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FINAL REPORT

UNIQUE DEVICE IDENTIFICATION (UDI) FOR MEDICAL DEVICES: ECONOMIC ANALYSIS OF THE FINAL RULE

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1.0 EXECUTIVE SUMMARY

The U.S. Food and Drug Administration (FDA) is finalizing a rule requiring unique device identification (UDI) for medical devices to meet the requirements of the Food and Drug Administration Amendments Act (FDAAA) and the Food and Drug Administration Safety and Innovation Act (FDASIA). The rule is intended to improve device safety and the reporting of device-related adverse events.

A UDI is a unique numeric or alphanumeric identifier assigned to each device product. This identifier will appear on the label of the device and consist of a device identifier portion, which identifies the product and the labeler, and, in many cases, a production identifier (lot, batch, serial number, donor identification number, or date). Lack of unique identifiers for medical devices hinders the identification of devices throughout their distribution and use, the reporting and analysis of adverse event data, and the timely removal of recalled devices from medical uses.

This report analyzes the requirements of the regulatory option selected for the final rule. This option (the "selected option") is compared, in most instances, to a rejected high-cost option and a rejected low-cost option. The high-cost option would have required all classes of devices to be labeled with both the device identifier and the production identifier (i.e., a variable barcode that changes with each lot, batch, date, etc.), while the low cost option would have required all classes of devices to be labeled with just the device identifier (i.e., a static barcode). FDA has, however, selected an option that allows for a reduced the regulatory burden. In the selected option, the labels and packages of Class II and Class III devices must bear the device identifier and the production identifier in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology (referred to as barcode, the most common form of AIDC). Class I devices must be labeled with the device identifier (i.e. a static barcode). Labelers of Class I devices are not required to include the variable production identifiers in their UDI. Furthermore, the selected option also excludes devices that are exempt from good manufacturing practice (GMP) requirements. Such devices include bed pans and home-use toothbrushes; such devices will not be subject to any UDI requirements.

1.1 Summary of the Final Rule

The final UDI rule will require a numeric or alphanumeric identifier to be placed on the label of most medical devices that are marketed and sold in the U.S., as well as on their device packages.[1]. The form of this UDI will be consistent with current barcoding configurations of two major barcoding organizations, GS1 (which is the issuing body for UPC and similar trade-related codes) and the Health Industries Business Communications Council (HIBCC), as well as the International Council for Commonality in Blood Banking Automation's (ICCBBA) ISBT 128 barcode format (for human tissue-based devices). As noted above, the UDI is considered to consist of a device identifier and a production

[1] Generally, the device package is the package containing one or more labeled devices of the same model or version.

identifier. The selected regulatory option for the final rule will allow Class I devices to use just the device identifier as the UDI on those devices (and UPC codes will also qualify as UDIs on Class I devices). Certain devices intended for multiple use and reprocessed before each use will require direct marking of the UDI on the device itself (many of these are surgical instruments). Standalone software (software that is not an integral component of a device) will be required to have the UDI displayed, for example, on the start-up page. Previously, at proposal, FDA would have required direct marking of implants, but the final rule will not require this.

Additionally, certain basic identification and contact information, as well as certain key attributes of the devices (e.g., sterile, MRI compatible, or containing latex) will need to be uploaded to a database that is being created and maintained by FDA. Medical device records throughout the required recordkeeping and reporting systems at labeling establishments will need to be modified so that UDIs can be included in such records. Additionally, any dates appearing on medical device labels will need to be presented in a prescribed format. FDA has now specified a date format that is consistent with international usage and international standards.

1.2 Labeler Costs to Implement Unique Device Identification

ERG identified a number of costs facing medical device labelers as they comply with the final rule, including planning costs, equipment costs (such as for digital printers for those establishments needing to print variable barcodes), or increased printing costs (for those printing variable barcodes who outsource printing), costs to obtain a UDI and register barcodes, costs to laser–etch (for example) UDIs on medical devices for which direct marking (DM) is required, costs to change labels to meet the requirements, costs to integrate UDI throughout the information systems at labeling firms to ensure integration among processing systems and to ensure all relevant records contain UDIs, and costs to meet data uploading requirements. Costs to all domestic medical device labelers are estimated for the final rule to be $356.6 million in the first year and $55.2 million in subsequent years.

For comparison purposes with various alternatives and to show the effect of FDA's rule, which specifies UDI implementation periods allowing up to 5 years (for Class I devices) and between 3 and 7 years for DM requirements[2], total annualized costs are presented on two bases: (1) immediate implementation and (2) under the specified implementation schedule, depending on Class or type of device. Because any delay in outlays results in lower costs over time, FDA's implementation schedule results in substantially lower costs than those estimated under a scenario in which all device labelers must immediately implement UDI, i.e., in the first scenario.[3]

[2] Class III devices must bear a UDI within 1 year of promulgation and certain implantable, live-saving, or life-sustaining devices that are not Class III devices must bear a UDI within 2 years of promulgation (as specified by FDASIA). Any other Class II devices must bear a UDI within 3 years of promulgation.

[3] The immediate implementation scenario is not intended to consider the cost implications associated with the difficulties of implementing such a complex rule in a short time frame.

1.2.1 Immediate Implementation Cost Scenario

Under the immediate implementation assumption and with costs annualized at 7 percent over 10 years, first-year costs are estimated at $356.6 million. With recurring costs of $55.2 million per year added in, total annualized costs to U.S. industry are estimated at $106.0 million per year (see Table 1-1). By comparison, FDA's rejected high-cost option would have cost $154.8 million per year, while the low cost option would have resulted in estimated costs to U.S. industry of $29.5 million per year.

ERG also estimates costs for foreign establishments and firms to implement the final rule under the immediate implementation scenario. ERG estimates that the costs to foreign labelers will be $102.3 per year. The estimate of costs that might be incurred by foreign establishments is considered very uncertain. We do not have detailed information on how devices are currently produced in the large numbers of foreign countries that export to the U.S., nor do we know what specific costs apply to the establishments in those countries. This estimate, therefore, is the best estimate that can be derived with the data available.

FDA may accredit a private nonprofit organization or State agency as an issuing agency. Three organizations, GS1, HIBCC, and ICCBBA, already perform functions in a manner that potentially could meet the accreditation criteria for issuing agencies listed in the rule. Nevertheless, ERG assumed that organizations applying to become accredited issuing agencies will incur costs to ensure that they understand and are comfortable with their legal responsibilities under this rule. Additionally, FDA will require issuing agencies to report and maintain information, which will also result in costs to an organization that becomes accredited. ERG estimates the costs to the three presumed issuing agencies at $790,500 in the first year, nearly all of which is allocated to executive and legal reviews of the FDA rule. The recurring annual costs are estimated at $82,200, including an allowance for ongoing executive and legal reviews. The total annualized costs to the three organizations performing functions similar to issuing agencies are estimated at $194,700 per year. (The first-year costs are assumed to be incurred in the first year after promulgation of the rule under both implementation scenarios). Under the immediate implementation scenario, total annualized costs to issuing agencies and U.S. industry are $106.2 million per year.

1.2.2 Actual Implementation Schedule

Under the actual implementation requirements, total costs to U.S. industry are lower than those estimated under the immediate implementation scenario, reduced from $106.0 million to $82.6 million per year (see Table 1-1). Under the rejected high-cost option, the total cost would have been $108.0 per year. The low-cost option was not analyzed under this scenario.

Costs to foreign establishments under the actual implementation schedule are estimated to be $74.7 million per year (see Table 1-1).

Total annualized costs of the final UDI rule for all affected entities (including foreign entities and issuing agencies, but excluding any costs to FDA) are estimated to be $157.4 million per year when the actual implementation schedule is considered (see Table 1-1).[4]

Table 1-1. Costs of the Final Rule for All Affected Entities

Entity	One-Time Costs	Recurring Costs	Immediate Implementation		With the Provided Additional Implementation Time
			Annualized One-Time Costs	Total Annualized Costs	
Domestic Industry	$356,590,521	$55,199,178	$50,770,468	$105,969,646	**$82,554,886**
Issuing Agencies	$790,500	$82,200	$112,549	$194,749	$194,749
Foreign Industry (a)	$230,350,545	$69,529,648	$32,796,735	$102,326,384	**$74,686,914**
Total Non-Federal Costs	**$587,731,566**	**$124,811,026**	**$83,679,753**	**$208,490,779**	**$157,436,549**

Source: ERG estimates.

1.3 Impacts on Labeling Firms and Establishments

ERG investigated impacts of the costs to implement UDI on all domestic labeling firms under the high-cost option. Measureable impacts were defined as costs as a percentage of revenues exceeding 1 percent. Among all domestic labelers under the base case, costs as a percentage of revenues exceed 1 percent only for a small number of firms that will be required to directly mark certain devices. A total of 32 firms out of an estimated 5,234 firms (0.6 percent) are estimated to incur compliance costs in excess of 1 percent of revenues.[5] If costs for DM are excluded, no firms will experience costs exceeding 1 percent of revenues. DM requirements are associated with costly equipment such as laser markers that must be used to inscribe the UDI on the device.

Among those estimated to experience costs greater than 1 percent of revenues, all are considered small businesses. These 32 firms are also 0.6 percent of an estimated 4,969 small businesses subject to the rule and considered highly affected (not including small businesses that are considered unlikely to be affected by the rule, such as those labeling custom devices, as well as those considered to be only

[4] FDA would also incur costs to administer the UDI database system. These costs are not estimated in this report.

[5] The count of 5,234 firms excludes those that are expected to meet exceptions or are considered to be mostly in compliance with the final rule in the baseline due to use of UPCs or assumed current use of variable barcodes and thus are subject to much lower or negligible costs per firm.

minimally affected, including those estimated to be currently meeting variable barcoding requirements or are labeling with UPCs).

For establishments, no establishments are expected to incur compliance costs greater than 1 percent of establishment revenues under the base case, unless they must satisfy DM requirements. When DM requirements are considered, 19 establishments are estimated to incur costs greater than 1 percent of revenues. These establishments are all considered single-facility firms and, therefore, are among the 32 entities identified as having costs exceeding 1 percent of revenues in the firm impact analysis.

The impacts discussed are not expected to be much different under FDA's selected option for the final rule. Because the only establishments that are estimated to incur costs greater than one percent are a subset of those that must meet DM requirements and because DM will be required under this option, as well, the impacts on firms discussed above could still occur. However, some multi-use device manufacturers that are required to direct mark these primarily Class I devices, could face substantially reduced total costs if all of their device labels require static barcodes only, rather than the more costly variable barcodes. To the extent that this situation occurs, this alternative could possibly reduce the number of firms estimated to incur costs exceeding 1 percent of revenues among firms with 10-19 employees. To the extent that all firms in this size range that must direct mark devices face sufficiently reduced costs, this will reduce the number of firms that are estimated to face costs exceeding 1 percent of revenues to 19, which is 0.4 percent of all firms and 0.5 percent of 4,215 highly affected small firms.[6] We do not, however, have any information on whether firms that only manufacture Class I devices and must direct mark some or all of those devices are among the groups of firms considered likely to face costs exceeding 1 percent of revenues.

1.4 Other Impacts

There may be additional impacts to other entities based on the premise that some UDI costs will be passed through to distributors and end users, including hospitals and consumers. However, because there are almost as many markets as there are types of devices, an analysis of device markets to determine the proportion of costs that might be passed through to consumers or others is not practical. However, on average, the costs estimated for the final rule on an annualized basis under the actual implementation scenario are about $157.4 million for all entities and about $82.6 million for U.S. industry. This latter figure, compared to total U.S. value of shipments in 2007 ($117.5 billion [U.S. Census, 2010]), is about 0.07 percent of total revenues. The percentage of costs passed through will depend on the relative demand and supply elasticities of each device market. However, the magnitude of costs that might be passed through, given the overall price increases that might be needed to recapture 100 percent of UDI costs, might generally be small, based on the magnitude of costs as a percentage of total shipments in the groups of industries that manufacture medical devices.

[6] In addition to the firms excluded from the count of small businesses discussed previously under the high-cost option, the firms that are estimated to currently label GMP-exempt devices or Class I devices only that are labeled with static barcodes are also removed from the counts under the selected option.

Impacts on trade might also occur. The effect of the UDI regulation on foreign trade is difficult to assess, however, because the numerous different device types each can define a separate market. A further complexity is that there are device markets in which the devices are not perfect substitutes, particularly the more expensive and/or innovative devices. For example, many doctors exhibit brand loyalty without much, if any, consideration of price; orthopedic surgeons often specialize in a particular brand of replacement joint. Furthermore, pricing signals in medical device markets are relatively poor due to the system of third-party payers (insurers) and the structure of the reimbursement system that generally reimburses by procedure, not for a particular device and these reimbursements can vary significantly, even hospital to hospital in the same city.

However, there are some basic changes in the balance of trade that might occur in many device markets depending on whether or not foreign establishments can meet UDI requirements at lower costs than domestic establishments. If foreign establishments can meet the requirements of the rule at a lower cost than can U.S. establishments, the balance of trade might shift in their favor. For highly differentiated device markets, however, the results are not as clear.

Although we have had to make broad assumptions regarding the incremental cost differences between foreign and domestic establishments, it would appear that costs to foreign firms might be, on average, somewhat less than those faced by domestic firms due to lower labor costs, even if capital costs are not substantially different. Thus, the balance of trade in some medical devices, from some countries, might shift towards more imports, although this might not hold true in some device markets or for all countries. As noted earlier, however, the costs of this rule relative to the value of device shipments is estimated to be very small, so it is likely that any impacts on trade will be, on average, small. Nevertheless, it is possible that certain device markets could experience much higher price increases than average and/or much greater trade impacts than average.

2.0 INTRODUCTION: KEY CHANGES TO THE RULE SINCE PROPOSAL

In its 2012 proposal for a Unique Device Identification (UDI) of Medical Devices, FDA presented a selected option in which labelers of Class II and III devices would need to create and print on their labels a human readable and barcoded number that contains identifiers linked to an establishment, a specific device, as well as a production identifier, such as a serial number, lot number, or expiration date. The production identifiers would need to change periodically, up to and including a change for every device if the labeler chooses to serialize. Labelers of Class I (and unclassified devices) would need to label with a number and barcode that identifies the establishment and device only, a simpler operation resembling a relatively simple labeling change for a device. Excepted from the proposed rulemaking, in particular, were custom devices, devices sold at retail, and devices exempt from Good Manufacturing Practices (GMP). Additionally, the proposed rule required each registrant of a device subject to UDI to upload specific information to a Global Unique Device Identification Database (GUDID). Specific, uniform formats for dates appearing on the label were also proposed. The report, titled *Unique Device Identifiers for Medical Devices*, dated May 2012, presents the results of an economic analysis of the proposed rule. This document also summarized the rule as proposed. See Section Three and Section Six of this report for more details on the proposed rule (ERG, 2012).

The key changes to the UDI rule since the rule was proposed in July 2012 that affect the economic analysis are summarized below:

- Label changes for date formats will need to be made only when UDI labeling is required (not by one year after promulgation).

- The required label format is now aligned with international standards. This may result in more labelers already in compliance, but ERG assumes only those small number of establishments currently assumed to be labeling with variable barcodes will already be in compliance.

- The Food and Drug Administration Safety and Innovation Act (FDASIA), enacted in July 2012, requires FDA to have labelers of Class III and certain implantable, life saving and life sustaining devices (hereinafter referred to as LS/LS devices) to have UDI in place on their labels within 2 years of promulgation. Many of these devices are Class III, and FDA is continuing to require Class III devices to display UDI within 1 year of promulgation, but a number of Class II devices and a very small number of Class I devices are considered implantable, life saving or life sustaining. The LS/LS devices, as a distinct group referred to in this report, are those that do not include the Class III devices that are also be considered a part of the wider LS/LS group. This affects ERG's timing assumptions when calculating the annualized costs of the rule. As was done in ERG (2012), all cost estimates are first made assuming that all costs of the rule are incurred in the first year after promulgation. The costs are then distributed to later years, depending

on Class and the effective date for each Class (but now LS/LS devices must meet the rule 2 years after promulgation).

- Direct marking of implants is no longer required; only devices intended for multiple use and sterilized between uses (multi-use devices) must be directly marked. All costs for direct marking of implants have been removed from the analysis.

- Direct marking of devices intended for multiple use is required for all devices intended to be reprocessed between uses. Previously, the direct marking requirement would have applied to such devices intended to be sterilized between uses. This wording change broadens the scope of this requirement in unknown ways. ERG does not attempt to quantify the cost effects of this, but discusses the potential impact on cost in the uncertainty section (see Section 7 of this report). FDA has also clarified that the requirement does not apply to reprocessed single-use devices.

- Direct marking for software has been clarified and the term "direct marking" is no longer used, although the basic requirement to include the UDI as part of the startup or "about" menu has not changed. The UDI requirement for software downloaded directly from the web has been clarified. The version number of the software is required to be included as (or as part of) the production identifier). ERG considers these clarifications and has not changed any assumptions about additional costs for software to meet UDI requirements.

- Devices sold at retail are no longer excepted from the rule, but UPC codes on Class I device labels are considered to meet the requirements of a UDI. This change means that Class I devices with UPC codes will not need to be relabeled, but the labelers of these devices will need to submit device data to FDA's GUDID, leading to additional costs incremental to those estimated in ERG (2012) for submitting GUDID data. ERG assumes majority of UPC-labeled devices are Class I and that the UPC-only establishments estimated in this analysis are all labeling Class I devices.

- Magnetic resonance imaging (MRI) compatibility has been added to the GUDID data requirements, if applicable. The number of data elements required for uploading has been considered in the cost estimate associated with GUDID requirements.

  FDA has confirmed that the Agency will be able to provide GMDN codes to labelers at no cost. Although labelers might have to update these codes (since the codes do change from time to time), FDA plans to assist labelers with this process to minimize the time involved. The costs estimated for GUDID tasks reflect a no-cost assumption for obtaining the codes themselves. However, the time to look up the proper codes is estimated. The costs also reflect an assumption of occasional GMDN code modification during GUDID updates.

- FDA now spells out a process for correcting misinformation within the UDI. ERG estimates costs for periodically providing new or modified data to the GUDID.

Other apparent changes to the rule are actually clarifications. ERG did not identify costs, and the clarifications should indicate that the no-cost assumption is appropriate or that an assumption of negligible costs is warranted. Additionally a few additional changes or clarifications are noted, below, but the differences did not translate into a measurable cost change.

- The process of applying for exceptions has been clarified. Due to a change in methodology for computing planning and administrative costs, the cost for applying for exceptions has been estimated separately, but no change in basic assumptions has been made.

- FDA has clarified that the UDI labeling requirements are generally prospective and not retrospective, but limits grandfathering of device labels to 3 years after the effective date of the rule. Given cycling of inventories and the possibility of requesting exceptions for very rare cases, ERG assumes that this limitation will have minimal impact on labelers.

- Changes to models that necessitate a new UDI are to be determined by the labeler and are not prescriptive; that is, *when the labeler* considers that a device is a new model or version, FDA requires a new UDI. The language in the proposed rule was intended to harmonize UDI with trading partner or issuing agency (e.g., GS1) requirements or need for information. This intent has been clarified in the final rule.

- FDA clarified the process for requesting exceptions; the exception process is meant to require relatively little time and effort by labelers.

- FDA added an exception for labelers of Class III devices to apply for a one-year extension of the time to comply under circumstances that could lead to shortages or other major issues.

- FDA clarified that NHRICS or NDCs that have become a part of the labeler code (e.g., within the HIBCC or GS1 device identification systems) can retain those numbers as their labeler code.

- UDI requirements for devices classified as Human Cells and Tissue Products (HCT/P) regulated as devices have been clarified; FDA considers the donor identification system currently used by these devices as the production identifier for such devices.

- Unclassified kits are now required to meet UDI requirements based on the highest device Class of any device contained within the kit (rather than in 5 years for all other

unclassified devices). ERG makes no special timing assumptions for these devices; FDA believes the numbers of such devices are extremely small.

Convenience kits, where multiple devices might be incorporated into a single package, are no longer required to have UDIs on their constituent devices (regardless if single use or multi-use), but the kit label must contain the UDI. ERG acknowledges the potential savings here, but does not specifically estimate that difference.

- Combination products that are not classified as drugs ("properly bear an NDC" on their label) are not required to contain a UDI on their label, but if they do not, the device within them must bear a UDI on the label. If the UDI is, however, placed on the label of the combination product (with or without an NDC appearing on the label as well), the device package within the combination product does not have to bear a UDI. Previously, the device constituent part of certain combination products was required to bear a UDI regardless of whether a UDI was present on the combination product. This simplification might result in some potential cost savings, but ERG does not specifically estimate a savings.

- Shelf packs, originally excepted from requiring each individual single-use product within the pack to bear a UDI only if the devices were Class I devices, now are nearly all excepted, regardless of class, but implantables (those devices implanted for more than 30 days) must still bear individual UDIs. ERG previously assumed the non-excepted devices that were not Class I would be excepted on a case-by-case basis. Implantables in shelf packs are assumed rare. ERG makes no changes to any costing assumptions based on these changes.

- FDA no longer requires labelers to provide to FDA notice of exceptions requested on the basis that the marking will interfere with safety or effectiveness, marking is technologically infeasible, or the device was previously marked; the justification for not marking is only required to be inserted in the design history file. ERG notes that this might reduce the costs of direct marking slightly, but did not estimate the cost savings.

3.0 ADDITIONAL PROFILE INFORMATION

3.1 Foreign Medical Device Establishments

3.1.1 Leading Countries that List Devices under Initial Labeling Types

FDA's Registration & Listing database (March, 2010), indicates that the total number of foreign establishments that are considered initial labelers totals 6,492 manufacturers, 3 reprocessors, and 276 specification developers, for a total of 6,771 initial labeling establishments. Table 3-1 summarizes the output from the R&L database.

Table 3-1. Numbers of Foreign Establishments by Type

Type of Registrant	Foreign Establishments
Manufacturers	6,492
Reprocessors	3
Specification Developers	276
Total Initial Labelers	**6,771**
Relabelers/Repackagers	320
Total Labelers	**7,091**

Source: FDA (2010).

A total of 90 countries export medical devices to the U.S. according to the database, of which 89 are associated with initial labelers. However, most establishments are located in and most listed devices are exported from a much smaller number of countries. Table 3-2 shows the top 20 countries ranked by the number of listings at initial labeling establishments that register and list. These countries account for 89 percent of foreign registrants and 91 percent of foreign device listings. As the table shows, although foreign listings comprise nearly half of all listings in the R&L database, Class I listings by foreign initial labeling establishments are much more common than other classes of listings, comprising 62 percent of all foreign listings.[7] This is a much higher percentage of listings than that seen for initial labelers in the U.S.; only 39 percent of total U.S.-based listings among initial labelers are Class I listings.

