Kingdom	3.5	1.2	3%
Italy	3.0	1.0	3%
Costa Rica	2.8	0.9	2%
Thailand	2.5	0.8	2%
France	2.9	1.0	2%
Singapore	1.9	0.6	2%
Dominican Rep	2.1	0.7	2%
Netherlands	2.2	0.7	2%

[1] Source: USITC Interactive Tariff and Trade DataWeb. Based on tariff and trade data from the U.S. Department of Commerce and the U.S. International Trade Commission aggregated for NAICS 339112, 339113, 339114, 339115, 334510. 334517. http://dataweb.usitc.gov/

[2] "Cost, insurance freight" value of imports for consumption in current dollars for the year reported.

Based on our cost analysis, we predict that, on average, foreign labelers may face lower compliance costs per establishment than domestic labelers. To the extent that these lower compliance costs per establishment for foreign labelers lead to smaller increases in average costs for foreign labelers than for domestic labelers, the prices of foreign medical devices could on average rise by less than the prices of domestic devices, stimulating imports of foreign medical devices. Even with lower relative compliance costs, however, the higher average costs of producing for export to the United States could lead some foreign labelers to discontinue exporting to the American market. That may especially be the case for foreign labelers that sell few products to the United States. Although we lack information about the share of foreign revenues attributable to exports to the United States, the Agency's medical device registration

and listing data indicates that over 50 percent of foreign labelers export fewer than 4 medical devices to the United States.

Most of the compliance costs are unlikely to be large enough to lead to significant disruption among domestic labelers. The shifts in international markets for devices could even encourage more domestic labelers to seek foreign markets for their medical devices. Although the United States is currently the largest consumer of medical products in the world, as foreign populations grow and foreign incomes rise, foreign demand for medical devices will increase. Increased foreign demand for medical devices will provide increased export opportunities for domestic labelers. For example, India has become a major importer of medical devices from the United States; exports to India from the United States increased by over 70 percent from 2005 to 2009. Moreover, India has lower tariffs on finished medical devices than on components, giving United States exporters a possible incentive to ship devices to India. The United States International Trade Commission estimates that exports to India will continue to expand, driven by population growth and an increasing middle class (Ref. 4). Even though we are unable to predict how the final rule will affect international trade, we expect that there will be some shifts in trade in medical devices. However, the impact of these shifts is uncertain.

II. References

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