Only 24 percent of all Class III listings are imported, mostly from the countries listed in the top 20. Other countries not shown in this table with notable numbers of Class III device listings are Dominican Republic (20 listings) and Australia (10 listings).

[7] Class I has been combined with a small number of unclassified and other devices.

Table 3-2. Top 20 Countries by Number of Listings among Foreign Initial Labelers that Register and List

Ranking	Country Name	Estabs.	Device Listings				
			Total	Class I (a)	Class II	Class III	% Class I
1	Germany (b)	734	11,083	7,622	3,408	53	69%
2	China	1,556	7,028	5,565	1,450	13	79%
3	Pakistan	129	3,870	3,846	24	0	99%
4	Great Britain (b)	375	2,972	1,251	1,678	43	42%
5	Japan (b)	340	2,627	814	1,802	11	31%
6	Mexico	143	2,479	875	1,562	42	35%
7	Taiwan	388	2,240	1,512	727	1	68%
8	France (b)	245	1,679	731	923	25	44%
9	Switzerland (b)	149	1,663	587	995	81	35%
10	Canada (b)	392	1,640	940	681	19	57%
11	India	116	1,604	1,411	190	3	88%
12	Italy (b)	280	1,066	567	479	20	53%
13	Ireland (b)	74	1,047	197	793	57	19%
14	South Korea	329	959	589	367	3	61%
15	Sweden (b)	145	920	422	484	14	46%
16	Malaysia	110	853	718	132	3	84%
17	Israel (b)	203	758	241	511	6	32%
18	Denmark (b)	62	521	179	338	4	34%
19	Hong Kong	135	434	315	119	0	73%
20	Netherland (b)	89	380	132	230	18	35%
Total Top 20		**5,994**	**45,823**	**28,514**	**16,893**	**416**	**62%**
Total All Foreign		6,771	50,362	31,040	18,844	478	62%
Top 20 as % of Total Foreign		**89%**	**91%**	**92%**	**90%**	**87%**	--
United States		6,266	55,192	21,796	30,523	1,502	39%
Total Foreign & Domestic		13,037	105,554	52,836	49,367	1,980	50%
Foreign as % of Total Foreign & Domestic		**52%**	**48%**	**59%**	**38%**	**24%**	--

Source: FDA, 2010.
(a)Includes unclassified and other.
(b)Tier 1 country (see text below).

Twelve of the top 20 countries are classified as Tier 1 countries by FDA; eight are not. Most of the countries ranked lower than the top 20 in this table are generally considered "emerging" nations, although some are classified by FDA as Tier 1 countries. FDA's Tier 1 classification relates to U.S. export requirements; however, we are, for the purposes of this document, using this designation as a

convenient means of grouping countries that may face similar costs of UDI implementation (given a presumed similar size of operations, which will be discussed further, below).

FDA Tier 1 countries are generally considered economically developed and 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). Prior to May 2004, the EU consisted of the United Kingdom, Spain, Ireland, Denmark, Greece, Belgium, Portugal, Germany, France, Italy, Luxembourg, Netherlands, Sweden, Finland, Austria, Bulgaria and Romania. In May 2004, the EU added: Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia. The 2004 additions include countries where the assumption of cost similarity with the U.S. might be questionable (e.g., relative intensity of capital to labor), we will, for now, include these with the Tier 1 countries. Conversely, some non-Tier 1 countries might have costs similar to those for U.S. establishments.

Eight of the top 20 countries by establishment numbers are not considered Tier 1 countries, although several are relatively industrialized. For seven of the eight non-Tier 1 countries in the top 20, Class I listings make up more than 60 percent of their exported device listings (Mexico is the exception). Additionally China and Pakistan, which are associated with very large numbers of listings, overwhelmingly export Class I devices to the U.S (79 percent and 99 percent of the device listings in these countries, respectively, are Class I devices).

3.1.2 Foreign Establishments that Will Be Subject to Static vs. Variable Barcoding Requirements

A major cost factor in the regulatory analysis is whether establishments will be subject to static barcoding requirements or variable barcoding requirements. Establishments that handle only Class I devices will be subject to static barcoding requirements only. ERG assumes that all establishments that will need to meet variable barcoding requirements on any of their devices will be affected by more cost categories and thus will incur greater costs than establishments of similar size that are only subject to static barcoding requirements. Furthermore, costs tend to rise with establishment size.

We do not know the size of establishment by employment or revenue category for foreign establishments that manufacture or otherwise handle devices as initial labelers. Data at this level of disaggregation are limited and do not necessarily map to the size of establishments that export medical devices to the U.S. However, we do have distributions of establishments by number of device listings and by whether the establishment handles only Class I devices.

Table 3-3 breaks down the numbers of establishments by ranges of numbers of listings, by whether they are in Tier 1 or other countries, and whether they handle only Class I devices.[8] As the table shows, the Tier 1 countries, despite being significantly less numerous (37 countries total) among the 89 countries with initial labelers that export to the U.S., are associated with 3,493 out of the total 6,771 foreign listing establishments considered initial labelers (52 percent of all foreign initial labeling establishments). A total of 42 percent of establishments in Tier 1 countries are expected to be subject only to static barcoding requirements, thus 58 percent will need to meet variable barcoding requirements. In comparison, among the non-Tier 1 countries, 67 percent of establishments handle only Class I devices, thus only 33 percent of establishments in these countries are expected to be subject to variable barcoding requirements.

3.1.3 Size of Foreign Initial Labeling Establishments Relative to Size of U.S. Establishments

In order to move forward with assigning costs to foreign establishments, we need to approximate differences in costs based on a general sense of the size of those foreign establishments. As noted earlier, we do not have information on employment size of establishment for foreign initial labeling establishments export devices to the U.S., although we do have distributions of establishment counts by ranges of numbers of device listings. About 81 percent of all foreign establishments initially label 10 or fewer device listings (last column of Table 3-3: 26 percent + 29 percent + 12 percent + 14 percent). This percentage is fairly constant among the foreign countries regardless of whether they are Tier 1 countries or not (see columns labeled % of All Tier 1 Estabs. and % of All Other Estabs. in Table 3-3). It is also not inconsistent with the U.S. distribution, in which 80 percent of establishments also handle 10 or fewer listings (see Table 3-4). At the other extreme, the establishments handling more than 101 devices are very rare, both in the U.S. and abroad. About 1 percent (foreign) to 2 percent (U.S.) of establishments falls into this category. The other percentages of establishments by range of listings handled are similar among foreign countries and the U.S.

None of our estimates in the U.S. analysis rely on numbers of device listings; rather employment size is the basis by which we assign costs to establishments. However, our cost estimates for U.S.

[8] The table shows percentages in two ways. First, the percentage of establishments by numbers of listings (i.e., by "size") shown for the Class I only group among Tier 1 countries is calculated as a percentage of total Class I only establishments. For example, there are 617 establishments in Tier 1 countries that list one device and list only Class I devices. This is 61% of all establishments that list only Class I devices in the Tier 1 countries. At the bottom of this column, however, the bold percentage indicates the percentage of all Tier 1 establishments that are Class I only establishments (42 percent). The next Tier 1 percentage column (% of all Tier 1 Estabs.) shows the percentages of all Tier 1 establishments by "size," regardless of class of device. Similar columns for the non-Tier 1 countries are calculated similarly. The final column calculates all foreign initial labeling establishments by "size" as a percentage of all establishments. Note that we do not show the percentage of establishments that are not Class I only establishments by "size" to save table space.

Table 3-3. Number of Foreign Initial Labeling Establishments by Number of Listings, Country Tier, and Class of Devices (Class I Only vs. All Others)

	Tier 1 Countries					Other Countries					All Countries	
Number of Listings	Class I Only Estabs.	Class I Only Estabs by Number of Listings as % of Total Class I Only Estabs.	All Other Estabs.	Total Estabs.	% of All Tier 1 Estabs.	Class I Only Estabs.	Class I Only Estabs. by Number of Listings as % of Total Class I Only Estabs.	All Other Estabs.	Total Estabs.	% of All Other Country Estabs.	Total	% of All Estabs.
1	617	61%	393	1,010	29%	573	77%	176	749	23%	1,759	26%
2 – 3	484	48%	520	1,004	29%	732	77%	221	953	29%	1,957	29%
4 – 5	137	35%	253	390	11%	267	66%	140	407	12%	797	12%
6 – 10	129	30%	304	433	12%	308	58%	220	528	16%	961	14%
11 – 25	72	19%	314	386	11%	211	52%	198	409	12%	795	12%
26 – 50	32	21%	123	155	4%	73	47%	82	155	5%	310	5%
51 – 100	6	9%	61	67	2%	17	31%	38	55	2%	122	2%
101 or more	7	15%	41	48	1%	6	27%	16	22	1%	70	1%
Total Establishments	**1,484**	**42%**	**2,009**	**3,493**	**100%**	**2,187**	**67%**	**1,091**	**3,278**	**100%**	**6,771**	**100%**

Source: FDA, 2010.

Table 3-4. Number of U.S. Initial Labeling Establishments by Number of Listings and Class of Devices (Class I Only vs. All Others)

Number of Listings	Class I Only	% of Class I Only Estabs.	All Others	Total	% of All Estabs.
1	1,173	60%	781	1,954	31%
2 – 3	748	46%	865	1,613	26%
4 – 5	210	31%	464	674	11%
6 – 10	179	23%	584	763	12%
11 – 25	109	17%	543	652	10%
26 – 50	29	9%	302	331	5%
51 – 100	18	11%	151	169	3%
101 or more	2	2%	108	110	2%
Total Establishments	**2,468**	**39%**	**3,798**	**6,266**	**100%**

Source: FDA, 2010.
Note: % of Class I Only Estabs. shows the percentage of Class I only establishments by "size" to total Class I only establishments, while the bold number at the bottom of the column shows the percentage of Class I only establishments to all initial labeling establishments in the U.S.

establishments are not directly calculated from the number of employees. Rather, they are based on a presumed increasing complexity of operations as establishment size increases. Essentially, we assume that more employees mean more device listings, greater numbers of production lines, and more manufacturing capacity. Thus, ERG assumes that the numbers of listings each foreign establishment handles similarly equates to the relative complexity of operations at foreign establishments. We therefore match the ranges of listings at foreign establishments to the employment size categories used for the U.S. analysis to provide a rough approximation of complexity of operations and, thereby, cost at foreign establishments. Although the number of employees at a foreign establishment may be more or less than these categories suggest, because the costs are assigned to U.S. establishments on the basis of presumed size of operations and complexity, not employment, this should not be a major issue.

In addition, although we have assumed that foreign establishments categorized by the number of listings can be matched to U.S. establishments categorized by the number of employees, costs will not necessarily be directly assigned by mapping U.S. establishment costs by size to the foreign establishments considered to be of similar size. This approach may be more valid for establishments in the Tier 1 countries, however, other methodologies will be considered for non-Tier 1 countries to account for potentially substantial differences in manufacturing processes in countries that may be much more labor intensive than U.S. operations.

In summary, for the purposes of developing an approach to assign costs that reflect the size and complexity of foreign establishments, we make the following assumptions:

- The U.S. export portion of an establishment can be considered an enterprise, even if the establishment manufactures these or other devices for domestic use or for export to non-U.S. markets.

- The complexity of the U.S. export enterprise generally increases as number of U.S. device listings increases.

- The complexity of enterprises based on number of listings is approximately equivalent to the complexity of U.S. establishments that manage a similar number of listings. However, specific circumstance, such as differing labor to capital ratios might apply, particularly in non-Tier 1 countries. Such circumstances might require some adjustments to costing assumptions.

- U.S. establishment employment sizes appear to be roughly correlated to the number of listings handled; for example, approximately 80 percent of U.S. establishments handle fewer than 10 device listings (as is true for foreign establishments), and approximately 80 percent of U.S. establishments employ fewer than 50 employees).

- Given these assumptions we assume the ranges of listings shown in Table 3-5 are equivalent to U.S. establishments by employment size in terms of complexity of operations.

Because these categories do not truly relate to numbers of employees for the purposes of this analysis, however, the listings size groups will continue to be used to describe the establishments in the foreign establishment cost analysis.

Finally, we assume that none of the foreign establishments produce only UPC-labeled devices or custom devices, and therefore assume no exceptions for these factors apply to any foreign establishments. Thus, we use the full number of foreign establishments in the smallest establishment size groups in the foreign cost analysis.

Table 3-5. Assumed Equivalence of Numbers of Listings at Foreign Initial Labeling Establishments to Size of Establishment as Defined for U.S. Establishments

Number of Listings per Establishment at Foreign Initial Labeling Establishments	Assumed Size of Enterprise Relative to U.S.-Based Establishment Sizes
1	1-4 employee size
2 – 3	5-9 employee size
4 – 5	10-19 employee size
6 – 10	20-49 employee size
11 – 25	50-99 employee size
26 – 50	100-249 employee size
51 – 100	250-499 employee size
101 or more	500+ employee size

ERG estimates.

3.1.4 Counts of R/Rs among Foreign Establishments

Foreign repackagers/relabelers (R/Rs) of medical devices will also be affected by UDI requirements. Table 3-6 presents a breakout of foreign R/R establishments, which is similar to Table 3-3 for initial labelers. The number of R/R establishments is much smaller than the number of initial labelers. Additionally, out of 320 such establishments, 250 (or 78 percent) relabel only Class I devices.

Table 3-6. Number of Foreign R/R Establishments by Number of Listings and Class of Devices (Class I Only vs. All Others)

Numbers of Listings	Tier 1 Countries				Other Countries				All Foreign R/Rs
	Class I Only		All Others	Total R/Rs	Class I Only		All Others	Total R/Rs	
1	31	31%	1	32	44	30%	6	50	82
2 – 3	24	24%	11	35	55	37%	9	64	99
4 – 5	26	26%	5	31	15	10%	5	20	51
6 – 10	4	4%	6	10	15	10%	5	20	30
11 – 25	5	5%	2	7	13	9%	3	16	23
26 – 50	5	5%	4	9	5	3%	2	7	16
51 – 100	5	5%	2	7	2	1%	4	6	13
101+	1	1%	3	4	0	0%	2	2	6
Total Establishments	101	75%	34	135	149	81%	36	185	320

Source: FDA, 2010.

3.1.5 Total Counts of All Foreign Labeling Establishments by Presumed Size of Establishment

Because there are very few foreign R/Rs and for analytical simplicity later in this report, Table 3-7 combines the counts of R/Rs by size and type of country with those for initial labelers. These establishment counts, by size, type of devices (i.e., whether subject to static or variable barcoding) and type of country will be used for cost estimating purposes in Section 4.6.

3.2 U.S. and Foreign Establishments with LS/LS Devices

3.2.1 U.S. Establishments

Because of the recently enacted FDASIA, FDA needed to identify LS/LS devices that will be subject to UDI requirements within two years of promulgation of the final UDI rule. These devices are predominantly Class II devices, so this means that for a subset of Class II devices, UDI must be

Table 3-7. Total Number of Foreign Labeling Establishments by Number of Listings, Country Tier, and Class of Devices (Class I Only vs. All Others)

	Tier 1 Countries					Other Countries					All Countries	
Numbers of Listings	**Class I Only**	**% of Estabs.**	**All Others**	**Total**	**% of All Estabs.**	**Class I Only**	**% of Estabs.**	**All Others**	**Total**	**% of All Estabs.**	**Total**	**% of All Estabs.**
1	648	41%	394	1,042	29%	617	26%	182	799	23%	1,841	26%
2 – 3	508	32%	531	1,039	29%	787	34%	230	1,017	29%	2,056	29%
4 – 5	163	10%	258	421	12%	282	12%	145	427	12%	848	12%
6 – 10	133	8%	310	443	12%	323	14%	225	548	16%	991	14%
11 – 25	77	5%	316	393	11%	224	10%	201	425	12%	818	12%
26 – 50	37	2%	127	164	5%	78	3%	84	162	5%	326	5%
51 – 100	11	1%	63	74	2%	19	1%	42	61	2%	135	2%
101 or more	8	1%	44	52	1%	6	0%	18	24	1%	76	1%
Total Establishments	1,585	44%	2,043	3,628	100%	2,336	207%	1,127	3,463	100%	7,091	100%

Source: FDA, 2010.

implemented in two years rather than three years. FDA created a file of applicable product codes (procodes), providing them to ERG to determine the number of establishments that might be subject to the expedited UDI requirements.[9] Previously, in the economic report for the proposed rule, ERG identified the proportion of establishments that handled Class I only devices, those that handled Class II devices or a mix of Class II and Class I devices, and those that handled any Class III devices using a 2010 version of FDA's Registration & Listing Database (ERG, 2012). The new designation of LS/LS devices was added to the previously developed table. This new table, which also uses the 2010 Registration & Listing database, continues to identify Class I only establishments, but separates the previously defined Class I & II establishments into those that handle Class I & II devices, but no LS/LS devices, and those that do label LS/LS devices.[10]

Table 3-8 presents the new breakouts of establishments by device class grouping. As the table shows, about 10 percent of all establishments not labeling Class III devices as well label at least one device considered LS/LS.

3.2.2 Foreign Establishments

Table 3-9 presents similar information to that of Table 3-8, except that it displays the results for foreign establishments. As the table shows, among all foreign labelers, proportionately more foreign establishments label only Class I devices than those among U.S. establishments, and a smaller percentage of foreign establishments label any LS/LS devices (about 7 percent vs. 10 percent of those in the U.S.).

[9] The list used may be reduced by several product codes prior to promulgation based on comments on the proposal.

[10] One R/R establishment, previously classified as labeling only Class I devices, relabels one LS/LS device that is classified as a Class I device. This establishment was placed with Class I & II establishments.

Table 3-8. Breakouts of U.S. Establishments by Class of Device Labeled

Type of Labeler	Class I Only (No LS/LS)		Class I & II Only (No LS/LS)		Class I & II (With LS/LS)		Any Class III (May Have LS/LS)		Total
	No. of Estabs.	Percent	No. of Estabs.	Percent	No. of Estabs.	Percent	No. of Estabs.	Percent	
Manufacturer	1,813	23.9%	2,193	28.9%	536	7.1%	359	4.7%	4,901
Reprocessor	8	0.1%	12	0.2%	1	0.0%	-	0.0%	21
Specification Developer	646	8.5%	475	6.3%	161	2.1%	64	0.8%	1,346
Repackager/Relabeler	828	10.9%	402	5.3%	59	0.8%	21	0.3%	1,310
All Labelers	3,295	43.5%	3,082	40.7%	757	10.0%	444	5.9%	7,578

Source: FDA, 2010.
Note: One Class I R/R moves to Class I&II (with LS/LS).

Table 3-9. Breakouts of Foreign Establishments by Class of Device Labeled

Type of Labeler	Class I Only (No LS/LS)		Class I & II Only (No LS/LS)		Class I & II Only (With LS/LS)		Any Class III (May Have LS/LS)		Total
	No. of Estabs.	Percent	No. of Estabs.	Percent	No. of Estabs.	Percent	No. of Estabs.	Percent	
Manufacturer	3,546	50.0%	2,284	32.2%	482	6.8%	180	2.5%	6,492
Reprocessor	3	0.0%	0	0.0%	0	0.0%	0	0.0%	3
Spec. Developer	122	1.7%	122	1.7%	27	0.4%	5	0.1%	276
Relabeler/Repackager	250	3.5%	54	0.8%	12	0.2%	4	0.1%	320
All Labelers	3,921	55.3%	2,460	34.7%	521	7.3%	189	2.7%	7,091

Source: FDA, 2010.
A few Class I only with Class I LS/LS devices were added to the Class I & II (with LS/LS).

4.0 COSTS OF THE FINAL RULE

4.1 Introduction

This section presents the costs of the final rule as well as the costs of two additional options that were considered but rejected by FDA. The first alternative option is a high-cost option and is equivalent to the variable barcoding option presented in Section 4 of the economic analysis of the proposed rule (ERG, 2012). The other alternative option is a low-cost option, discussed as the static barcoding alternative in ERG (2012). The selected option for the final rulemaking, is slightly different from the alternative analyzed in ERG (2012) labeled as the Class I static barcoding alternative (which was discussed briefly in Section 2 of this report), but is essentially the same in terms of allowing Class I devices to have barcodes that do not contain production information (e.g., lot numbers) placed on their labeling.

Costs are developed for initial labelers for the three options (high-cost, low-cost and selected options) in Section 4.2, then are developed for repackagers/relabelers (R/Rs) in Section 4.3. Total costs for U.S. industry are presented in Section 4.4. Costs for barcode issuing agencies are then addressed in Section 4.5. Section 4.6 presents costs to foreign labelers. Section 4.7 combines the costs to U.S. and foreign industry, and adds in the costs to barcode issuing agencies to estimate the total cost of the rule under an assumption that all costs are incurred in the first year after promulgation. Section 4.8 then arrays the costs to U.S. and foreign industry over time because many costs will not be borne by industry until later years, given the implementation schedule allowed by the final rule, and calculates the net present value and annualized costs using timing of investment assumptions. Finally, Section 4.9 presents a summary of costs to all entities under the selected option, comparing the immediate implementation scenario costs to those estimated using timing assumptions.

4.2 Initial Labelers

4.2.1 Overview

The following sections present each of the major cost categories for initial labelers discussed in the economic report for the proposed rule:

- Planning and Administrative Costs (Section 4.2.2)
- Barcode Registration Costs (Section 4.2.3)
- Equipment Costs (Section 4.2.4)
- Direct Marking Costs (Section 4.2.5)
- Label Revision Costs (Section 4.2.6)
- Software Costs (Section 4.2.7)
- GUDID Costs (Section 4.2.8)

In all these cost categories, inflation to 2012 dollars has been accounted for in the tables, except for a few items. ERG determined that wages for management occupations had actually declined slightly

from the previous 2009 wages (BLS, 2013a), but we did not change the dollar per hour for management (it remains at $75/hour, with fringe included). Labor wages for other job categories were checked using BLS data (2013a), and were also not changed because the wages for the categories used had declined very slightly in the interim. Given that all of these wage data were from 2011 and given the upturn in the economy, ERG determined that the best estimate of 2012 wages would be the wage data collected for 2009, so no wage data were changed. Equipment prices, such as those for scanners, printers, and verifiers, as well as those for direct marking lasers, also appeared to have declined slightly (Barcodesinc.com, 2013; Scanplanet.com, 2013), so we have also not changed equipment costs associated with barcoding labels or devices from those estimated in the economic report for the proposal. Costs for registering barcodes with HIBCC also have not changed (HIBCC, 2013). ERG used the producer price index data (BLS, 2013b) for a variety of associated NAICS (as indicated in table references) to update label material costs and software costs.

Changes to any costing methodologies due to regulatory changes or comments on the rulemaking are discussed in each of these cost subsections and such changes and any changes made to update to 2012 dollars are reflected in the summary tables in each cost subsection.

All costs are first discussed as they apply to an option that FDA investigated but rejected: an option that would have required all establishments[11] to apply a UDI that contains an establishment identifier, a device identifier, and a production identifier (e.g., a lot number), which, therefore, must change frequently, and is considered a variable barcode. We refer to this option as the high-cost option.

The next option discussed can be characterized as the static barcode requirement for all devices option, hereinafter called the low-cost option. This option requires only the establishment identifier and the device identifier be included in the barcode (production identifier is not required). The barcode, therefore, would not change through the life of the device and, thus, UDI requirements can be met with a one-time label revision. This is a simple option that does not incur costs in many of the cost categories that will be discussed below.

The last option discussed is FDA's selected regulatory option for the final rulemaking. In the selected option, devices that are not subject to Good Manufacturing Practices (GMPs) are not required to bear a UDI or submit information to the GUDID. Furthermore, only Class II and Class III devices must bear a variable barcode; Class I devices (and unclassified devices) can use a static barcode that does not include the production identifier. This option, thus, is a hybrid between the high-cost variable barcode for all devices and the low-cost static barcode for all devices options.

As was done in the economic analysis for the proposed rule (ERG, 2012), the costs in the following sections reflect an assumption that all affected establishments are faced with immediate

[11] Except those minimally affected because they supply custom devices—granting them an exception to UDI, or those that are essentially in compliance with most of the final rule, such as establishments producing only Class I devices with UPCs on the labels.

implementation in the first year. Section 4.8 presents the total costs of the rule distributed over the years in which implementation must occur, depending on Class of device or whether it is an LS/LS device.

4.2.2 Planning and Administrative Costs

4.2.2.1 High-Cost Option

The major changes to planning and administrative costs were made based on comments to the proposed rule. Several commenters noted that planning and implementation was going to be a major effort and involve much interdepartmental interaction. Additionally they raised issues about the short Class III implementation period of one year, which indicated a need to address some of the "scramble factor" that might entail more time to plan than initially thought. Because FDASIA added some further requirements for LS/LS devices, which will compress the time for planning and implementation for some additional establishments (notably, establishments handling only Class I and II devices that must now meet a 2-year instead of a 3-year implementation schedule), ERG is also accounting for a similar, but less intensive, factor for these establishments. Furthermore, given issues discussed in comments to the proposed rule that relate to placement of UDI on the lowest level of packaging due to size constraints or other issues, we have estimated time for a certain portion of establishments to request exceptions, allowing UDI to be placed on a higher level of packaging for some devices.

Previously (see Section 4.3.1.1 in the economic report for the proposed rule [ERG, 2012]), ERG had collected data indicating that a small facility (10-49 employees) might need 120 hours to plan and implement the rule requirements and then used factors for decreasing and increasing the time needed. ERG started over with a new approach, breaking out each major task, and accounting for additional interdepartmental communication needs throughout the planning and implementation stage.

First, ERG considers certain planning time factors that will not affect all establishments, but only a small proportion of establishments. These factors include time needed for exceptions and time needed to expedite UDI requirements for Class III and LS/LS devices. The section below discusses the impacts on certain establishments. Then, ERG addresses the planning time factors that all establishments will face. The hours needed by all establishments for these tasks are discussed in the subsequent section.

Additional Time for Certain Establishments to Meet UDI Requirements

ERG first considered the issue of requesting exceptions. ERG assumed that the identification of problematic devices, documenting the issue with the device, and communicating the issue to FDA will entail about 4 hours per device listing. We also assumed that an establishment with one listed device issue might have many other related listings with the same problem, but that many establishments might have no such problems. We assume 10 percent of establishments in each size category might need to request an exception for some of their listings. Thus, we developed a hypothetical profile of establishments by size having a certain number of affected listings. The numbers of listings considered affected relate generally to some subset of the numbers of listings presumed to be associated with each size of establishment (see Section 3, which discusses the range of device listings that might be associated

with size of establishment, either in the U.S. or in foreign countries). Table 4-1 shows, by establishment size, the numbers of affected listings, the number of hours per establishment, and the prorated numbers of hours per establishment, given the assumption that only 10 percent of establishments are affected. For affected establishments, time involved is estimated to total between 4 and 240 hours per affected establishment, depending on size, which is 0.4 to 24 hours per establishment prorated over all establishments.

ERG then considered what a reasonable factor for shortened implementation might be for Class III devices. With only a year to prepare, ERG considered that the first few months might require additional time from a regulatory affairs manager and manufacturing managers to quickly get things in motion. The numbers of managers involved in the additional effort is assumed dependent on the numbers of production lines. As the economic analysis report for the proposal indicated, we characterized the smallest two size categories as running one manual line per establishment. The next two size categories were assumed to employ 1 automated line. The 100-249 employees size was characterized as operating 2 to 3 automated production lines, with the 250-499 employee size establishments operating mostly 4 to 5 automated lines (some operating 6 or more), and the 500+ employee size establishments mostly operating 6 or more automated lines, with some operating 4 to 5 lines. Using these estimated numbers and types of lines from ERG (2012), we proceeded to estimate the level of effort needed to coordinate and plan the large effort to bring Class III devices and their production lines into compliance We assumed that at establishments with fewer than 50 employees, the burden falls on one manager, but that as the size of the operation increases and the number of lines increase, each line is assumed to have a manager, and communication among managers is necessitated, so the 50-99 employee size (with one line) has a regulatory affairs manager and a line manager in communication for a total of two persons needing time for expediting the process. In a similar manner, a 3-line operation will have four persons involved, a 5-line operation will have six persons involved, and an operation with more than 6 lines might have as many as 9 involved (on average) (see Table 4-1). The amount of time is expected to entail 50 percent of each person's time for a "kick-start" period of 4 weeks (80 hours per person), except for the two smallest size categories with manual lines. Because of the simpler operations in these two size categories, ¼ of the time is allotted to the establishments with 1-4 employees, and ½ the time is allotted to the establishments with 5-9 employees.

As is discussed in Section 3.2, about 6 percent of establishments have at least one Class III device listing. However, a number of exceptions apply (e.g., custom devices). When exceptions are accounted for, the percentage of non-excepted establishments that label Class III devices rises to 7 percent under the high-cost option.[12] The number of hours needed for expediting the shortened implementation period for Class III devices is prorated over the total number of establishments by multiplying the hours per establishment by 7 percent.

[12] This is discussed in more detail in Section 4.8.

Table 4-1. Hours Estimated for Exception Requests and for Meeting Expedited Deadlines for UDI Implementation

Establish-ment Size	Assumed Listings Requiring Exception	Hours Needed to Request Exception	Time for Exceptions over All Estabs. (Per Estab. Avg.)	Managers Required for Expediting	Class III Implementa-tion Factor	Time for Shortened Implementa-tion for Class III over All Estabs. (Per Estab. Avg.)	LS/LS Imple-mentation Factor	% of Estabs. with LS/LS	Time for Shortened Implement-ation for LS/LS Devices Over All Estabs. (Per Estab. Avg.)
1-4	1	4	0.4	1	20	1.5	10	1.2	2.7
5-9	1	4	0.4	1	40	2.9	20	2.5	5.4
10-49	3	12	1.2	1	80	5.8	40	5.0	10.8
50-99	6	24	2.4	2	160	11.7	80	9.9	21.6
100-249	15	60	6	4	320	23.3	160	19.9	43.2
250-499	30	120	12	6	480	35.0	240	29.8	64.8
500+	60	240	24	9	720	52.5	360	44.7	97.2

Source: ERG estimates.

Note: Distributions of LS/LS establishments and Class III establishments account for reduced numbers of other Class devices due to exceptions.

A similar factor was used for the LS/LS devices, but because the implementation schedule is not substantially shortened (a two-year implementation schedule is required), expediting the schedule is assumed to require half the time per affected establishment as the Class III expediting time (see Table 4-1). Thus, while a 1-4 employee size establishment might require 20 hours to expedite UDI on a Class III device, the same size establishment will require only 10 additional hours to expedite UDI on a Class II LS/LS device. About 12 percent of all establishments will be subject to the shortened LS/LS requirements (not including those already needing to meet Class III requirements, since it is assumed all devices in Class III or LS/LS will be expedited as a group at an establishment with both).[13] The hours needed to expedite per establishment are prorated over all establishments so that average per-establishment hours can be developed.

All per-establishment averages will be added to the time that all establishments will need to plan for UDI implementation, as discussed in the next section.

Planning and Administrative Time per Establishment at All Affected Establishments

As discussed in the economic report for the proposal, all affected establishments will need to perform certain tasks, including reading and understanding the rule, revising Standard Operating Practices documents (SOPs), and, generally, implementing the requirements. Previously, we estimated a small (10-99 employee establishment) will need 10 hours for reading and understanding, 30 hours for revising or writing SOPs, and 80 hours for implementation. Larger and smaller establishments had those hours adjusted upwards and downwards by a factor as discussed in the economic report for the proposal.

Upon review, ERG determined that given the complexity of the rule and the probable need to also review guidance documentation, that the hours estimated for reading and understanding the rule might be underestimated. We assume that 30 hours per person involved in planning will be needed to read and understand the rule initially, thus the total hours for this task in each establishment size depends on the number of managers expected to be involved in the planning process (see discussion above and Table 4-1). Table 4-2 repeats this number, but also presents an additional number of persons that the lead manager must also interact with, such as directors of IT, graphics managers, and engineering managers who will lead line retrofits. In the smallest facilities, one manager wears all of these hats, so no additional interactions must occur, and engineering production line changes are not an issue at manual lines. The reading and understanding task thus ranges from 30 hours to 270 hours, depending on size of the establishment. All managers are assigned a wage of $75/hour (which is unchanged from the economic report for the proposal—see previous discussion in Section 4.2.1).

Revising SOPs should roughly correspond to numbers of lines. For simplicity, the number of managers initially involved is used as a proxy for the numbers of lines, and the number of hours is

[13] As Table 3-8 shows, this number is 10 percent. However, as will be discussed in Section 4.8, when excepted establishments (custom device manufacturers) and UPC-only establishments are removed, the percentage rises to 12 percent.

Table 4-2. Hours and Costs Per Establishment for Planning and Administration under the High-Cost Option

Establish-ment Size	Number of Assumed Line & Other Managers	Number of Assumed Interactors (IT,Graphics, Line Engineering Mgrs.)	Read & Understand	Write or Revise SOPs	Planning & Implementation Communications				Additional Hours for Requests for Exceptions	Additional Hours for Shortened Implementa-tion	Total Hours	Total Cost per Estab.
					Line Modifica-tions	Label Redesign	IT Systems	GUDID				
1-4	1	0	30	20	0	0	0	0	0.4	2.7	53	$3,982
5-9	1	0	30	20	0	0	0	0	0.4	5.4	56	$4,185
10-49	1	1	30	40	40	40	80	40	1.2	10.8	282	$21,150
50-99	2	1	60	80	60	60	120	60	2.4	21.6	464	$34,800
100-249	4	3	120	160	140	140	280	140	6	43.2	1,029	$77,189
250-499	6	5	180	240	220	220	440	220	12	64.8	1,597	$119,759
500+	9	8	270	360	340	340	680	340	24	97.2	2,451	$183,838

Source: ERG estimates.

Costs for all hours are based on the median hourly wage rate for management occupations in NAICS 3391, $75/hour (BLS, 2009). Benefits are calculated at 29% of wages (BLS, 2010). Hourly wage rates do not vary substantially among the relevant NAICS; the wage rate for NAICS 3391 has been used for simplicity.

assumed to be 40 per revised SOP per line (including some time for all establishments to write new SOPs for GUDID tasks). Because of the simpler nature of manual lines, the two smallest establishment categories are adjusted downwards, with the 1-4 and 5-9 employee establishments assumed to require ½ of the time for the one SOP they are expected to revise or write. In this way, Table 4-2 shows that the time involved to revise SOPs ranges from 20 to 360 hours per establishment, depending on the size of the establishment.

The next item, "implementation time" is conceived of as the additional time needed for communications among all of the planning entities to make sure the UDI process is properly executed. There are four major areas in which communication must be maintained. These include engineered line modifications to place variable labeling equipment in-line, the label redesign process, the software acquisition and implementation process, and the GUDID process. Because the one manager (or likely, the owner) at the two smallest establishment sizes is undertaking all of the management tasks alone, no additional coordination/communication time is assumed at these establishments. Elsewhere, a total of 20 hours per manager involved (including IT, graphics, and engineering management personnel) is estimated to be needed for each of these planning areas, except for the software acquisition area, which is assigned 40 hours. Software is given additional hours to account for the fact that establishment personnel are either very involved in the purchase decision-making (smaller establishments that need software are often firm-facilities), or must coordinate with an owner firm or parent to ensure a seamless system across multiple facilities. Note that these hours for management involvement in all of these UDI implementing activities are additional to any hours estimated for installation or other activities in each of the cost categories.

Table 4-2 then adds the prorated hours for the exceptions and schedule expediting calculated in Table 4-1 to the hours needed for each affected establishment. The total hours for all tasks per establishment are then shown. These hours range from 53 hours at the smallest establishments to 2,451 hours at the largest establishments, costing between about $4,000 to $184,000 per establishment.

No other time assumptions are changed from those described in Section 4.3.1.1 in the economic report for the proposed rule (ERG, 2012). In the economic report for the proposal, we estimated that 2.5 hours will be needed for establishments that must meet only minimal requirements, i.e., those who label devices bearing UPCs or that handle custom devices, to read and understand the rule up to the point that they realize they are excluded, or that they only need to be concerned with the GUDID (additional time for implementing GUDID requirements for what are called "UPC establishments" is estimated in the GUDID cost category in Section 4.2.8, for simplicity). We have left this time for reading and understanding the rule unchanged for these two types of establishments.

We also have not changed our assumptions about current practices for variable barcoding. The same number of establishments by size is assumed to already use variable barcoding as that assumed in ERG (2012). Although the number of establishments using variable barcoding may have increased, we lack data on how these numbers may have changed. For more information on these variable barcoding assumptions, see ERG (2012). As before, those establishments assumed to use variable barcoding (larger

establishments) were expected to incur 5 to 30 hours, depending on size, to confirm that they were already in compliance with most of the requirements under this option.

Overall Cost Summary for the High-Cost Option

Table 4-3 is a revised version of Table 4-2 in ERG (2012). It incorporates all of the additional hours and dollars shown in Table 4-2 (in the current report), using the basic methodology explained in ERG (2012). As the table shows, the total one-time cost of planning and administration for all medical device establishments is $124.7 million.

4.2.2.2 The Low-Cost Option

In the low cost option, many cost categories do not apply. It becomes mostly a label redesign project. Nearly all categories of hours are expected to be reduced and the number of managers involved decreases significantly. One manager is expected to be able to handle the transition, with some coordination with a graphics manager in the larger establishment sizes. Reading and understanding the rule is allotted half the time (15 hours) of that for understanding the rule relative to variable barcoding (less guidance material is likely to be read in the static barcode scenario). SOPs do not need to be revised because the lines do not need to be changed in any way, but SOPs for GUDID tasks will need to be written (4 hours are allotted). Planning and implementing time and coordination will only involve label redesign, which is expected to be simpler because less space might be needed, and GUDID setup time. The simpler redesign process implementation is assumed to take half the time of the variable barcode scenario (10 hours per manager), but the GUDID planning time remains unchanged. Because of the much simpler process involved, no expediting time is estimated to be needed. There may be a reduction in time needed for exceptions, as well, but this is not estimated. As in the high-cost option, the smallest establishments are assumed to require no additional coordination time among the various additional managers because one manager is assumed to handle all the management tasks. Table 4-4 shows the results of these assumptions in a table similar to Table 4-2. Costs per establishment are expected to range from $1,500 to $7,700 per establishment.

The overall cost for planning and administration under the low-cost option is shown in Table 4-5. This table also incorporates an assumption that a larger portion of establishments across all sizes of establishment are in compliance already with UDI labeling requirements under the low-cost option as compared to the portion assumed to be in compliance with UDI labeling requirements under the high-cost option. This larger proportion considered in compliance results from an assumption that many establishments might already label with either a static or variable barcodes under the low-cost option. As this table shows, the costs are much reduced from the high-cost option, totaling $13.8 million in first-year costs.

4.2.2.3 The Selected Option

The cost estimate for the selected option (variable barcodes, with production identifiers, for Class II and Class III devices, with static barcodes, without production identifiers, for Class I devices) starts with the high cost option then adjusts planning and administrative costs downwards to account for Class I

Table 4-3. Aggregate Cost of Planning and Administration, High Cost Option

Establish-ment Type	Number of Establishments, by Size Class								Establishment First-Year Costs, by Size Class							Aggregate Costs
	1-4	5-9	10-49	50-99	100-249	250-499	500+	Total	1-4	5-9	10-49	50-99	100-249	250-499	500+	
325413	10	19	71	23	23	17	10	174	$44,090	$82,018	$1,501,954	$773,471	$1,565,948	$1,767,061	$1,533,099	$7,267,641
334510	44	37	151	49	57	36	23	397	$198,320	$158,111	$3,194,178	$1,635,499	$3,938,690	$3,668,502	$3,448,018	$16,241,318
334517	12	12	45	20	8	6	6	108	$51,713	$53,280	$954,366	$651,330	$570,576	$585,908	$847,221	$3,714,393
339112	81	98	311	104	119	51	34	797	$362,094	$421,229	$6,584,913	$3,423,664	$8,251,422	$5,236,693	$4,965,404	$29,245,419
339113	165	189	527	155	119	60	28	1,244	$741,907	$813,480	$11,151,674	$5,125,282	$8,309,540	$6,134,194	$4,093,858	$36,369,935
339114	72	97	145	30	18	7	2	370	$324,217	$415,125	$3,057,872	$983,074	$1,228,940	$737,511	$236,986	$6,983,725
339115	56	48	143	39	26	8	8	327	$253,589	$204,610	$3,020,891	$1,278,444	$1,811,379	$771,450	$1,115,514	$8,455,877
Spec. Dev.	722	210	330	51	25	6	3	1,346	$2,875,466	$878,798	$6,972,159	$1,770,524	$1,907,811	$678,558	$561,539	$15,644,855
Reproc.	-	11	2	2	2	4	-	21	$0	$46,034	$42,300	$69,599	$154,378	$479,035	$0	$791,345
Total, All NAICS	1,162	721	1,725	472	396	195	113	4,784	$4,851,397	$3,072,685	$36,480,306	$15,710,887	$27,738,684	$20,058,910	$16,801,638	$124,714,509

Source: ERG estimates. See ERG 2012.

Note: Numbers of establishments exclude 1,379 labelers that meet exceptions for all their devices (i.e., ERG assumes that 70 percent of establishments in the 1-4 size class and 30 percent of the 5-9 size class meet exceptions because they manufacture custom devices only). Additionally, 10 percent of the remaining manufacturers, 104 establishments, in these size groups are assumed to use UPCs and are considered already in compliance with UDI labeling requirements and are excluded from the number of establishments (additional hours for GUDID planning tasks for UPC establishments are estimated in Section 4.2.8). The costs for all of these establishments to read and understand the rule, however, are included in the aggregate costs.

Table 4-4. First-Year Administrative and Planning Costs per Establishment, Low-Cost Option, by Employee Size Class and Number of Managers

Establish-ment Size	Number of Assumed Managers	Number of Assumed Interactors, Graphics	Read & Understand	Write New SOP	Plan & Implement				Requests for Exceptions	Factor for Shortened Implementa-tion	Total Hours	Total Cost per Establishment
					Line Modifica-tions	Label Redesign	IT Systems	GUDID				
1-4	1	0	15	4	0	0	0	0	0.4	0	19.4	$1,455
5-9	1	0	15	4	0	0	0	0	0.4	0	19.4	$1,455
10-49	1	0	15	4	0	10	0	20	1.2	0	50.2	$3,765
50-99	1	0	15	4	0	10	0	20	2.4	0	51.4	$3,855
100-249	1	1	15	4	0	20	0	40	6	0	85	$6,375
250-499	1	1	15	4	0	20	0	40	12	0	91	$6,825
500+	1	1	15	4	0	20	0	40	24	0	103	$7,725

Source: ERG estimates.

Table 4-5. Aggregate Cost of UDI Plan Development Under the Low-Cost Option

Establish-ment Type	Number of Establishments, by Size Class								Establishment First-Year Costs, by Size Class							Aggregate Costs
	1-4	5-9	10-49	50-99	100-249	250-499	500+	Total	1-4	5-9	10-49	50-99	100-249	250-499	500+	
325413	10	19	71	23	23	17	10	174	$18,646	$28,678	$255,335	$82,004	$105,548	$62,874	$31,918	$585,003
334510	44	37	151	49	57	36	23	397	$83,870	$55,283	$543,016	$173,397	$265,476	$130,530	$71,785	$1,323,358
334517	12	12	45	20	8	6	6	108	$21,870	$18,629	$162,244	$69,055	$38,458	$20,847	$17,638	$348,741
339112	81	98	311	104	119	51	34	797	$153,130	$147,282	$1,119,447	$362,981	$556,164	$186,328	$103,376	$2,628,709
339113	165	189	527	155	119	60	28	1,244	$313,754	$284,433	$1,895,805	$543,388	$560,082	$218,263	$85,231	$3,900,954
339114	72	97	145	30	18	7	2	370	$137,112	$145,148	$519,844	$104,227	$82,833	$26,242	$4,934	$1,020,339
339115	56	48	143	39	26	8	8	327	$29,165	$71,542	$513,557	$135,542	$122,091	$27,449	$23,224	$922,570
Spec. Dev.	722	210	330	51	25	6	3	1,346	$1,050,562	$305,540	$1,241,157	$196,134	$157,565	$38,671	$23,596	$3,013,225
Reproc.	-	11	2	2	2	4	-	21	$0	$16,005	$7,530	$7,710	$12,750	$27,300	$0	$71,295
Total, All NAICS	1,162	721	1,725	472	396	195	113	4,784	$1,808,108	$1,072,540	$6,257,935	$1,674,438	$1,900,968	$738,505	$361,702	$13,814,195

Source: ERG estimates. See ERG 2012.

Note: numbers of establishments reflect numbers of non-exempt manufacturers (i.e., ERG assumes that 70 percent of establishments in the 1-4 size class and 30 percent of the 5-9 size class are exempted because they manufacture custom devices). Additionally, 10 percent of the remaining manufacturers in these size groups are assumed to use UPCs and are considered to need minimal time to plan. Additional time for these UPC establishments to plan for GUDID tasks is presented in Section 4.2.8.

only establishments that will face only the costs associated with static barcode planning. The total number of establishments that will save planning time and costs under the selected option remain unchanged from those estimated to save time and costs in ERG (2012). See Table 6-25 in this previous report for counts of Class I only and GMP-exempt establishments that are estimated to experience cost savings relative to the high-cost option. Table 4-6 shows the first-year cost savings from the high cost option, the annualized cost savings, and the total first-year cost of the selected option. This total first-year cost is $81.7 million, for a $43.0 million cost savings over the high-cost option.

Table 4-6. Initial Labelers: Estimated Cost Savings Associated with Administrative & Planning Expenditures under the Selected Option (Includes Savings from GMP-Exempt Device Exclusion)

Est. Size	Number Estabs. with Savings	First Year Incre-mental Cost/ Estab.	Total First Year Savings	Recur-ring Incre-mental Costs/ Estab.	Total Annual-ized Incre-mental Costs/ Estab.	Total Annualized Savings on Admin. & Planning	First-Year Cost under High-Cost Option	Total First-Year Cost of Planning & Administra-tion under the Selected Option
1-4	457	$2,527	$1,156,088	NA	$360	$164,601	$4,851,397	$3,695,309
5-9	284	$2,730	$774,756	NA	$389	$110,308	$3,072,685	$2,297,929
10-49	679	$17,385	$11,802,172	NA	$2,475	$1,680,364	$36,480,306	$24,678,134
50-99	178	$30,945	$5,495,839	NA	$4,406	$782,484	$15,710,887	$10,215,048
100-249	141	$70,814	$10,005,897	NA	$10,082	$1,424,615	$27,738,684	$17,732,787
250-499	66	$112,934	$7,429,515	NA	$16,079	$1,057,796	$20,058,910	$12,629,395
500+	36	$176,113	$6,316,340	NA	$25,075	$899,305	$16,801,638	$10,485,298
Total	1,841		$42,980,608			$6,119,472	$124,714,509	$81,733,900

Source: See ERG, 2012, Section Six.

4.2.3 Barcode Registration Costs

Barcode registration costs and assumptions remain unchanged from the economic report for the proposal (ERG, 2012) for the low-cost and high-cost options. Although several commenters noted that the GTIN Sunrise should reduce the number of registrants, ERG had already assumed nearly all initial labelers are registered either with GS1 or HIBCC, even if they do not yet have their barcodes printed on labels. Table 4-7 repeats the barcode registration costs that were reported in ERG (2012) for the high-cost option. The total cost under the low-cost and high cost options is $0.6 million in the first year. The selected option, however, saves about $30,000 dollars in first-year costs because of the GMP-exempt exception (see Table 4-8). Thus, the total first-year cost for the selected option remains approximately $548,000.

Table 4-7. Costs for Barcode Registration

Firm Size	Adjusted Number of Firms	Cost per Firm To Register	Aggregate Costs to Register
Small	397	$500	$198,300
Medium	76	$4,000	$304,153
Large	4	$20,000	$75,794
Total	476		$578,246

Source: Hankin, 2010; HIBCC, 2013; ERG, 2012.

Table 4-8. Initial Labelers: Estimated Cost Savings Associated with Barcode Registration under the Selected Option

Est. Size	Number GMP-Exempt	% Assumed to Be Registered	Number Assumed without Registration	Cost of Registra-tion	Total First Year Cost Savings	Annualized Cost Savings for Registration
1-4	102	85%	15	$500	$7,648	$1,089
5-9	63	85%	9	$500	$4,745	$676
10-49	151	90%	15	$500	$7,568	$1,077
50-99	40	95%	2	$500	$990	$141
100-249	32	95%	2	$4,000	$6,300	$897
250-499	15	95%	1	$4,000	$2,933	$418
500+	8	99%	0	NA	$0	$0
Total	410		44		$30,185	$4,298

Source: See ERG, 2012.

4.2.4 Equipment Costs

Equipment costs are those for printers, verifiers, and scanners capable of handling the demands of a variable barcode. Costs for operating that equipment are also estimated. The methodology for assigning costs is described in Section 4.3.1.3 in the economic report for the proposal (ERG, 2012).

4.2.4.1 High Cost Option

The wage rates assumed for additional hours for quality control inspections declined very slightly in the intervening years, but ERG is assuming no decline in those wages. Equipment costs, as noted earlier, also declined, but ERG is not assuming a decline in these costs either. ERG is also not changing any of the assumptions used in ERG (2012). Thus, the cost estimate for equipment under the high cost option remains unchanged and is repeated here as Table 4-9. The total cost first-year cost is $71.5 million. Recurring costs for operating the equipment and verifying barcodes are $36.5 million per year.

Table 4-9. Equipment Investments for UDI Requirements

Establishments, by Baseline Label Printing System	Manual Lines (% Establish-ments)	Automated Lines (% Establish-ments) (b)	Equipment Costs, by Number of Production Lines (a)					Total
			Manual	Automated				
			1 line	1 line	2-3 lines	4-5 lines	6+ lines	
Number of establishments, by assumed number of prod. lines			1,883	2,176	359	148	110	4,677
Per establishment costs to install full on-line label printing system			NA	$43,594	$46,813	$93,625	$119,438	
Per establishment cost to install supplemental label system			NA	$21,094	$21,094	$24,063	$31,719	
Per establishment FTEs to operate verifiers			0	0.15	0.30	0.60	1.00	
Per establishment cost to operate verifiers (c)			$0	$6,947	$13,894	$27,787	$46,312	
Per establishment costs to print labels--manual lines			$450	NA	NA	NA	NA	
Establishments using outside label printers	**40%**	**40%**						
Switch to new outside label printer, add lot #s (10% of 40%) (d)	NA	4%	NA	NA	NA	NA	NA	NA
Move entire label operation in-house (2% of 40%)	NA	1%	NA	$758,914	$134,446	$110,958	$105,229	$1,109,547
Add small supplemental label, applied in-house (88% of 40%)	NA	35%	NA	$16,157,528	$2,665,586	$1,254,753	$1,229,599	$21,307,466
Man. line: switch to new outside label printer, add lot #s (20% of 40%)	8%	NA	NA(d)	NA	NA	NA	NA	NA
Man. line: move entire label operation in-house (75% of 40%)	30%	NA	$254,238	NA	NA	NA	NA	$254,238
Man. line: add small supplemental label, applied in-house (5% of 40%)	2%	NA	$16,949	NA	NA	NA	NA	$16,949
Establishments printing labels in-house with printing systems that do not accommodate variable information	**0%**	**45%**						
Modify entire label printing operation (60% of 45%)	0%	27%	$0	$25,613,354	$4,537,554	$3,744,816	$3,551,480	$37,447,204
Add small supplemental label, applied in-house (40% of 45%)	0%	18%	$0	$8,262,372	$1,363,084	$641,635	$628,772	$10,895,863
Establishments w/label printing systems accommodating var. data	**60%**	**15%**						
Modify label with existing printing equipment (100% of 15%)	NA	15%	$0	NA	NA	NA	NA	NA
Man. line: modify label w/existing equipment (100% of 60%)	60%	NA	$508,476	NA	NA	NA	NA	$508,476
Total Investment								$71,539,744
Total labor for operating verifiers			$0	$15,116,928	$4,987,826	$4,116,423	$5,100,335	$29,321,512
Total O&M (10 percent of equipment cost) plus Labor								$36,475,487

(a) See ERG, 2012. Numbers of establishments are from Table 4-3, adjusted for the 3 percent of manufacturers who are assumed to be printing variable barcodes at the present time. These counts exclude small manufacturers assumed to be manufacturing custom devices or who are assumed to be using UPCs exclusively

(b) See assumptions discussed in ERG, 2012.

(c) Assumes a wage rate plus 29 percent fringe of $22.27 per hour (BLS, 2009) for inspectors in NAICS 339 for the number of FTEs noted in the line above.

(d) Incremental costs for outside printer labels assumed primarily costs of coordination, which is passed through to labelers. See labeling costs, below.

4.2.4.1 Low Cost Option

No equipment costs are incurred under the low-cost option because the option is basically a relabeling option.

4.2.4.2 Selected Option

Under this option, the establishments handling only Class I devices and those that handle only GMP-exempt devices are assumed not to incur any equipment costs. Table 4-10 presents the cost savings to these establishments, based on the assumptions and calculations explained in ERG (2012). These establishments save a total of $28.2 million in the first year and $14.4 million in recurring years. It is difficult to array the costs by size of establishment presented in Table 4-9, so we compute only the total first-year and recurring year costs based on the difference between these totals and the totals shown in Table 4-9. The total first-year costs for the selected option are computed to be $43.4 million and the total recurring costs for the selected option are computed to be $22.1 million.

4.2.5 Direct Marking

Direct marking of implants will no longer be required under any of the three scenarios; however, under all three scenarios the cost of marking multi-use devices will be required. All assumptions for multi-use device direct marking remain the same as those discussed in the economic report for the proposal (ERG, 2012). ERG investigated a PPI for the types of lasers used for markings and determined that the index had dropped very slightly. Therefore, we continue to assume that the costs of laser equipment have not changed since our initial data gathering as reported in ERG (2012). Also remaining the same is the assumption that costs for marking software (digitally) will be negligible. Because virtually all multi-use devices are Class I devices, ERG assumes, also as previously assumed, that no costs will be incurred for 510(k) or PMA-related changes. ERG also continues to assume that a small portion of multi-use devices might need an exception due to size or shape limitations. Because the rule now applies to devices that are reprocessed (rather than sterilized), more devices might need marking. FDA, however, was unable to provide ERG a list of additional devices that might be affected, so an estimate of the effect of this word change was not possible. ERG discusses this issue in Section 7, Uncertainty.

Table 4-11 presents the estimated one-time costs ($118,000) and recurring year costs ($29,000) for requesting exceptions. These costs have not changed from those reported in ERG (2012), although the costs may be less than those estimated here because FDA is no longer requiring notification for certain exceptions (e.g., if marking interferes with safety and effectiveness or if marking is technologically impossible); the documentation must only be placed in the device history file. Next, Table 4-12 presents the first-year costs for upgrading lasers at establishments currently assumed to mark devices to enable the lasers to etch barcodes into the devices ($3.7 million). Table 4-13 then presents the total first-year costs and recurring year costs for direct marking of multi-use devices. First-year costs total $11.1 million and recurring year costs total $1.1 million. These costs apply under all options discussed in this report and have not changed from those reported in ERG (2012).

Table 4-10. Initial Labelers: Estimated Cost Savings Associated with Equipment Expenditures under the Selected Option

Est. Size	Number Estabs. with Savings	First Year Incre-mental Cost/ Estab.	Total First Year Savings	Recur-ring Incre-mental Costs/ Estab.	Total Recurring Costs	Total Annual-ized Incre-mental Costs/ Estab.	Total Savings on Equipment
1-4	457	$414	$189,369	$41	$18,937	$100	$45,899
5-9	284	$414	$117,495	$41	$11,750	$100	$28,478
10-49	679	$23,341	$15,845,693	$9,281	$6,300,616	$12,604	$8,556,686
50-99	178	$23,341	$4,145,417	$9,281	$1,648,314	$12,604	$2,238,528
100-249	141	$24,236	$3,424,466	$16,317	$2,305,587	$19,768	$2,793,154
250-499	66	$41,641	$2,739,435	$36,583	$2,406,640	$42,511	$2,796,674
500+	36	$47,266	$1,695,199	$46,407	$1,664,415	$53,137	$1,905,773
Total	1,841		$28,157,075		$14,356,258		$18,365,192

Source: Per-establishment averages are taken from Table 4-9.

Table 4-11. Costs for Establishments to Document Exceptions to the Direct Part Marking Requirements

Establish-ment Size	Estimated Estab. with Multi-Use Items	Number of Multi-Use Estab. Document-ing Exception	Assumed Products per Estabs. Affected	Cost per Estab. (a)	Total First Year Costs for Multi-Use Estabs.	New Products	Recurring Costs per Estab. (a)	Aggregate Recurring Costs
1-4	94	5	1	$750	$3,528	0.3	$188	$882
5-9	67	3	1	$750	$2,504	0.3	$188	$626
10-49	188	9	2	$1,500	$14,095	1	$375	$3,524
50-99	58	3	4	$3,000	$8,743	1	$750	$2,186
100-249	64	3	10	$7,500	$24,157	3	$1,875	$6,039
250-499	28	1	30	$22,500	$30,950	8	$5,625	$7,737
500+	18	1	50	$37,500	$33,737	13	$9,375	$8,434
Total	517	26			$117,714			$29,428

(a) Assuming 10 hours per exception at a fully loaded wage rate of $75.
Source: ERG estimates. See ERG. 2012.

Table 4-12. Cost of Software Upgrades for Establishments Already Marking on Devices

Estab. Size	Total Number of Multi-Use Item Estabs.	Assumed Baseline Com-pliance Multi-Use Items	Aggregate Cost of Software Upgrade (a)	Per Estab. Cost of Redesign to Include Barcode (b)	Aggregate Cost of Redesign	Total Cost for Estabs. Already Marking
1-4	94	75%	$33,873	$1,250	$70,568	$104,441
5-9	67	75%	$24,037	$2,500	$100,154	$124,190
10-49	188	75%	$67,655	$5,000	$563,791	$631,446
50-99	58	75%	$20,983	$10,000	$349,720	$370,704
100-249	64	75%	$23,191	$20,000	$773,035	$796,226
250-499	28	75%	$9,904	$50,000	$825,328	$835,232
500+	18	75%	$6,477	$75,000	$809,677	$816,154
Total	517		$186,120		$3,492,272	$3,678,392

Source: Table 4-11 and ERG estimates. See ERG, 2012.

(a) Design changes and software upgrades to allow barcodes to be printed are estimated to cost $600 among the 80 percent of establishments with DM equipment not currently capable of barcoding.

(b) Redesign costs are assumed the same as redesign costs for main label (see ERG, 2012).

Table 4-13. Costs to Install and Operate Marking Equipment for Establishments Not Currently Marking Devices

Estab. Size	Total Number of Multi-Use Item Estabs.	Multi-Use Item Estab. Needing Equipment (a)	Assumed No. of Lines (b)	Capital Cost plus Installation for YAGs/High Speed Lasers per Estab. by Size (c)	Capital Cost plus Installation Assuming CO_2 Lasers	One Time Costs for Multi-Use Items (d)	Total O&M Costs (e)
1-4	94	19	1	$96,250	$21,000	$451,635	$45,163
5-9	67	13	1	$96,250	$21,000	$320,491	$32,049
10-49	188	38	1	$96,250	$21,000	$902,065	$90,207
50-99	58	12	1	$96,250	$21,000	$279,776	$27,978
100-249	64	13	2	$192,500	NA	$2,557,456	$255,746
250-499	28	6	4-6+	$640,938	NA	$3,600,837	$360,084
500+	18	4	4-6+	$820,313	NA	$3,011,323	$301,132
Total	517	103				$11,123,585	$1,112,359

(a) Subtracts those applying for exceptions as calculated in Table 4-11 and assumes a 75 percent baseline compliance rate among multi-use device establishments.

(b) Assumptions about numbers of lines are the same as those used in Table 4-9.

(c) Includes engineering costs assumed at 75% of capital expenditures. Also assumes that two largest sizes install 1-2 fully automated lasers at $150,000 per laser. Only smaller operations are assumed to use CO_2 lasers due to high cost of materials.

(f) O&M assumed at 10 percent of one-time costs.

Source: ERG estimates and discussions with vendors (see ERG, 2012).

4.2.6 Label Redesign

4.2.6.1 High-Cost Option

No changes were made to any of the assumptions used to estimate the high-cost option at proposal for either the cost of redesign or the cost of label materials and printer coordination time. Costs of labeling materials were inflated by the PPI of NAICS 322121, converted paper products. No other updates were made. Costs to redesign for both the date format change and the UDI are included in the costs of redesign; even if the date, which now must be ISO compliant, is already in compliance, no cost savings are assumed. The total one-time cost of label redesign is $43.0 million (see Table 4-14). The total recurring costs are associated with label materials and printer coordination. These recurring costs are $9.4 million (see Table 4-15).

Additionally, ERG undertook a new analysis based on changes that might be necessitated by the date format change. Certain device manufacturers may be using date stamps on their packaging (the metal stamps that emboss an expiration date, e.g., into the device packaging). ERG assumes that many establishments, once required to print variable information labels, might include a date in their labeling, instead of continuing to use date stamps. Additionally, some establishments might currently be in compliance because they export some of their devices to, e.g., the EU. However, a certain number of

Table 4-14. Derivation of Incremental Device Labeling Redesign Cost, Per Establishment and in Aggregate under the High-Cost Option

Employment Size	Number of Establishments	Costs Per Establishment	Aggregate Costs
1-4	1,211	$1,250	$1,513,842
5-9	777	$2,500	$1,941,599
10-49	1,725	$5,000	$8,624,279
50-99	472	$10,000	$4,722,088
100-249	396	$20,000	$7,918,441
250-499	195	$50,000	$9,746,853
500+	113	$75,000	$8,485,628
Total	4,889	-	$42,952,729

Source: Estimated by ERG. No establishments are assumed to be presenting label information in the precise format required by the rule. Although some manufacturers might print variable barcodes, the new date format requirement is assumed to require some of these to need to redo labels. The number affected is not known, so all establishments except custom manufacturers are assumed affected (those labeling UPCs are also assumed to be affected by the date format change).

Table 4-15. Derivation of Incremental Device Labeling Materials Cost, Per Establishment and Aggregate

Employ-ment Size	Number of Estabs. (a)	Estimated Materials, Parts Container Costs by Estab. Size	Assumed Cost Share for Labels	Baseline Label Material Cost	Incremental Annual Label Cost (Materials)					Coordination with Outside Printer (c)			Aggregate Cost (Time & Materials (b)
					Percent	Amount	Per Estab.	Aff. Estabs.	Total Cost	Hrs.	Cost	Aff. Estabs.	
1-9	1,883	$439,100,484	0.2%	$878,201	10%	$87,820	$47	1,883	$87,820	50	$3,750	151	$751,664
10-49	1,725	$2,188,233,794	0.2%	$4,376,468	10%	$437,647	$254	1,725	$437,647	100	$7,500	86	$1,084,468
50-99	451	$2,253,835,296	0.2%	$4,507,671	10%	$450,767	$999	451	$450,767	200	$15,000	18	$721,512
100-249	359	$6,500,381,977	0.2%	$13,000,764	10%	$1,300,076	$3,621	359	$1,300,076	800	$60,000	11	$1,946,279
250-499	167	$4,918,738,602	0.2%	$9,837,477	10%	$983,748	$5,886	167	$983,748	1,200	$90,000	5	$1,435,043
Over 500	91	$17,111,014,996	0.2%	$34,222,030	10%	$3,422,203	$37,555	91	$3,422,203	2,400	$180,000	0	$3,422,203
Total	4,677	$33,411,305,148	-	$66,822,610	-	-	-	4,677	$6,682,261	-	-	271	$9,361,169

(a) Includes all establishments except those currently assumed to be using variable barcodes and custom and UPC establishments in the 1-9 employment size category.
(b) Assumes a wage rate of $75/hour for a print shop manager and a medical device manager to coordinate (each require the same number of hours for coordination, so hours of coordination time are multiplied by two). Hours are multiplied by two to account for outside label price increases due to an assumed cost pass-through from printers to account for coordination at the printing shop
(c) Includes costs for 2 percent of establishments with 1-9 employees (38 establishments–not including UPC establishments) to add a supplemental label at a cost of $2,625 per year (see ERG, 2012).
Source: For establishments and materials, parts, and container costs, U.S. Census Bureau, 2010. For distributions by establishment size, see Table 4-3. All other estimates and calculations prepared by ERG. See ERG, 2012.

establishments might not take this approach and do not currently meet the date stamp format requirements. After conversing with one manufacturer of date stamp dies (Manufacturer of Date Stamp Dies, 2013) and observing prices in internet searches, ERG determined that date stamp dies might cost in the range of $50 to $150. We take the mid-point of this estimate ($100) and add a 50 percent factor for installation, order time, etc. to create an estimate of $150 per line. Assuming that this affects a relatively small number of establishments after variable printing capabilities are addressed, we have further assumed that 10 percent of establishments might need to change their date stamp dies. Table 4-16 presents the results of this analysis. According to our estimates, the aggregate costs to establishments needing to replace date stamp dies are modest, totaling $102,000 in first-year costs. In this table, the potentially affected are the percentages of establishments currently assumed not to be using variable barcoding. The number assumed affected represents 10 percent of these assumed potentially affected establishments. ERG believes this assumption overstates the number of affected establishments when virtually all establishments in the high-cost option will be printing variable labels.

4.2.6.1 Low-Cost Option

In the low-cost option, all labels are assumed to be redesigned due to the date format change, even if a static barcode already appears on the label. Thus, the one-time cost for label redesign shown in Table 4-14) are incurred under the low-cost option as well ($43.0 million in the first year). Materials costs are assumed for labelers not already printing static barcodes, but additional costs such as costs for supplemental labels and coordination with outside printers are avoided under the static barcode alternative. The label materials costs are shown in Table 4-17 and total $3.2 million per year. For date stamp costs under this option, ERG believes the 10 percent of affected establishment estimate is reasonable, thus, we do not increase the estimate of affected establishments for the low-cost option. This cost remains $102,000 in the first year.

4.2.6.2 The Selected Option

Initial labelers are all assumed to redesign their labels, so the one-time cost of label redesign as shown in Table 4-14 apply ($43.0 million). ERG does not calculate the small cost savings accruing to establishments that handle only GMP exempt devices, (which although subject to date format revisions, do not require significant design changes) so this may slightly overstate the one-time costs of label redesign. For costs savings on materials and printer coordination time, Table 4-18 shows the costs savings that might be realized for the establishments that only handle Class I devices or GMP-exempt devices. These savings are due to coordination time savings for the Class I device only establishments and both coordination time and label materials costs saved by the establishments with GMP-exempt devices, which will not be required to label with a UDI. As the table shows, the selected option saves the Class I and GMP-exempt only establishments $1.6 million. Thus, the recurring costs under the selected option for label materials are $7.8 million. As we did for the low-cost option, we assume the date stamp costs remain unchanged under this option ($102,000 in first-year costs).

Table 4-16. Costs for Certain Establishments to Change Date Stamp Dies to Comply with the High-Cost Option

Employment Size of Estabs.	Number of Estabs.	Assumed Potentially Affected	Number Assumed Affected	# Lines	Cost of New Die	Total Cost of Dies per Estab.	Aggregate First-Year Cost
1-4	1,211	100%	121	1	$150	$150	$18,166
5-9	777	100%	78	1	$150	$150	$11,650
10-49	1,725	100%	172	1	$150	$150	$25,873
50-99	472	95%	45	1	$150	$150	$6,729
100-249	396	90%	36	3	$150	$450	$16,035
250-499	195	85%	17	5	$150	$750	$12,427
500+	113	80%	9	8	$150	$1,200	$10,862
Total	4,889		477				$101,741

Source: Manufacturer of Date Stamp Dies, 2013, and ERG estimates.

Table 4-17. Incremental Costs of Label Material under the Low-Cost Option

Employ-ment Size	Incremental Annual Label Cost (Materials)		
	Per-Establishment Costs	No. of Affected Establishments	Total Cost
1-9	$47	1,836	$85,628
10-49	$254	1,655	$419,972
50-99	$999	430	$429,823
100-249	$3,621	285	$1,032,670
250-499	$5,886	84	$493,058
Over 500	$37,555	20	$734,868
Total		4,310	$3,196,019

(a) Includes only establishments not currently applying a static barcode to labels and those labeling with UPCs and excludes establishments associated with custom devices.
Source: Costs per establishment are from Table 4-15. For distributions by establishment size, see Table 4-4. All other estimates and calculations are prepared by ERG (see ERG, 2012).

4.2.7 Software

4.2.7.1 The High-Cost Option

The costs of the high-cost option that were presented in ERG (2012) are inflated to 2012 dollars using PPI for NAICS 54161, Technical and Management Consulting Services for costs of software and

Table 4-18. Initial Labelers: Estimated Costs Savings for Label Materials and Printer Coordination under the Selected Option

Est. Size	Number Estabs. with Savings	Number GMP-Exempt	Materials Savings per Estab.	Total Materials Savings (a)	% Assumed Needing to Coordinate with Printers Under Variable Barcoding	Coordin-ation Time Savings per Estab.	Total Coordina-tion Cost Savings	Total Recurring Label Cost Savings	Total Recurring Label Costs under the High Cost Option	Total Recurring Costs under the Selected Option
1-4	457	102	$47	$4,755	8%	$3,750	$137,224	$141,980	$751,664	$521,592
5-9	284	63	$47	$2,951	8%	$3,750	$85,142	$88,092		
10-49	679	151	$254	$38,402	5%	$7,500	$254,580	$292,982	$1,084,468	$791,485
50-99	178	40	$999	$39,554	4%	$15,000	$106,562	$146,115	$721,512	$575,397
100-249	141	32	$3,621	$114,078	3%	$60,000	$254,337	$368,415	$1,946,279	$1,577,864
250-499	66	15	$5,886	$86,321	3%	$90,000	$177,624	$263,945	$1,435,043	$1,171,098
500+	36	8	$37,555	$300,289	0%	$180,000	$0	$300,289	$3,422,203	$3,121,914
Total	1,841	410		$586,350			$1,015,468	$1,601,818	$9,361,169	$7,759,351

(a) Savings apply to GMP-exempt only establishments.
Source: See Table 4-15 and ERG, 2012.

software maintenance. All other costs (e.g., labor costs), assumptions, and methodology remain identical to those presented in ERG (2012). In 2012 dollars, the total first-year costs are estimated to be $178.6 million, with recurring costs totaling $21.9 million (see Table 4-19).

4.2.7.1 The Low Cost Option

Because the low-cost option is basically a re-labeling exercise, the costs of software and software integration will not occur. No first-year or recurring costs are incurred under this option.

4.2.7.2 The Selected Option

The selected option will save the establishments that label Class I devices and GMP-exempt devices from needing to install, integrate and operate a software system for managing variable information. Table 4-20 presents the cost savings associated with these establishments, measured against the high-cost option. For simplification, we have assumed that Class I only/GMP-exempt only establishments are single facility firms, but this means we cannot easily match the costs savings to the original high-cost option costs by establishment size. However, with the cost savings shown of $54.6 million in first-year costs and $7.5 million in recurring year costs subtracted from the costs shown in Table 4-19, the total first year cost of the selected option for software and related expenditures is $124.0 million and the total recurring year costs are $14.4 million.

4.2.8 GUDID

4.2.8.1 High-Cost Option

ERG has modified the methodology for calculating GUDID costs under all options (costs are the same under all three). These changes are based on (1) the addition of Class I UPC-labeled devices to those devices whose information must be submitted to the GUDID (affecting the 104 UPC establishments excluded from nearly all other aspects of the rule), (2) a reconsideration of time needed to gather data (including identifying proper GMDN codes), and (3) an ability, based on our new analysis of the Registration and Listing database and assumptions mapping numbers of listings to size of establishments, to better account for time incurred for uploading and verifying UDI data based on numbers of listings (using assumed numbers of UDIs per listing).

FDA has confirmed that the Agency will be able to provide access to GMDN codes at no cost to medical device registrants. FDA plans to provide the GMDN codes using a lookup system within the GUDID. Although this system could make it easier to find codes than in the GMDN database provided by the GMDN organization, this module has not yet been constructed, so time to learn and use the system is estimated based on knowledge of the time and effort now needed to look up GMDN codes. After discussions with FDA staff knowledgeable of the time needed to search for GMDN codes, we determined that the time to access the proper codes is not insubstantial. According to this source (FDA, 2013a), the first time the database is accessed, there is definitely a learning curve. ERG estimates that it will take one employee roughly 2 days to learn how to use the GMDN database. ERG assumed that one person will complete this training at small establishments (up to 99 employees), two will do so at medium-sized establishments (up to 500 establishments), and three at large establishments (500+ employees).

Table 4-19. Software and Associated Costs for UDI Compliance under the High-Cost Option

Cost Element	Employment Size by Firm							Total
	Smallest (1-4) (a)	Small (5-19)	Medium (20-99) (b)	Large (100-199) (c)	Larger (200-499) (d)	V. Large (500-999) (e)	Largest (1000+) (e)	
Initial Investment Costs								
Software	$209	$8,265	$16,530	$33,060	$57,292	$80,399	$139,357	
Installation, Integration, Verif. & Testing	$600	$1,000	$5,000	$25,000	$45,000	$150,000	$250,000	
Validation	$0	$1,000	$2,000	$3,500	$55,000	$250,000	$400,000	
Total software investment	$809	$10,265	$23,530	$61,560	$157,292	$480,399	$789,357	
No. of employees assumed needing training	1	10	50	175	375	750	1,250	
Training-first year (@$100/employee)	$100	$1,000	$5,000	$17,500	$37,500	$75,000	$125,000	
Number of firms	1,162	1,403	1,019	210	159	68	212	4,232
Reduction for double-counted firms (f)	0%	0%	3%	10%	30%	35%	41%	210
Exclusion for firms with UDI software (f)	0%	0%	1%	9%	14%	18%	29%	85
Aggregate First-Year Investment	$1,055,477	$15,800,373	$27,956,856	$13,607,412	$18,656,510	$20,156,198	$81,372,602	$178,605,427
Recurring Annual Costs								
Recurring training costs (25% 1st yr.)	$25	$250	$1,250	$4,375	$9,375	$18,750	$31,250	
Recurring validation costs (10% 1st yr.)	$0	$100	$200	$350	$5,500	$25,000	$40,000	
Annual maintenance contract (18%)	$38	$1,488	$2,975	$5,951	$10,313	$14,472	$25,084	
Total recurring annual costs	$63	$1,838	$4,425	$10,676	$25,188	$58,222	$96,334	
Aggregate Recurring Costs	$72,648	$2,577,572	$4,336,497	$1,837,465	$2,412,379	$2,112,949	$8,573,207	$21,922,717

(a) The smallest firms (1-4 employees) are assumed to perform limited production and purchase simpler software, with simple testing and no validation.
(b) Assumes compliance can be achieved with use of single UDI server (only one establishment and line assumed).
(c) Same software costs as for medium firm although greater testing costs are assumed to be required and two software licenses are needed.
(d) Assumes 75 percent of firms use two software licenses and 25 percent of firms have complex ERP systems that require more expensive software and more time-consuming integration.
(e) Assumes much more complex installation requirements associated with ERP systems, with more establishments to consider for the very largest firms.
(f) All firm counts are adjusted to account for 3 percent of manufacturers who are assumed to be printing variable barcodes at this time (adjustments for exemptions for custom operations among the smaller firms and UPC codes were made as shown in ERG, 2012, Table 4-3). Specification developers and reprocessors are assumed not to use variable barcodes currently. Additionally, 209 firms have been double counted by breaking out firms by establishment types owned (see Section 3 in ERG, 2012), primarily large firms. A percentage reduction is calculated, assuming most of such firms are the largest firms, to reduce the number of firms by approximately 209 (actual number double counted is 210).
Source: Estimated by ERG based on discussions with software providers (see ERG, 2012). Firm counts use total registered firms (see ERG, 2012, Table 4-3) distributed with data on firms in the affected NAICS by employment size in SBA, 2013a, and adjusted as discussed in footnote (f).

Table 4-20. Initial Labelers: Estimated Cost Savings Associated with Software Expenditures under the Selected Option

Est. Size	Number Estabs. with Savings	First Year Incre-mental Cost/ Estab.	Total First Year Savings	Recur-ring Incre-mental Costs/ Estab.	Total Recurring Costs	Total Annual-ized Incre-mental Costs/ Estab.	Total Savings on Software
1-4	457	$909	$415,568	$63	$28,603	$192	$87,771
5-9	284	$11,265	$3,197,068	$1,838	$521,549	$3,442	$976,740
10-49	679	$27,437	$18,626,379	$4,256	$2,889,211	$8,162	$5,541,188
50-99	178	$27,437	$4,872,877	$4,256	$755,851	$8,162	$1,449,639
100-249	141	$64,734	$9,146,798	$8,741	$1,235,130	$17,958	$2,537,428
250-499	66	$117,625	$7,738,148	$15,209	$1,000,581	$31,957	$2,102,319
500+	36	$294,578	$10,565,117	$30,880	$1,107,528	$72,821	$2,611,763
Total	1,841		$54,561,954		$7,538,453		$15,306,847

Source: Table 4-19 and ERG, 2012. Note that these costs were estimated for firms. It is assumed that most Class I Only establishments are single-facility firms, so these employment sizes also approximate the size of the firm.

Each listing should need one GMDN code. It is expected that the first few listings will take more time for staff to locate the proper GMDN code than later lookups will. The first 3 listings are assumed to entail about 3 hours per listing (which includes training time) to look up the appropriate code. Thereafter, the time should be reduced to about 1.25 hours per code. These assumptions translate to hours per establishment ranging from 3 hours at the smallest establishments to 318 hours at the largest establishments to identify the proper GMDN code for each listing.

Locating the proper GMDN code is only one part of the task to load UDI data into the GUDID. Additional tasks depend on whether the data systems are considered automated, or if they are considered manual (the breakout between manual and automated establishments is from ERG, 2012). The additional tasks by type of data system are the same as those addressed in the economic report for the proposal (ERG, 2012), and are computed on the basis of establishments, unchanged from the approach used previously.

For manual systems (associated with establishments that have fewer than 50 employees and that may not have the most sophisticated (or any) database management systems), time will be required to gather and compile the additional data needed for inputting, accessing FDA's website, and hand-entering the data into the web entry system. Following input, time will also be needed to download the UDI information from the GUDID after uploading and proof it against the master data.

ERG makes the following assumptions in order to estimate the time involved for these smaller establishments. These assumptions are more generous than our previous assumptions and are based on new data analysis as discussed in Section Three. We use the numbers of listings by assumed size at U.S. establishments presented in Table 3-5 in Section 3 and our assumptions that relate those numbers of listings by establishment size to estimate the average numbers of listings by size. In these three small size groups, we assume that the establishments with 1-4 employees will average 1 listing, those with 5-9 will average 3 listings, and those with 10-49 employees will average 5 listings. Listings, though, translate into many more potential UDIs, as each trade name and package content size (e.g., package of 10, package of 25) will map to a different UDI. We assume that 1 listing equates to 10 UDIs on average.

For each UDI, data gathering is estimated to entail ½ hour of effort, with input time totaling 20 minutes per UDI and proofing also entailing 15 minutes per UDI to account for minor changes needed to correct typos. These estimates are based on a review of the required UDI elements and a discussion with FDA concerning the numbers of fields the GUDID will have (Tomkins, 2013). We estimate that the GUDID will have about 30 fields to populate, and it is assumed that there will be shortcuts available such that repetitive information such as listing number and name and address of establishment will not need to be re-entered. These assumptions lead to the estimates of hours shown in Table 4-21 for the three smallest establishment sizes.

For larger establishments, we have made few changes. As before, for the larger establishments, the data gathering effort is already accounted for in the substantial efforts to prepare and validate the UDI tracking software. ERG assumes that this software will be configured such that a GUDID spreadsheet will be one of the outputs available, which would consist of all of the UDIs with the GUDID fields populated with the appropriate UDI data. This spreadsheet can be translated into SPL, with each record output as a separate SPL file, as required for uploading. We continue to estimate, based on recent conversations (2012) with SPL providers. that translating a spreadsheet of data fields into SPL will not be time intensive and that, either using a third party or using in-house staff, the cost of such a translation will be about $100 (see ERG, 2012, for more information). We also assume at least once more in the first year, a revised database will need to be translated as well. Once translated, we estimate about a half-hour will be needed to upload the files to the GUDID database, which means an hour for two uploads in the first year. For validating the uploaded data, we assume that time will be needed to create a data comparison program. This program would be designed to take the data for each UDI as downloaded from the GUDID and compare each UDI to the UDI data in the establishment's master database. A total of 8 hours is assumed to be needed to create and validate the program. Little time beyond this is anticipated because it is unlikely that the uploaded data and the downloaded data will be different. After this initial programming, validating downloaded data is assumed to require minimal time.

For recurring year costs, we assume that 25 percent of the first-year hours will be incurred for training to account for turnover, but that 35 percent of first-year hours will be needed to account for potential need for establishments to update their GMDN codes, which are occasionally revised. This may overstate the number of hours needed to update GMDN codes, however, because FDA expects to assist

Table 4-21. Per Establishment and Total Cost to Upload UDI Data to the GUDID under the High-Cost Option

Cost Element	Employment Size							Total
	1-4	5-9	10-49	50-99	100-249	250-500	500+	
Initial Investment Costs per Establishment								
Hours to gather, prepare and organize files	5	15	25	NA (a)	NA (a)	NA (a)	NA (a)	
GMDN training (assumes 2 days per person)	16	16	16	16	32	32	64	
Hours to look up GMDN codes	3	9	12	30	55	105	318	
Hours to validate submission process	3	8	13	8	8	8	8	
Hours to access and upload to GUDID	3	10	17	0.5	0.5	0.5	0.5	
Hourly wage with benefits	$75	$75	$75	$75	$75	$75	$75	
Subtotal cost per establishment	$2,238	$4,313	$6,125	$4,106	$7,181	$10,931	$29,269	
Conversion to SPL	$0 (c)	$0 (c)	$0 (c)	$200	$200	$200	$200	
Total costs per establishment	$2,238	$4,313	$6,125	$4,306	$7,381	$11,131	$29,469	
Total establishments (mfgs., reprocessors & spec. dev.) (d)	1,211	777	1,725	472	396	195	113	4,889
Costs to understand GUDID system (UPC estabs. only) (e)	$36,678	$41,673	$0	$0	$0	$0	$0	
Aggregate First-Year Investment	**$2,746,454**	**$3,390,932**	**$10,564,742**	**$2,033,449**	**$2,922,400**	**$2,169,893**	**$3,334,145**	**$27,162,015**
Recurring Costs per Establishment								
Hours to access, add or correct, proof and upload to FURLS (includes GMDN updates)	5	15	23	14	22	40	114	
Additional GMDN training (25% turnover)	4	4	4	4	8	8	16	
Hourly wage with benefits	$75	$75	$75	$75	$75	$75	$75	
Additional SPL conversions (4 x year) @ $100 per file	NA	NA	NA	$400	$400	$400	$400	
Total costs per establishment	$663	$1,389	$2,024	$1,317	$2,273	$3,586	$9,764	
Aggregate Recurring Costs	**$803,093**	**$1,079,044**	**$3,490,677**	**$621,988**	**$900,104**	**$699,032**	**$1,104,723**	**$8,698,660**

(a) Costed in MIS software reconfiguration costs. See Table 4-19.

(b) Based on the median hourly wage rate for management occupations in NAICS 3391 (BLS, 2009). Benefits are calculated at 29% of wages (BLS, 2010).

(c) Web entry.

(d) From Table 4-3; adds in establishments assumed to use UPCs only (10 percent of non-exempt establishments in the 1-9 employment size groups).

(e) Assumes 10 hours per UPC establishment, which total 49 establishments in the 1-4 category and 56 establishments in the 5-9 category.

the establishments in identifying changes to the codes. Additional SPL conversions of revised files are assumed to occur four times per year at larger establishments.

When all of these assumptions are used, the aggregate costs of GUDID data development and uploading can be calculated. As Table 4-21 shows, first-year costs are $27.2 million and recurring year costs are $8.7 million. Note that the table also accounts for additional time for UPC establishments to understand the GUDID implications (they were not assigned this cost in Section 4.2.2, as discussed in that section).

4.2.8.2 The Low-Cost Option

Firms and establishments under the low-cost option will incur the same costs as those estimated under the high-cost option.

4.2.8.3 The Selected Option

Because GMP-exempt devices are not required to have UDIs, FDA will not require establishments labeling GMP-exempt devices to upload data on these devices into the GUDID. A number of establishments (the GMP-exempt devices only establishments) will not be involved in any GUDID activities. The costs savings to these establishments are calculated in Table 4-22. These savings total $2.2 million in first-year costs and $0.7 million in recurring year costs. The total costs of the selected option, therefore, will be $24.9 million in the first year and $8.0 million per year thereafter.

Table 4-22. Initial Labelers: Estimated Costs Savings Associated with GUDID under the Selected Option

Est. Size	Number GMP-Exempt	First Year Cost per Estab.	Total First Year Cost Savings	Recurring Year Cost per Estab.	Total Recurring Year Cost Savings	Annual-ized Cost per Estab.	Total Annualized Cost Savings
1-4	102	$2,238	$228,174	$663	$67,624	$982	$100,110
5-9	63	$4,313	$272,862	$1,389	$87,909	$2,003	$126,758
10-49	151	$6,125	$927,027	$2,024	$306,297	$2,896	$438,285
50-99	40	$4,306	$170,507	$1,317	$52,154	$1,930	$76,431
100-249	32	$7,381	$232,520	$2,273	$71,616	$3,324	$104,722
250-499	15	$11,131	$163,258	$3,586	$52,594	$5,171	$75,838
500+	8	$29,469	$235,629	$9,764	$78,073	$13,960	$111,621
Total	410		$2,229,978		$716,267		$1,033,766

Source: Table 4-21.

4.2.9 Total Costs of the Options for Initial Labelers

4.2.9.1 The High-Cost Option

Costs for each of the cost categories described here are summarized for the initial labelers in Table 4-23. This table presents first-year costs, recurring year costs, and annualized costs for the high-cost option. As the table shows, the total first-year costs for initial labelers are $460.6 million. Recurring costs total $77.6 million per year. The total annualized cost is $143.2 million per year.

Table 4-23. Total Investment and Annual Recurring Costs for UDI Implementation for Initial Labelers under the High-Cost Option

Cost Element	First-Year	Annualized and Recurring
Labeling and Database Requirements		
Administration and planning	$124,714,509	NA
Barcode registration costs	$578,246	NA
Equipment and other investments	$71,539,744	$36,475,487
Incremental label cost and time	NA	$9,361,169
Label redesign cost & date stamps	$43,054,471	NA
Software (with training)	$178,605,427	$21,922,717
Recordkeeping and reporting		
-GUDID costs	$27,162,015	$8,698,660
Total Labeling and Database Requirements	$445,654,411	$76,458,033
Direct Marking		
Total Direct Marking	$14,919,691	$1,141,787
Total--All Cost Items	**$460,574,103**	**$77,599,820**
Annualized Investment Total (a)	**-**	**$65,575,391**
Total Annualized Costs	**-**	**$143,175,210**

Source: See previous tables.
(a) Includes annualized first-year costs and O&M costs estimated at 10 percent of one-time cost totals for multi-use devices (Table 4-13) and recurring costs for exceptions (Table 4-11).
(b) First-year costs are annualized at 7 percent over 10 years.

4.2.9.2 The Low-Cost Option

Costs for each of the cost categories are summarized in Table 4-24. This table presents first-year costs and recurring year costs for the low-cost option. As the table shows, the total first-year costs for initial labelers are $99.4 million. Recurring costs total $13.0 million per year. The total annualized cost is $27.2 million per year.

Table 4-24. Total Investment and Annual Recurring Costs for UDI Implementation for Medical Device Manufacturers under the Low-Cost Option

Cost Element	First-Year	Annualized and Recurring
Administration and planning	$13,814,195	NA
Barcode registration costs	$578,246	NA
Direct marking	$14,919,691	$1,141,787
Equipment and other investments	NA	NA
Incremental label materials cost	NA	$3,196,019
Label redesign cost	$42,952,729	NA
Software (with training)	NA	NA
GUDID	$27,162,015	$8,698,660
Total	$99,426,876	$13,036,466
Annualized Investment Total (a)	-	$14,156,150
Total Annualized Costs	-	$27,192,616

(a) First-year costs are annualized at 7 percent over 10 years.
Source: See previous tables.

4.2.9.1 The Selected Option

Table 4-25 shows the cost savings associated with the selected option. Because costs for the high-cost option were not estimated on a size basis, and the total cost savings have been summarized only as annualized costs, the total annualized costs of the selected option are calculated on the basis of the total annualized cost savings of $42.4 million subtracted from the total annualized costs of the high-cost option of $143.2 million. The total annualized costs of the selected option for initial labelers are thus $100.7 million.

Table 4-25. Initial Labelers: Total Costs Savings under the Selected Option

Est. Size	Total Admin. and Planning Savings	Total Registration Savings	Total Equipment Savings	Total Recurring Label Cost Savings	Total Software Savings	Total GUDID Cost Savings	Total Savings for Initial Labelers under the Selected Option
1-4	$164,601	$1,089	$45,899	$141,980	$87,771	$100,110	$541,450
5-9	$110,308	$676	$28,478	$88,092	$976,740	$126,758	$1,331,052
10-49	$1,680,364	$1,077	$8,556,686	$292,982	$5,541,188	$438,285	$16,510,582
50-99	$782,484	$141	$2,238,528	$146,115	$1,449,639	$76,431	$4,693,338
100-249	$1,424,615	$897	$2,793,154	$368,415	$2,537,428	$104,722	$7,229,231
250-499	$1,057,796	$418	$2,796,674	$263,945	$2,102,319	$75,838	$6,296,989
500+	$899,305	$0	$1,905,773	$300,289	$2,611,763	$111,621	$5,828,750
Total	$6,119,472	$4,298	$18,365,192	$1,601,818	$15,306,847	$1,033,766	$42,431,393

Source: See previous tables.

4.3 Repackagers/Relabelers

4.3.1 Overview

No assumptions changed for repackagers/relabelers (R/Rs) unless they changed for the initial labelers as well. For example, planning and administrative costs are assumed to be half the cost of similar size initial labeling establishments, which have been reassessed in this report. Updates to 2012 dollars are reflected in the new tables presented here for each of the cost categories. The cost categories examined are:

- Planning and Administrative Costs (Section 4.3.2)
- Barcode Registration Costs (Section 4.3.3)
- Equipment Costs (Section 4.3.4)
- Label Revision Costs (Section 4.3.5)
- Software Costs (Section 4.3.6)
- GUDID Costs (Section 4.3.7)

4.3.2 Planning and Administrative Costs

4.3.2.1 The High-Cost Option

For reasons discussed in ERG (2012), the R/Rs are expected to need somewhat less time to plan and implement the UDI rule. As in the previous analysis, R/Rs are assumed to require half the time of the initial labeling establishments to meet variable barcoding and other requirements of UDI under the high-cost option. However, because we have increased the estimated time to plan and implement the UDI rule in Section 4.2.2.1, the hours and costs for R/Rs under the high-cost option have risen as well. Table 4-26 presents the one-time planning and administrative costs to R/Rs, which total $7.7 million.

Table 4-26. First Year Administrative and Planning Costs for R/Rs under the High-Cost Option

Relabeler Size	Percentage of Establishments (a)	Distribution of R/Rs	Assumed Cost/Facility (b)	Aggregate Cost
1-4	56%	736	$1,991	$1,466,474
5-9	16%	212	$2,092	$444,525
10-49	21%	272	$10,575	$2,879,239
50-99	4%	47	$17,400	$819,901
100-249	2%	28	$38,595	$1,067,677
250-499	1%	10	$59,879	$578,585
>500	0%	4	$91,919	$401,501
Total	-	1,310		$7,657,903

(a) Percentage of establishments is from Table 3-10 in ERG, 2012.
(b) Half the planning time is assumed to be needed for R/Rs as for manufacturers; see Table 4-2 for per-establishment costs for manufacturers.

4.3.2.2 The Low-Cost Option

As in the previous analysis for initial labelers (ERG, 2012), some R/Rs are estimated to currently have static or variable barcodes on their labeling, thus are already complying with the UDI labeling component of the rule. These establishments, as before, are assumed only to need minimal hours to read and understand the rule. (GUDID planning costs will be discussed separately). All other assumptions and estimates are carried through from the previous report, including that R/Rs will face similar planning and administrative costs as initial labelers to meet the low cost option. The number of hours was increased for planning and administrative tasks under the low-cost option for initial labelers, as discussed in Section 4.2.2.2 of this report, however, so the costs for R/Rs under the low-cost option have also increased. Table 4-27 presents the costs of the low-cost option for planning and administrative tasks for R/Rs. The total one-time costs are $2.6 million.

4.3.2.3 The Selected Option

Table 4-28 presents the cost savings for R/Rs associated with the selected option, and then presents the costs as shown in Table 4-26, under the high-cost option. When the cost savings are subtracted from the costs of the high-cost option, we compute the costs of the selected option. As the table shows, the cost for planning and administration for R/Rs is estimated to be $7.2 million.

Table 4-27. Planning and Administrative Costs for R/Rs under the Low-Cost Option

Relabeler Size	Number of Relabelers	Percentage Without Static Barcodes	Number Needing Full Planning Effort	Planning Cost	Reading Cost (a)	Total Cost
1-4	736	95%	700	$1,017,985	$6,904	$1,024,890
5-9	212	95%	202	$293,650	$1,992	$295,642
10-49	272	95%	259	$973,847	$2,553	$976,400
50-99	47	90%	42	$163,488	$884	$164,372
100-249	28	70%	19	$123,450	$1,556	$125,006
250-499	10	40%	4	$26,379	$1,087	$27,466
>500	4	15%	1	$5,061	$696	$5,757
Total	1,310		1,226	$2,603,859	$15,671	$2,619,532

(a) 2.5 hours at a fully loaded management wage of $75/hour is assumed for those in compliance to read the rule.
Source: Table 4-26 and ERG estimates.

Table 4-28. Repackagers/Relabelers: Estimated Cost Savings Associated with Administrative & Planning Expenditures under the Selected Option

Est. Size	Number Estabs. with Savings	First Year Incre-mental Cost/ Estab.	Total First Year Savings	Recur-ring Incre-mental Costs/ Estab.	Total Annual-ized Incre-mental Costs/ Estab.	Total Annualized Savings on Planning & Admin. under the Selected Option	Total One-Time Cost of Planning & Admin. under the High Cost Option	Total Cost of Planning and Admin. under the Selected Option
1-4	466	$536	$249,909	NA	$76	$35,581	$1,466,474	$1,430,893
5-9	134	$637	$85,697	NA	$91	$12,201	$444,525	$432,324
10-49	172	$6,810	$1,173,343	NA	$970	$167,058	$2,879,239	$2,712,181
50-99	30	$13,545	$403,899	NA	$1,928	$57,506	$819,901	$762,395
100-249	18	$32,220	$564,049	NA	$4,587	$80,308	$1,067,677	$987,369
250-499	6	$53,054	$324,410	NA	$7,554	$46,189	$578,585	$532,397
500+	3	$84,194	$232,727	NA	$11,987	$33,135	$401,501	$368,366
Total	829		$3,034,034			$431,978	$7,657,903	$7,225,924

Source: From Table 4-26.

4.3.3 Barcode Registration

The costs and assumptions for barcode registration for R/Rs have not been changed from ERG (2012). They are the same for all three options. Although it is likely that the number of R/Rs that have registered barcodes is greater than zero, we continue to assume all R/Rs must register. Table 4-29 presents these costs, which total $1.6 million. The low-cost option is associated with the same cost for registration, but the selected option saves registration costs associated with the GMP-exempt establishments, which do not have to meet UDI requirements. These savings total approximately $77,000 (see Table 4-30). Costs for the selected option remain about $1.6 million.

Table 4-29. Costs for Barcode Registration for R/Rs under the High-Cost Option

Firm Size	Number of Firms	Initial Cost per Firm To Register UDI	Aggregate Costs to Register UDI
Small	1,044	$500	$522,195
Medium	144	$4,000	$574,152
Large	24	$20,000	$481,451
Total	1,212		$1,577,798

Source: Hankin, 2010; HIBCC, 2013; Table 4-17 in ERG 2012; and ERG estimates.

Table 4-30. Repackagers/Relabelers: Estimated Cost Savings Associated with Barcode Registration under the Selected Option

Est. Size	Number GMP-Exempt	Cost of Registration	Total First Year Cost Savings	Annualized Cost Savings for Registration
1-4	73	$500	$36,261	$5,163
5-9	21	$500	$10,460	$1,489
10-49	27	$500	$13,406	$1,909
50-99	5	$500	$2,320	$330
100-249	3	$4,000	$10,897	$1,551
250-499	1	$4,000	$3,806	$542
500+	0	NA	$0	$0
Total	129		$77,150	$10,984

Source: Table 4-29.

4.3.4 Equipment Costs

4.3.4.1 High-Cost Option

No equipment costs or assumptions have changed from the economic report for the proposal. Table 4-31 shows these costs, which total $11.3 million in first-year costs and $4.2 million in recurring costs.

4.3.4.2 Low-Cost Option

The low-cost, static barcoding option is not associated with any equipment costs for R/Rs, as assumed previously in ERG (2012).

4.3.4.3 The Selected Option

Table 4-32 presents the costs savings associated with Class I only/GMP-exempt only establishments facing no cost for equipment under the selected option. As this table shows, total first-year cost savings total $7.1 million and total recurring costs savings total $2.7 million. When these cost savings are subtracted from the costs of the high-cost option, therefore, the total first-year costs to R/Rs under the selected option for equipment are $4.2 million and the total recurring costs are $1.6 million.

4.3.5 Label Revision Costs

4.3.5.1 High-Cost Option

The cost to redesign labels has not changed from that estimated in the economic report for the proposal (ERG, 2012), and it is repeated here as Table 4-33. First-year costs total $4.6 million.

Table 4-31. Equipment Investments for UDI Requirements for Relabelers and Repackagers

Establishments, by Baseline Label Printing System	Manual Lines (% Estabs.)	Auto-mated Lines (% Estabs.)	Equipment Costs, by Number of Production Lines (a)					Investment Total
			Manual	Automated				
			1 line	1 line	2-3 lines	4-5 lines	6+ lines	
Number of establishments, by assumed number of prod. lines			949	319	28	8	6	1,310
Per estab. costs to install full on-line label printing system			NA	$43,594	$46,813	$93,625	$119,438	
Per estab. cost to install supplemental label system			NA	$21,094	$21,094	$24,063	$31,719	
Per establishment FTEs to operate verifiers			$0	0.15	0.30	0.60	1.00	
Per establishment cost to operate verifiers (b)			$0	$6,947	$13,894	$27,787	$46,312	
Per estab. costs to print labels--manual lines			$0	NA	NA	NA	NA	
Establishments using outside label printers	**40%**	**40%**						
Switch to outside new label printer, add lot #s (10% of 40%) (c)	NA	4%	NA	NA	NA	NA	NA	NA
Move entire label operation in-house (2% of 40%)	NA	1%	NA	$111,388	$10,360	$6,246	$5,438	$133,433
Add small supplemental label, applied in-house (88% of 40%)	NA	35%	NA	$4,901,082	$205,405	$70,630	$63,547	$5,240,664
Man. line: switch to new outside label printer, add lot#s (20% of 40%)	8%	NA	NA(c)	NA	NA	NA	NA	NA
Man. line: move entire label operation in-house (75% of 40%)	30%	NA	$0	NA	NA	NA	NA	$0
Man. line: add small supplemental label, applied in-house (5% of 40%)	2%	NA	$0	NA	NA	NA	NA	$0
Establishments printing labels in-house with printing systems that do not accommodate variable information	**0%**	**45%**						
Modify entire label printing operation (60% of 45%)	NA	27%	$0	$3,759,352	$349,655	$210,797	$183,544	$4,503,348
Add small supplemental label, applied in-house (40% of 45%)	NA	18%	$0	$1,212,694	$105,037	$36,118	$32,496	$1,386,344
Establishments w/label printing systems accommodating variable data	**60%**	**15%**						
Modify label with existing printing equipment (100% of 15%)	NA	15%	$0	NA	NA	NA	NA	NA
Man. line: modify label w/existing equipment (100% of 60%)	60%		$0	NA	NA	NA	NA	$0
Total Investment								$11,263,789
Total labor			$0	$2,218,759	$384,352	$231,715	$263,591	$3,098,416
Total O&M (10 percent of equipment cost) plus Labor								$4,224,795

(a) See Table 4-9.

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

(c) Incremental costs for outside printer labels assumed primarily costs of coordination, which is assumed passed through to labelers. This cost is captured in later in Table 4-37.

Table 4-32. Repackagers/Relabelers: Estimated Cost Savings Associated with Equipment Expenditures under the Selected Option

Est. Size	Number Estabs. with Savings	First Year Incre-mental Cost/ Estab.	Total First Year Savings	Recur-ring Incre-mental Costs/ Estab.	Total Recurring Costs	Total Annual-ized Incre-mental Costs/ Estab.	Total Savings on Equipment
1-4	466	$0	$0	$0	$0	$0	$0
5-9	134	$0	$0	$0	$0	$0	$0
10-49	172	$31,261	$5,386,259	$10,073	$1,735,560	$4,451	$2,502,442
50-99	30	$31,261	$932,187	$10,073	$300,369	$4,451	$433,092
100-249	18	$24,236	$424,281	$16,317	$285,655	$3,451	$346,064
250-499	6	$38,829	$237,427	$31,670	$193,653	$5,528	$227,457
500+	3	$50,078	$138,424	$51,320	$141,857	$7,130	$161,565
Total	829		$7,118,578		$2,657,094		$3,670,620

Source: Per-establishment averages are taken from Table 4-31.

Table 4-33. Derivation of Incremental Device Labeling Redesign Cost, Per Establishment and in Aggregate for Relabelers and Repackagers

Establishment Size	Number of Establishments	Costs Per Establishment	Percent Incurring Cost	Aggregate Cost
1-4	736	$1,250	100.0%	$920,587
5-9	212	$2,500	100.0%	$531,108
10-49	272	$5,000	100.0%	$1,361,357
50-99	47	$10,000	100.0%	$471,213
100-249	28	$20,000	100.0%	$553,279
250-499	10	$50,000	100.0%	$483,126
500+	4	$75,000	100.0%	$327,599
Total	1,310	-	-	$4,648,270

Source: Estimated by ERG. No firms are assumed to be presenting label information in the precise format required by the final rule.

Another first-year cost that could affect some R/Rs is the cost of replacing date stamp dies to comply with the date format requirements. Unlike the manufacturers, for whom we assumed a certain percentage were already labeling with variable barcodes and who likely do not use date stamps, we have assumed that R/Rs are not labeling currently with variable barcodes, so 100 percent are considered potentially affected. The same 10 percent factor with R/Rs as was used for initial labelers to represent the

number that are assumed affected given that many R/Rs may opt to put their dates on labels, since the labels will be changing as the barcode changes. Similarly, the same cost per die per line is also used to compute cost per establishment. The aggregate cost of new date stamps under these assumptions can be seen in Table 4-34. The first-year cost totals about $22,000.

The cost of label materials has been inflated to 2012 dollars using the PPI for NAICS 322121 (converted paper products), although no other assumptions have changed. Table 4-35 presents the costs of label materials and printer coordination costs for the R/Rs. These costs now total $1.0 million.

Table 4-34. Cost of Date Stamp Dies under the High-Cost Option

Employment Size of Estabs.	Number of Estabs.	Assumed Potentially Affected	Number Assumed Affected	# Lines	Cost of New Die	Total Cost of Dies per Estab.	Aggregate First-Year Cost
1-4	736	100%	74	1	$150	$150	$11,047
5-9	212	100%	21	1	$150	$150	$3,187
10-49	272	100%	27	1	$150	$150	$4,084
50-99	47	100%	5	1	$150	$150	$707
100-249	28	100%	3	3	$150	$450	$1,245
250-499	10	100%	1	5	$150	$750	$725
500+	4	100%	0	8	$150	$1,200	$524
Total	1,310		131				$21,518

Source: Manufacturer of Date Stamp Dies, 2013, and ERG estimates.

Table 4-35. Derivation of Incremental Device Labeling Materials Cost and Time, Per Establishment, For Relabelers and Repackagers under the High-Cost Option

Employment Size	Number of Establishments	Average Per Establishment Incremental Cost	Total Incremental Material Cost	Coordination with Outside Printer			Aggregate Cost (Time & Materials) (a)
				Hrs.	Cost	Aff. Estabs.	
1-9	949	$47	$44,250	50	$3,750	76	$378,742
10-49	272	$254	$69,083	100	$7,500	14	$171,185
50-99	47	$999	$47,072	200	$15,000	2	$75,345
100-249	28	$3,621	$100,181	800	$60,000	1	$149,976
250-499	10	$5,886	$56,869	1,200	$90,000	0	$82,958
500+	4	$37,555	$164,041	2,400	$180,000	-	$164,041
Total	1,310	-	$481,497	-	-	93	$1,022,247

(a) Includes costs for 2 percent of establishments with 1-9 employees (19 establishments) to add a supplemental label at a cost of $2,625 per year (see Table 4-14). Also adds material costs to the total. Cost is multiplied by two to account for outside label price increases due to an assumed cost passthrough from printers to account for coordination at the printing shop.

4.3.5.2 Low-Cost Option

Label redesign costs remain the same as in the high-cost option ($4.6 million), as do date stamp die costs ($22,000) because all R/Rs are assumed to be affected by the date format change (this was also assumed in the economic report for the proposal; ERG, 2012). See Table 4-33 and Table 4-34. However, the number of R/Rs that must incrementally add a barcode to their label (because some are assumed to already apply a static barcode) is reduced under this option, which reduces materials costs. Additionally, no printer coordination is required (see ERG, 2012). Thus, label material costs total $268,000 (see Table 4-36).

Table 4-36. Incremental Cost of Label Materials for R/Rs under the Low-Cost Option

Employment Size	Number of Affected Establishments	Average Per Establishment Incremental Cost	Total Incremental Material Cost
1-9	901	$47	$42,038
10-49	259	$254	$65,629
50-99	42	$999	$42,365
100-249	19	$3,621	$70,127
250-499	4	$5,886	$22,748
500+	1	$37,555	$24,606
Total	1,226		$267,512

Source: See Table 4-35.

4.3.5.3 Selected Option

For the selected option, all assumptions remain the same as those presented in ERG (2012), although materials cost savings, which are conservatively assumed to apply only to GMP-exempt establishments, are inflated by the PPI for converted paper products. Table 4-37 presents the cost savings and the total cost of the selected option. As the table shows, the selected option saves $358,000 over the high-cost option, so total costs are $664,000.

4.3.6 Software Costs

4.3.6.1 High-Cost Option

The costs to acquire, install, validate and use software to manage variable barcoding for R/Rs have changed only to the extent that software costs and maintenance costs have been updated to 2012 dollars. Table 4-38 presents the updated costs for software to meet the high-cost option. The first-year costs total $13.7 million and the recurring year costs total $1.2 million.

Table 4-37. Repackagers/Relabelers: Estimated Cost Savings Associated with Label Materials and Printer Coordination under the Selected Option

Est. Size	Number Estabs. with Savings	Number GMP-Exempt	Materials Savings per Estab.	Total Materials Savings (a)	% Assumed Needing to Coordinate with Printers	Coordination Cost Savings per Estab.	Total Coordination Cost Savings	Total Recurring Label Cost Savings	Total High-Cost Option Costs of Labeling	Total Cost of the Selected Option
1-4	466	73	$47	$3,382	8%	$3,750	$139,817	$143,199	$378,742	$276,850
5-9	134	21	$47	$976	8%	$3,750	$40,332	$41,307		
10-49	172	27	$254	$6,803	5%	$7,500	$64,612	$71,415	$171,185	$99,770
50-99	30	5	$999	$4,635	4%	$15,000	$17,892	$22,527	$75,345	$52,818
100-249	18	3	$3,621	$9,865	3%	$60,000	$31,512	$41,377	$149,976	$108,600
250-499	6	1	$5,886	$5,600	3%	$90,000	$16,510	$22,110	$82,958	$60,848
500+	3	0	$37,555	$16,154	0%	$180,000	$0	$16,154	$164,041	$147,888
Total	829	129		$47,415			$310,674	$358,089	$1,022,247	$664,159

(a) Applies only to GMP-exempt establishments.
Source: Table 4-18.

Table 4-38. Software and Associated Costs for R/Rs for UDI Compliance under the High-Cost Option

Cost Element	Employment Size by Firm					Total
	Smallest (1-4) (a)	Small (5-19) (a)	Medium (20-199) (b)	Large (200-499) (c)	Largest (500+ (d)	
Initial Investment Costs						
Software	$209	$8,265	$16,530	$33,060	$57,292	
Installation, Integration, Verif. & Testing	$600	$1,000	$5,000	$25,000	$45,000	
Validation	$0	$1,000	$2,000	$3,500	$55,000	
Total software investment	$809	$10,265	$23,530	$61,560	$157,292	
No. of employees assumed needing training	1	10	50	175	375	
Training-first year (@$100/employee)	$100	$1,000	$5,000	$17,500	$37,500	
Number of firms	727	318	131	13	24	1,212
Aggregate First-Year Investment	$660,319	$3,577,517	$3,724,020	$1,028,424	$4,689,141	$13,679,421
Recurring Annual Costs						
Recurring training costs (25 percent of first-year)	$25	$250	$1,250	$4,375	$9,375	
Recurring validation costs (10 percent of first-year)	$0	$100	$200	$350	$5,500	
Annual maintenance contract (18%)	$38	$1,488	$2,975	$5,951	$10,313	
Total recurring annual costs	$63	$1,838	$4,425	$10,676	$25,188	
Aggregate Recurring Costs	$27,279	$472,461	$388,379	$77,409	$248,250	$1,213,778

(a) The smallest firms (1-4 employees) are assumed to perform limited production and to purchase simpler software, with simpler testing and no validation.
(b) Assumes compliance can be achieved with use of single UDI server (only one establishment and line assumed).
(c) Same as for medium firm although greater testing costs are assumed to be required and two software licenses are needed.
(d) Assumes 75 percent of firms use two software licenses and 25 percent of firms have complex ERP systems that require more expensive software and more time-consuming integration.
Source: Estimated by ERG based on discussions with software providers and as discussed in ERG, 2012. Firm counts use total registered firms in ERG, 2012, Table 4-17, distributed with data on firms in the affected NAICS by employment size from SBA, 2013a.

Note: Most R/Rs are not assumed to require integration of information into ERP systems as a result of the rule, although they might integrate information for their own purposes.

4.3.6.2 Low-Cost Option

The low-cost option does not require specialized software. No costs are incurred by R/Rs for this cost item under this option.

4.3.6.3 Selected Option

All assumptions remain the same as those used in the economic report for the proposal (ERG, 2012). Cost, and, thus, cost savings have been inflated to 2012 dollars. Table 4-39 shows the results of updating the dollars, indicating that the total first-year cost savings to R/Rs under the selected option total $6.3 million and the recurring costs saved total $0.9 million. Because the savings do not map easily to the high-cost options by size, we present only the total cost of this cost category for the selected option. When the costs savings are subtracted from the $13.7 million first-year costs of the high-cost option, we estimate that the total first-year cost of software under the selected option for R/Rs is $7.4 million. Total recurring costs are $0.3 million ($1.2 million under the High-Cost Option minus $0.9 million cost savings).

Table 4-39. Repackagers/Relabelers: Estimated Cost Savings Associated with Software Expenditures under the Selected Option

Est. Size	Number Estabs. with Savings	First Year Incre-mental Cost/ Estab.	Total First Year Savings	Recur-ring Incre-mental Costs/ Estab.	Total Recurring Costs	Total Annual-ized Incre-mental Costs/ Estab.	Total Savings on Software
1-4	466	$909	$423,419	$63	$29,144	$192	$89,429
5-9	134	$11,265	$1,514,458	$1,838	$247,059	$3,442	$462,684
10-49	172	$11,265	$1,940,959	$1,838	$316,636	$3,442	$592,985
50-99	30	$28,530	$850,752	$4,425	$131,963	$8,487	$253,091
100-249	18	$28,530	$499,458	$4,425	$77,473	$8,487	$148,584
250-499	6	$79,060	$483,427	$10,676	$65,279	$21,932	$134,108
500+	3	$194,792	$538,439	$25,188	$69,623	$52,922	$146,284
Total	829		$6,250,911		$937,177		$1,827,166

Source: Table 4-19. Note that these costs were estimated for firms. It is assumed that most Class I Only establishments are single-facility firms, so these employment sizes also approximate the size of the firm.

4.3.7 GUDID Costs

4.3.7.1 The High-Cost Option

The R/Rs will have access to the manufacturer's GUDID submissions when they begin the process of creating their own GUDID files. This substantially saves time in gathering the data, and GMDN costs are not incurred because the original manufacturer will have identified the proper code. We assume that the

data gathering task takes half the time of that assigned to manufacturers (applicable to the smaller firms). All other assumptions remain the same as those used for the manufacturers. Table 4-40 presents the GUDID-related costs for R/Rs, which total $1.8 million in the first year and $0.5 million per year in recurring years.

4.3.7.2 The Low-Cost Option

GUDID costs for R/Rs under the low-cost option are unchanged from those estimated under the high-cost option.

4.3.7.3 The Selected Option

Most GUDID costs remain unchanged from the high-cost option, except that establishments labeling only GMP-exempt devices will not incur GUDID costs under the selected option. Table 4-41 presents the cost savings associated with these establishments. The selected option saves $176,000 in the first year and about $47,000 per year in recurring costs. When the costs savings are subtracted from the high-cost option costs, we estimate that the first-year cost under the selected option is $1.6 million in the first year, with $0.4 million in recurring costs.

4.3.8 Total Costs to R/Rs

4.3.8.1 High-Cost Option

Costs for each of the cost categories described here under the high-cost option are summarized for the R/Rs in Table 4-42. This table presents first-year costs, recurring year costs, and annualized costs for the high-cost option. As the table shows, the total first-year costs for R/Rs are $40.6 million. Recurring costs total $5.8 million per year. The total annualized cost is $11.6 million per year.

4.3.8.2 Low-Cost Option

Costs for each of the cost categories described here under the low-cost option are summarized for the R/Rs in Table 4-43. This table presents first-year costs, recurring year costs, and annualized costs for the high-cost option. As the table shows, the total first-year costs for R/Rs are $10.7 million. Recurring costs total $0.7 million per year. The total annualized cost is $2.3 million per year.

4.3.8.3 Selected Option

Table 4-44 shows the cost savings associated with the selected option. Because costs for the high-cost option were not estimated on a size basis, and the total cost savings have been summarized only as annualized costs, the total annualized costs of the selected option is calculated on the basis of the total annualized cost savings of $6.4 million per year subtracted from the total annualized costs of the high-cost option of $11.6 million per year. The total annualized costs of the selected option for R/Rs are thus $5.2 million.

Table 4-40. Per Establishment and Total Cost for R/Rs to Upload UDI Data to GUDID under the High-Cost Option

	Employment Size							
	1-4	**5-9**	**10-49**	**50-99**	**100-249**	**250-500**	**500+**	**Total**
Initial Investment Costs per Establishment								
Hours to gather, prepare and organize files	3	8	13	NA (a)	NA (a)	NA (a)	NA (a)	
Hours to validate submission process	3	8	13	8	8	8	8	
Hours to access and upload to GUDID	3	10	17	0.5	0.5	0.5	0.5	
Hourly wage with benefits	$75	$75	$75	$75	$75	$75	$75	
Subtotal cost per establishment	$625	$1,875	$3,125	$638	$638	$638	$638	
Conversion to SPL	$0 (c)	$0 (c)	$0 (c)	$200	$200	$200	$200	
Total costs per establishment	$625	$1,875	$3,125	$838	$838	$838	$838	
Total Establishments (d)	736	212	272	47	28	10	4	1,310
Aggregate First-Year Investment	**$460,294**	**$398,331**	**$850,848**	**$39,464**	**$23,169**	**$8,092**	**$3,658**	**$1,783,856**
Recurring Costs								
Submitting changes	2.1	6.3	10.4	2.1	2.1	2.1	2.1	
Hourly wage with benefits	$75	$75	$75	$75	$75	$75	$75	
Additional SPL conversions (4 x year) @ $100 per file	NA	NA	NA	$400	$400	$400	$400	
Total costs per establishment	$156	$469	$781	$559	$559	$559	$559	
Aggregate Recurring Costs	**$115,073**	**$99,583**	**$212,712**	**$26,359**	**$15,475**	**$5,405**	**$2,443**	**$477,049**

(a) Costed in MIS software reconfiguration costs.

(b) Based on the median hourly wage rate for management occupations in NAICS 3391 (BLS, 2009). Benefits are calculated at 29% of wages (BLS, 2010).

(c) Web entry.

(d) From Table 4-26.

Table 4-41. Repackagers/Relabelers: Estimated Costs Savings Associated with GUDID under the Selected Option

Est. Size	Number GMP-Exempt	First Year Cost per Estab.	Total First Year Cost Savings	Recurring Year Cost per Estab.	Total Recurring Year Cost Savings	Annual-ized Cost per Estab.	Total Annualized Cost Savings
1-4	73	$625	$45,327	$156	$11,332	$245	$17,785
5-9	21	$1,875	$39,225	$469	$9,806	$736	$15,391
10-49	27	$3,125	$83,786	$781	$20,946	$1,226	$32,876
50-99	5	$838	$3,886	$559	$2,596	$679	$3,149
100-249	3	$838	$2,281	$559	$1,524	$679	$1,849
250-499	1	$838	$797	$559	$532	$679	$646
500+	0	$838	$360	$559	$241	$679	$292
Total	129		$175,662		$46,977		$71,987

Source: Table 4-30 and 4-40.

Table 4-42. Total Investment and Annual Recurring Costs for UDI Implementation for Relabelers and Repackagers under the High-Cost Option

Cost Element	First-Year	Annual Recurring
Administration and planning	$7,657,903	NA
Registration Costs	$1,577,798	NA
Equipment and other investments	$11,263,789	$3,098,416
Incremental label cost	NA	$1,022,247
Label redesign cost & date stamps	$4,669,788	NA
Software (with training)	$13,679,421	$1,213,778
Recordkeeping & Reporting (GUDID)	$1,783,856	$477,049
Total	$40,632,554	$5,811,491
Annualized Investment Total (a)	-	$5,785,162
Total Annualized Costs	-	$11,596,652

(a) First-year costs are annualized at 7 percent over 10 years.
Source: See previous tables.

Table 4-43. Total Investment and Annual Recurring Costs for UDI Implementation under the Low-Cost Option

Cost Element	First-Year	Annual Recurring
Administration and planning	$2,619,532	NA
Barcode registration	$1,577,798	NA
Equipment and other investments	NA	NA
Incremental label materials cost	NA	$267,512
Label redesign cost	$4,669,788	NA
Software (with training)	NA	NA
GUDID	$1,783,856	$477,049
Total	$10,650,974	$744,561
Annualized Investment Total (a)	-	$1,516,459
Total Annualized Costs	-	$2,261,020

(a) First-year costs are annualized at 7 percent over 10 years.

Source: See previous tables.

Table 4-44. Repackagers/Relabelers: Total Estimated Cost Savings under the Selected Option

Est. Size	Total Admin. and Planning Savings	Total Registration Savings	Total Equipment Savings	Total Recurring Label Cost Saving	Total Software Savings	GUDID Cost Savings	Total Cost Savings for Initial Labelers under the Selected Option
1-4	$35,581	$5,163	$0	$143,199	$89,429	$17,785	$291,157
5-9	$12,201	$1,489	$0	$41,307	$462,684	$15,391	$533,073
10-49	$167,058	$1,909	$2,502,442	$71,415	$592,985	$32,876	$3,368,684
50-99	$57,506	$330	$433,092	$22,527	$253,091	$3,149	$769,695
100-249	$80,308	$1,551	$346,064	$41,377	$148,584	$1,849	$619,733
250-499	$46,189	$542	$227,457	$22,110	$134,108	$646	$431,051
500+	$33,135	$0	$161,565	$16,154	$146,284	$292	$357,430
Total	$431,978	$10,984	$3,670,620	$358,089	$1,827,166	$71,987	$6,370,824

Source: See previous tables.

4.4 Total Cost to U.S. Industry

4.4.1.1 High-Cost Option

When the costs for initial labelers and R/Rs are combined, the total cost to U.S. industry under the high-cost option can be estimated. Table 4-45 shows the first-year costs, recurring year costs, and annualized costs for all of the affected U.S. medical device industry. The total first-year costs are $501.2 million, recurring costs are $83.4 million per year and the total annualized cost of the high-cost option is $154.8 million per year.

Table 4-45. Total Investment and Annual Recurring Costs for UDI Implementation under the Final Rule—Manufacturers, Reprocessors, Specification Developers, and Relabelers/Repackagers—under the High-Cost Option

Cost Element	First-Year	Annual Recurring
Labeling and Database Requirements		
Administration and planning	$132,372,411	NA
Registration costs	$2,156,044	NA
Equipment and other investments	$82,803,532	$39,573,903
Incremental label cost	NA	$10,383,416
Label redesign cost	$47,724,259	NA
Software (with training)	$192,284,848	$23,136,495
Recordkeeping and reporting		
-GUDID costs	$28,945,870	$9,175,709
Total Labeling and Database Requirements	$486,286,965	$82,269,523
Direct Marking		
Total Direct Marking	$14,919,691	$1,141,787
Total	**$501,206,657**	**$83,411,310**
Annualized Investment Total (a)	-	**$71,360,552**
Total Annualized Costs for Industry	-	**$154,771,862**

(a) First-year costs are annualized at 7 percent over 10 years.
Source: See previous tables.

4.4.1.2 Low-Cost Option

When the costs for initial labelers and R/Rs are combined, the total cost to U.S. industry under the low-cost option can be estimated. Table 4-46 shows the first-year costs, recurring year costs, and annualized costs for all of the affected U.S. medical device industry. The total first-year costs are $110.1 million, recurring costs are $13.8 million per year and the total annualized cost of the low-cost option is $29.5 million per year.

Table 4-46. Total Investment and Annual Recurring Costs for UDI Implementation for Medical Device Manufacturers and R/Rs under the Low-Cost Option

Cost Element	First-Year	Annualized and Recurring
Administration and planning	$16,433,727	NA
Barcode registration costs	$2,156,044	NA
Equipment and other investments	NA	NA
Direct marking	$14,919,691	$1,141,787
Incremental label material cost	NA	$3,463,531
Label redesign cost	$47,622,517	NA
Software (with training)	NA	NA
GUDID	$28,945,870	$9,175,709
Total	$110,077,850	$13,781,028
Annualized Investment Total (a)	-	$15,672,609
Total Annualized Costs	-	$29,453,637

(a) First-year costs are annualized at 7 percent over 10 years.
Source: See previous tables.

4.4.1.3 Selected Option

When the cost savings for initial labelers and R/Rs are combined and subtracted from the costs of the high-cost option, the total cost to U.S. industry under the selected option can be estimated. Table 4-47 shows the first-year costs, recurring year costs, and annualized costs for all of the affected U.S. medical device industry. The total first-year costs are $356.6 million, recurring costs are $55.2 million per year and the total annualized cost of the selected option is $106.0 million per year.

4.5 Costs to Issuing Agencies

Costs to issuing agencies remain the same as that estimated in ERG (2012) except that the wage rate of a software developer has been changed from the rate used in the economic analysis report for the proposed rule. To be consistent with other management level rates used for industry, we are using the same $75/hour rate used to calculate costs to automate labeler lists. Additionally we are assuming these costs apply to three agencies, rather than just two. An additional issuing agency has been added because of FDA's decision that ISBT 128 meets the requirements of UDI, which may involve a separate issuing agency. These costs are incurred under all three options. First year costs, as shown in Table 4-48, are $0.8 million, with recurring costs of $82,200.

Table 4-47. Total Costs Savings and Total Costs of the Selected Option

Cost Element	First-Year High-Cost Option	Selected Option First-Year Cost Savings	First Year Cost of Selected Option	Annual Recurring High-Cost Option	Selected Option Recurring Cost Savings	Recurring Cost of Selected Option
Labeling and Database Requirements						
Administration and planning	$132,372,411	$46,014,642	$86,357,769	NA	NA	NA
Registration costs	$2,156,044	$107,335	$2,048,710	NA	NA	NA
Equipment and other investments	$82,803,532	$35,275,653	$47,527,879	$39,573,903	$17,013,352	$22,560,550
Incremental label cost	NA	NA	NA	$10,383,416	$1,959,907	$8,423,509
Label redesign cost	$47,724,259	$0	$47,724,259	NA	NA	NA
Software (with training)	$192,284,848	$60,812,864	$131,471,984	$23,136,495	$8,475,629	$14,660,866
Recordkeeping & Reporting (GUDID)	$28,945,870	$2,405,640	$26,540,230	$9,175,709	$763,244	$8,412,466
Total Labeling and Database Requirements	$486,286,965	$144,616,135	$341,670,830	$82,269,523	$28,212,132	$54,057,391
Direct Marking						
Total Direct Marking	$14,919,691	$0	$14,919,691	$1,141,787	$0	$1,141,787
Total	**$501,206,657**	**$144,616,135**	**$356,590,521**	**$83,411,310**	**$28,212,132**	**$55,199,178**
Annualized Investment Total (a)	-					**$50,770,468**
Total Annualized Costs for Industry	-					**$105,969,646**

(a) First-year costs are annualized at 7 percent over 10 years.

Source: See previous tables.

Note: GMP-Exempt exclusion cost savings are not fully reflected in administration & planning costs and are not reflected at all in incremental label costs and GUDID costs. Class I savings for a small portion of incremental label costs (costs of coordinating labels with contract printers) are also not reflected in the incremental label costs.

Table 4-48. Cost to Issuing Agencies for Meeting FDA Requirements

Cost Element	Number of Hours	Wages (a)	Total Cost
First-year Costs			
Informing labelers of requirements	80	$75	$18,000
Set up list of labelers (to automate data collection)	20	$75	$4,500
Initial application	80	$75	$18,000
Executive and legal reviews	Not est.	NA	$750,000
Aggregate First-Year Investment	**NA**	**NA**	**$790,500**
Recurring Costs			
Maintaining a list of labelers	12	$75	$2,700
Application renewal	20	$75	$4,500
Recurring executive and legal reviews (10 percent of first year)	Not est.	NA	$75,000
Aggregate Recurring Costs	**NA**	**NA**	**$82,200**

(a) Wage rate of $75 reflects management wage plus fringe.
Note: These costs are estimated assuming that any costs associated with the inability to reuse numbers when a device is discontinued (as is currently done) will be negligible. Additionally, GS1 and HIBCC generally require a change in the UDI if there is a significant change to the product. It is assumed that any changes that require a UDI change by FDA would also require a change by GS1 and HIBCC or trading partners.
Source: Based on data from GS1 (assuming UDI is the GTIN) and HIBCC (assuming UDI is the HIBC) websites. Identification numbers offered by these organizations include barcoding capability (AIDC technology) and an option for production identifiers and appear to match the rule requirements, assuming the organizations are in compliance with ISO/IEC 15459-4.

4.6 Costs to Foreign Establishments under the Selected Option

The costing analysis for the foreign establishments is developed only for the selected option. It uses most of the assumptions that were used to construct the costs for domestic establishments, relying on the assumptions about foreign establishment "size" as discussed in Section 3.1.5. As indicated in this section, ERG is not considering initial labelers and R/Rs separately. There are relatively few R/Rs and these are assigned the costs associated with initial labelers, which may overstate costs somewhat. As Section 3.1.5 discussed, we have mapped costs and/or assumptions in many cases from U.S. establishment sizes to foreign establishments by assuming that numbers of U.S. listings at establishments equate generally to the complexity of operations seen at U.S operations, which is believed to be reflected in the numbers of employees. Employment size at foreign establishments is not relevant because a foreign establishment may produce many other device types domestically or for other non-U.S. markets. The number of U.S. listings, however, points to numbers of lines devoted to U.S. exports, which we have mapped to sizes of establishments in the U.S. Numbers of employees is a more consistent measure of

device production complexity in the U.S. because very little production in the U.S. is listed as for export only; virtually all of a U.S. establishment's employment is engaged in production affected by UDI requirements.

One of the complicating factors in the analysis of foreign establishments is the potential range of production methods in countries such as Switzerland vs. countries such as Pakistan. Clearly, there are large differences in capital to labor ratios and wages between most of the Tier 1 countries and most of the non-Tier 1 countries. To take these differences into account, ERG is analyzing the Tier 1 countries separately from the non-Tier 1 countries and making different assumptions about how a labor-intensive country might tackle the challenges of meeting UDI requirements differently than those made for U.S. establishments (Tier 1 countries are assumed to take a similar route to compliance as the U.S., however). Note that because of the potential for great variations among the manufacturing processes in so many different countries, and because of numerous other unknowns, ERG considers the cost estimates presented here to be considerably more uncertain than those estimates made for U.S. establishments. We investigate the impact of uncertainty on the foreign establishment cost estimates discussed below in Section 7, Uncertainty Analysis.

ERG first investigated the difference in wages. We used wage adjustment factors based on a measure of per-capital GDP adjusted by purchasing power parity (PPP).[14] Because so many countries are involved, to simplify the analysis, ERG investigated the estimated wage differentials between the U.S. and the top 20 foreign countries by numbers of listings (see Table 3-2 in Section 3). These top 20 countries were split into Tier 1 and other, then the weighted average (weighted by percentage of listings among each of the two groups) of the adjusted per-capita GDP for Tier 1 and non-Tier 1 countries was estimated. Table 4-49 shows the results of this analysis. As the table shows, adjusted per-capita GDP in the Tier 1 countries analyzed averages about 77 percent of the equivalent U.S. figure, while among the non-Tier 1 countries in the top 20 countries, adjusted per-capita GDP averages about 28 percent of the U.S figure. Although not all countries have been included in this analysis, the overall share of device listings among establishments in the top 20 countries is 89 percent. Thus, the countries not evaluated should have a relatively small influence on these percentages.

ERG is assuming that materials, equipment, and software costs, as applicable, do not change from those costs faced by U.S. establishments, since much of these capital goods might be purchased in the global marketplace. This could overstate costs to the extent that these goods can be purchased from domestic sources.

[14] PPP is "the rate at which the currency of one country would have to be converted into that of another country to buy the same amount of goods and services in each country." (http://www.imf.org/external/pubs/ft/fandd/basics/ppp.htm)

Table 4-49. Calculation of Wage Adjustment Factors

Tier 1 Countries						Other Countries					
Country Name	**Total Device Listings**	**% of Device Listings**	**Per Capita GDP (PPP)**	**Weighted Per Capita GDP**		**Country Name**	**Total Device Listings**	**% of Device Listings**	**Per Capita GDP (PPP)**	**Weighted Per Capita GDP**	
Germany	11,083	42%	$39,100	$16,442		China	7,028	36%	$9,100	$3,285	
Great Britain	2,972	11%	$36,700	$4,138		Pakistan	3,870	20%	$2,900	$577	
Japan	2,627	10%	$36,200	$3,608		Mexico	2,479	13%	$15,300	$1,948	
France	1,679	6%	$35,500	$2,262		Taiwan	2,240	12%	$38,500	$4,430	
Switzerland	1,663	6%	$45,300	$2,858		India	1,604	8%	$3,900	$321	
Canada	1,640	6%	$41,500	$2,582		South Korea	959	5%	$32,400	$1,596	
Italy	1,066	4%	$30,100	$1,217		Malaysia	853	4%	$16,900	$741	
Ireland	1,047	4%	$41,700	$1,657		Hong Kong	434	2%	$50,700	$1,130	
Sweden	920	3%	$41,700	$1,456							
Israel	758	3%	$32,200	$926							
Denmark	521	2%	$37,700	$745							
Netherlands	380	1%	$42,300	$610							
Total	26,356	100%		$38,502		Total	19,467	100%		$14,029	
Total U.S. per capita GDP					$49,800	Total U.S. per capita GDP					$49,800
Wage adjustment factor					**77%**	**Wage adjustment factor**					**28%**

Source: Total devices listings based on FDA Registration & Listing Database, online version, March 4, 2010 (FDA, 2010). Estimates of per capita GDP adjusted by purchasing power parity (PPP) were downloaded from the CIA World Factbook on March 4, 2013 at https://www.cia.gov/library/publications/the-world-factbook/rankorder/2004rank.html.

ERG used the calculated wage adjustment percentages by country group to adjust wages downwards. Thus all labor cost categories shown in the preceding sections have been adjusted by the factor of 77 percent (for Tier 1 countries) and 28 percent (for non-Tier 1 countries).

The estimated numbers of establishments by type of country and by size and by whether the establishment will be subject to static barcoding requirements under the selected option (establishments labeling only Class I devices) or variable barcoding requirements (all others) were presented in Section 3.1.2, Table 3-3. These counts are used as the basis of assigning and aggregating costs in the sections below. No foreign establishments are assumed to be GMP exempt, custom manufacturers or UPC-only establishments.

We discuss, first, the costs to establishments in Tier 1 countries in Section 4.6.1. Costs to non-Tier 1 countries are then discussed in Section 4.6.2. Costs for DM, however, are discussed separately in Section 4.6.3. Section 4.6.4 discusses the total costs to foreign establishments, adding in the costs for DM.

4.6.1 Tier 1 Countries

4.6.1.1 Class I Only Establishments

Other than the wage adjustments discussed above, basically all assumptions remain the same for the Class I only establishments in Tier 1 countries as those for Class I only U.S. establishments. Table 4-50 presents the per-establishment costs and aggregate costs by establishments grouped by ranges of listings ("size") that are calculated as discussed below. Most of the respective per-establishment or per-firm costs for U.S. establishments can be seen throughout Section Four under the low cost option.

Planning and administrative costs on a per establishment basis are all labor costs, so they are adjusted downwards using the 77 percent factor to represent that Tier 1 wages might average about 77 percent of U.S. wages. The per-establishment costs are based on the low-cost option cost planning costs for this group of establishments.

As for U.S. entities, only the smallest foreign establishments are expected not to have registered barcodes, and these costs per entity remain the same as that for U.S. firms (we assumed firm = establishment in this analysis for simplicity, which might overstate costs if firms own several foreign establishments). Static barcoding requirements do not trigger needs for printing equipment, so this cost is estimated to be $0.

Incremental label materials and label redesign costs, however, will be incurred; 10 percent of establishments (like that for the U.S. establishments) are assumed to require new date stamps. Label material costs do not have a labor component in this group of establishments, so those costs remain the same. Label redesign costs are predominantly labor costs. Non -labor costs could include label inventory that might be lost among establishments with short implementation requirements and printing plate changes might be incurred among establishments not using digital printing techniques but these are expected to constitute a very small percentage of costs. Thus, per-establishment label redesign costs are

Table 4-50. Costs for Establishments with Class I Devices (only) in Tier 1 Countries

Cost	Establishment Costs by Size Class						
	1 Listing	**2-3 Listings**	**4-10 Listings**	**11-25 Listings**	**26-50 Listings**	**51-100 Listings**	**101+ Listings**
Tier 1, Class I Countries	648	508	296	77	37	11	8
Administration and Planning							
Per establishment cost	$1,120	$1,120	$2,899	$2,968	$4,909	$5,255	$5,948
Total cost	$725,987	$569,138	$858,119	$228,563	$181,624	$57,808	$47,586
Barcode Registration							
Per establishment cost	$500	$500	$500	$0	$0	$0	$0
Total cost	$324,000	$254,000	$148,000	$0	$0	$0	$0
Incremental Label Materials							
Per establishment cost	$47	$47	$254	$999	$3,621	$5,886	$37,555
Total cost	$30,218	$23,689	$75,104	$76,919	$133,991	$64,741	$300,443
Label Redesign							
Per establishment cost	$963	$1,925	$3,850	$7,700	$15,400	$38,500	$57,750
Total cost	$623,700	$977,900	$1,139,600	$592,900	$569,800	$423,500	$462,000
GUDID First Year							
Per establishment cost	$1,723	$3,321	$4,716	$3,316	$5,684	$8,571	$22,691
Total cost	$1,116,423	$1,686,878	$1,396,010	$255,318	$210,292	$94,282	$181,528
GUDID Recurring							
Per establishment cost	$511	$1,070	$1,558	$1,014	$1,751	$2,761	$7,518
Total cost	$330,873	$543,468	$461,253	$78,096	$64,770	$30,373	$60,147
Date Stamp							
Per establishment cost	$15	$15	$15	$15	$45	$75	$120
Total cost	$9,720	$7,620	$4,440	$1,155	$1,665	$825	$960

Source: Previous tables and ERG estimates.

adjusted downward using the 77 percent factor under the assumption that the change in the percentage needed to characterize this adjustment accounting for a small percentage of non-labor costs is negligible. The date stamp costs (installation costs) do have a labor component, but these costs are so small to begin with, ERG has not estimated any difference in per-establishment costs for this cost item. See label redesign, date stamp, and incremental label materials costs for the low-cost option in Section 4.2.6.1.

Software costs are not incurred at Class I only establishments. GUDID costs per establishment are assumed all labor costs and so are adjusted downwards by the 77 percent factor.

Table 4-51 presents the aggregation of the per-establishment costs shown in Table 4-50. As the table shows, the total costs to Class I only Tier 1 establishments is $13.2 million in first year costs, $2.3 million per year in recurring costs, and $4.1 million per year in annualized costs.

Table 4-51. Aggregate Costs for Establishments with Class I Devices (only) in Tier 1 Countries (Excluding DM)

Cost Element	First-Year	Annualized and Recurring
Administration and planning	$2,668,824	$0
Barcode registration costs	$726,000	$0
Equipment and other investments	$0	$0
Incremental label materials	$0	$705,104
Label redesign and date stamps	$4,815,785	$0
Software (with training)	$0	$0
GUDID	$4,940,729	$1,568,980
Total	$13,151,338	$2,274,084
Annualized Investment Total (a)	-	$1,872,455
Total Annualized Costs	-	$4,146,538

(a) First-year costs are annualized at 7 percent over 10 years.
Source: See previous tables.

4.6.1.2 Other Establishments

Other establishments, which label a mix of devices, including Class II and Class III devices, are subject to variable barcoding requirements. These establishments will have additional costs, such as printing equipment and software costs. Additionally, other cost items are sometimes more expensive because of the additional complexities of meeting variable barcoding requirements. The per-establishment costs of each of the cost items discussed below for U.S. establishments can be seen in tables associated with the high-cost option in the U.S. establishment analysis. Table 4-52 presents the per-establishment costs estimated for foreign establishments that label at least some Class II and/or Class III devices. The adjustments made to these costs relative to the costs estimated for U.S. establishments are discussed below.

Table 4-52. Costs for Establishments with Other than Class I Devices in Tier 1 Countries

Cost	Establishment Costs by Size Class						
	1 Listing	**2-3 Listings**	**4-10 Listings**	**11-25 Listings**	**26-50 Listings**	**51-100 Listings**	**101+ Listings**
Tier 1, Other Countries	394	531	568	316	127	63	44
Planning and Administration							
Per establishment cost	$3,066	$3,222	$16,285	$26,796	$59,436	$92,214	$141,555
Total cost	$1,208,194	$1,711,074	$9,250,064	$8,467,425	$7,548,321	$5,809,491	$6,228,430
Barcode Registration							
Per establishment cost	$500	$500	$500	$0	$0	$0	$0
Total cost	$197,000	$265,500	$284,000	$0	$0	$0	$0
Equipment First Year							
Per establishment cost	$374	$374	$21,104	$21,104	$21,913	$35,108	$45,279
Total cost	$147,484	$198,767	$11,987,127	$6,668,895	$2,782,971	$2,211,797	$1,992,270
Equipment Recurring							
Per establishment cost	$37	$37	$7,415	$7,415	$12,843	$24,833	$40,092
Total cost	$14,436	$19,455	$4,211,557	$2,343,049	$1,631,054	$1,564,449	$1,764,055
Incremental Label Materials							
Per establishment cost	$2,934	$2,934	$6,029	$12,549	$49,821	$75,186	$176,155
Total cost	$1,156,048	$1,558,024	$3,424,318	$3,965,467	$6,327,314	$4,736,689	$7,750,835
Label Redesign							
Per establishment cost	$963	$1,925	$3,850	$7,700	$15,400	$38,500	$57,750
Total cost	$379,225	$1,022,175	$2,186,800	$2,433,200	$1,955,800	$2,425,500	$2,541,000
Software First Year							
Per establishment cost	$748	$10,575	$25,770	$25,770	$68,480	$163,167	$446,149
Total cost	$294,521	$5,615,325	$14,637,360	$8,143,320	$8,696,960	$10,279,529	$19,630,534
Software Recurring							
Per establishment cost	$57	$1,757	$4,092	$4,092	$9,589	$21,766	$48,159
Total cost	$22,372	$933,073	$2,324,199	$1,293,040	$1,217,809	$1,371,279	$2,119,006

Cost	Establishment Costs by Size Class						
	1 Listing	**2-3 Listings**	**4-10 Listings**	**11-25 Listings**	**26-50 Listings**	**51-100 Listings**	**101+ Listings**
GUDID First Year							
Per establishment cost	$1,723	$3,321	$4,716	$3,316	$5,684	$8,571	$22,691
Total cost	$678,813	$1,763,252	$2,678,830	$1,047,797	$721,812	$539,977	$998,401
GUDID Recurring							
Per establishment cost	$511	$1,070	$1,558	$1,014	$1,751	$2,761	$7,518
Total cost	$201,179	$568,074	$885,107	$320,498	$222,319	$173,954	$330,806
Date Stamp							
Per establishment cost	$15	$15	$15	$15	$45	$75	$120
Total cost	$5,910	$7,965	$8,520	$4,740	$5,715	$4,725	$5,280

Source: Previous tables and ERG estimates.

Planning and administrative costs are all labor costs so they are adjusted downward by the 77 percent factor (see Table 4-2 which provides the per-establishment cost estimates for establishments subject to variable barcoding requirements).

Barcode registration costs are assigned only to smaller foreign establishments because we assume the larger establishments have already registered, similar to the assumption made for U.S. firms. Costs per registrant remain the same as in the U.S. analysis.

Equipment costs are more complicated. The overall assumptions of how establishments will respond to the UDI requirements have not changed, and the foreign establishments are mapped to numbers of production lines in a similar manner to their U.S. counterparts (as designated by the size mapping discussed in Section 3.2). However, some of the equipment costs have a labor component. Because installation is estimate to be 1.25 times equipment costs, the total costs of equipment and installation are divided by 2.25 to estimate the capital portion of equipment costs[15]. Engineering and installation tasks are considered to be predominately labor costs (75 percent). O&M costs (which are 10% of total equipment and installation costs) are assumed to be 50 percent labor. Verifier operator costs are 100 percent labor (these costs, shown in Table 4-9 in aggregate are divided by the number of establishments estimated to incur those costs, depending on numbers and types of production lines). As shown in Table 4-53 the costs per establishment, divided into labor groupings and equipment groupings for both first year and recurring year costs, range from $374 to $45,279 for first year costs and from $37 to $40,092 for recurring year costs, depending on size/number of estimated production lines.

Label materials costs, as discussed in Section 4.2.6 , also have two components, the materials themselves, and a labor cost for coordinating printing with outside printers for the establishments estimated to continue to outsource their labeling. The labor component is adjusted downward by the 77 percent wage factor; the materials costs are not adjusted. To the extent that labeling materials are available domestically, this may overstate materials costs.

Label redesign costs have a very minor non-labor component. For simplicity, therefore, the entire cost per establishment is adjusted downwards by the 77 percent factor.

The same date stamp assumptions are made for this group of establishments as was made for the Class I establishments, although this might overstate the costs to this group, given that the switch to variable printing might change these establishments' methods of printing dates on packaging. The cost effect is very small, in any case.

[15] cap cost + 1.25*cap cost (i.e., installation cost) = total equipment cost plus installation, therefore 2.25*cap cost = total equipment cost plus installation. This means that cap cost = total equipment cost plus installation/2.25.

Table 4-53. Derivation of Foreign Equipment Costs

Cost Item	1 Line Manual	Automatic Lines			
		1 line	2-3 lines	4-5 lines	6+ lines
U.S. Estimates of Per-Establishment Equipment Costs					
Domestic per-establishment estimate of equipment plus installation	$414	$23,341	$24,236	$38,829	$50,078
Portion due to equipment cost	$184	$10,374	$10,771	$17,257	$22,257
Portion due to installation	$230	$12,967	$13,464	$21,572	$27,821
Portion of installation due to labor	$173	$9,725	$10,098	$16,179	$20,866
Portion of installation due to equipment	$58	$3,242	$3,366	$5,393	$6,955
Costs of verifier operation	$0	$6,947	$13,894	$27,787	$46,312
Portion of O&M costs assumed labor	$21	$1,167	$1,212	$1,941	$2,504
Portion of O&M costs assumed materials	$21	$1,167	$1,212	$1,941	$2,504
Total first-year labor costs	$173	$9,725	$10,098	$16,179	$20,866
Total recurring-year labor costs	$21	$8,114	$15,105	$29,729	$48,816
Tier 1 Country Labor and Equipment Costs					
First year labor costs assuming a 77 percent of U.S. wages factor	$133	$7,489	$7,776	$12,458	$16,067
Equipment	$242	$13,616	$14,138	$22,650	$29,212
Total first year costs	**$374**	**$21,104**	**$21,913**	**$35,108**	**$45,279**
Recurring year costs	**$37**	**$7,415**	**$12,843**	**$24,833**	**$40,092**
Non-Tier 1 Country Labor and Equipment Costs					
First year labor costs assuming a 28 percent of U.S. wages factor	$48	NA	$2,828	$4,530	$5,842
Equipment	$242	NA	$14,138	$22,650	$29,212
Total first-year costs	**$290**	NA	**$16,965**	**$27,180**	**$35,055**
Recurring-year costs	**$26**	NA	**$5,441**	**$10,265**	**$16,172**

Source: From Table 4-9.
Note: All non-Tier 1 establishments are assumed to use multiple manual lines up to a listing size equated with 2-3 automated lines, which is why the 1 automated line category is shown with NAs.

To calculate the effects of any adjustments on software costs, ERG split the costs per firm shown in Table 4-19 in Section 4.2.7.1 into those for labor and software, for first year costs, and between labor and maintenance contracts for recurring costs. Software and maintenance contracts are assumed unaffected by labor adjustments because of the likelihood that the software firms are primarily U.S.-based or compete in the U.S. market so U.S. costs apply worldwide. Table 4-54 shows the split between these costs and the estimated per firm costs generated assuming that the labor components are adjusted downwards by 77 percent. The first-year costs for Tier 1 country establishments range from $748 to $736,000 and the recurring costs range from $57 to $80,000. As noted earlier, ERG assumes that

Table 4-54. Derivation of Foreign Software Costs

	Employment Size by Firm						
Cost Item	**Smallest (1-4)**	**Small (5-19)**	**Medium (20-99)**	**Large (100-199)**	**Larger (200-499)**	**V. Large (500-999)**	**Largest (1000+)**
Maps to Listing Size	1	2-3	4-25	26-99	51-100	101+	NA
Domestic Cost Breakouts							
Labor cost first year	$700	$3,000	$12,000	$46,000	$137,500	$475,000	$775,000
Non-labor first year	$209	$8,265	$16,530	$33,060	$57,292	$80,399	$139,357
Labor cost recurring	$25	$350	$1,450	$4,725	$14,875	$43,750	$71,250
Recurring non-labor	$38	$1,488	$2,975	$5,951	$10,313	$14,472	$25,084
Tier 1 Countries Software Costs							
Labor costs first year (77 percent U.S. wage factor)	$539	$2,310	$9,240	$35,420	$105,875	$365,750	$596,750
Non-labor first year	$209	$8,265	$16,530	$33,060	$57,292	$80,399	$139,357
Labor cost recurring	$19	$270	$1,117	$3,638	$11,454	$33,688	$54,863
Recurring non-labor	$38	$1,488	$2,975	$5,951	$10,313	$14,472	$25,084
Total first-year costs	**$748**	**$10,575**	**$25,770**	**$68,480**	**$163,167**	**$446,149**	**$736,107**
Recurring-year costs	**$57**	**$1,757**	**$4,092**	**$9,589**	**$21,766**	**$48,159**	**$79,947**
Non-Tier 1 Countries Software Costs							
Labor costs first year (28 percent U.S. wage factor)	NA	NA	NA	$12,880	$38,500	$133,000	$217,000
Non-labor first year	NA	NA	NA	$33,060	$57,292	$80,399	$139,357
Labor cost recurring	NA	NA	NA	$1,323	$4,165	$12,250	$19,950
Recurring non-labor	NA	NA	NA	$5,951	$10,313	$14,472	$25,084
Total first-year costs	**NA**	**NA**	**NA**	**$45,940**	**$95,792**	**$213,399**	**$356,357**
Recurring-year costs	**NA**	**NA**	**NA**	**$7,274**	**$14,478**	**$26,722**	**$45,034**

Source: Table 4-19.

establishments equal firms. This assumption might overstate costs to the extent that one firm owns several establishments and can consolidate software costs at the firm level.

GUDID costs are all labor costs. These costs are adjusted downwards by the 77 percent wage factor.

The results of these adjustments can be seen in Table 4-55. Total first-year costs to this group of foreign establishments are estimated to be $155.7 million, with recurring costs totaling $52.4 million per year. The total annualized costs to these foreign establishments are estimated to be $74.6 million per year.

Table 4-55. Aggregate Costs for Establishments with Other than Class I Devices in Tier 1 Countries

Cost Element	First-Year	Annualized and Recurring
Administration and planning	$40,222,998	$0
Barcode registration costs	$746,500	$0
Equipment and other investments	$25,989,311	$11,548,055
Incremental label materials cost	$0	$28,918,696
Label redesign and date stamp cost	$12,986,555	$0
Software (with training)	$67,297,549	$9,280,780
GUDID	$8,428,882	$2,701,938
Total	$155,671,795	$52,449,469
Annualized Investment Total (a)	-	$22,164,161
Total Annualized Costs	-	$74,613,630

(a) First-year costs are annualized at 7 percent over 10 years.

Source: See previous tables.

4.6.2 Non-Tier 1 Countries

4.6.2.1 Class I Only Establishments

Most of the assumptions discussed for the Class I only Tier 1 country establishments apply to the Class I only non-Tier 1 country establishments, except that the wage adjustment factor used is 28 percent. We discuss each of the major cost categories where the assumptions (other than wage rate) change from Class I Tier 1 establishments.

For barcode registration, we assume no establishments currently have registered barcodes. This may be unlikely, especially among the largest establishments, but is used is a conservative assumption, given that no information is available on the prevalence of barcoding or barcode registration in these countries.

We assume that foreign establishments that label up to 25 listings will use manual methods to handle GUDID data gathering and uploading. These assumptions are based on assumptions used to compute hours for smaller U.S. establishments that use web-based entry. Costs of most listing sizes are assumed to map to either the manual or the automated (SPL uploading) approach used by U.S. establishments. Thus, foreign establishments with up to 10 listings are assumed to map to costs for U.S. establishments up to the 10-49 employee size group. The next U.S. size group, 50-99, is assumed to automate their process. However, the next foreign listing size group (with 11-25 listings) is assumed to continue to use manual methods for uploading. Foreign establishments with more than 25 listings are assumed to correspond to U.S. establishment sizes of 100-249 (those with 26-50 listings), 250-500 (those with 51-100 listings) and 500+ (those with 101+ listings). Because GUDID costs are all considered labor costs, we adjust the domestic GUDID costs by the wage factor of 28 percent (yielding $21/hour).

For the one listing size category that does not correspond well to U.S. size category cost assumptions, we assume this 11-25 listings group lists, on average, 20 devices and that 10 UDIs are associated with each listing for an average of 200 UDIs per establishment. First, we assume the number of hours for GMDN training and code lookup are the same as those for U.S. establishments in the 50-99 employee size group (16 hours for training and 30 hours for lookup). Next we calculate the other tasks, as follows: gathering of additional data for each GUDID entry is expected to take 30 minutes per UDI, or 100 hours. Manual entry of GUDID information is assumed to take 20 minutes per UDI, or 67 hours; validation and proofing of information is assumed to take 15 minutes per UDI, or 50 hours. These assumptions are the same as those used for the smaller U.S. establishments. All of these tasks total 263 hours, or $5,521 with the non-Tier 1 country wage assumption. Recurring costs are calculated as 35 percent of all costs not including GMDN-related training costs, which are assumed at 25 percent of first year costs to account for turnover. The other recurring costs are calculated as 35 percent of first-year costs to allow for possible code revision costs. Total recurring hours are estimated to be 90, at a cost of $1,899.

Table 4-56 shows the per-establishment costs by cost category, given these assumptions and adjustments.

Table 4-57 shows the aggregate costs to the Class I only foreign establishments. As the table shows, first-year costs are estimated to be $10.3 million, recurring year costs are estimated to be $2.3 million per year, and annualized costs are estimated to be $3.8 million per year.

4.6.2.2 Other Establishments

As for foreign establishments in Tier 1 countries that label a mix of devices including Class II and/or Class III devices, these types of establishments in non-Tier 1 countries will also face additional cost categories and higher per-establishment costs that the Class I only establishments (see the high-cost option costs for U.S. establishments as a reference). Table 4-58 presents the cost components and the estimated per-establishment costs that are calculated using the assumptions and adjustments discussed below.

Table 4-56. Costs for Establishments with Class I Devices (only) in Other (non-Tier 1) Countries

Cost	Establishment Costs by Size Class						
	1 Listing	**2-3 Listings**	**4-10 Listings**	**11-25 Listings**	**26-50 Listings**	**51-100 Listings**	**101+ Listings**
Class I other countries	617	787	605	224	78	19	6
Planning and Administration							
Per establishment cost	$407	$407	$1,054	$1,079	$1,785	$1,911	$2,163
Total cost	$251,366	$320,624	$637,791	$241,786	$139,230	$36,309	$12,978
Barcode Registration							
Per establishment cost	$500	$500	$500	$2,000	$2,000	$2,000	$10,000
Total cost	$308,500	$393,500	$302,500	$448,000	$156,000	$38,000	$60,000
Incremental Label Materials							
Per establishment cost	$47	$47	$254	$999	$3,621	$5,886	$37,555
Total cost	$28,772	$36,700	$153,506	$223,764	$282,467	$111,825	$225,332
Label Redesign							
Per establishment cost	$350	$700	$1,400	$2,800	$5,600	$14,000	$21,000
Total cost	$215,950	$550,900	$847,000	$627,200	$436,800	$266,000	$126,000
GUDID First Year							
Per establishment cost	$627	$1,208	$1,715	$5,521	$2,067	$3,117	$8,251
Total cost	$386,551	$950,303	$1,037,575	$1,236,760	$161,207	$59,218	$49,508
GUDID Recurring							
Per establishment cost	$186	$389	$567	$1,899	$637	$1,004	$2,734
Total cost	$114,561	$306,163	$342,823	$425,340	$49,652	$19,077	$16,404
Date Stamp							
Per establishment cost	$15	$15	$15	$15	$45	$75	$120
Total cost	$9,255	$11,805	$9,075	$3,360	$3,510	$1,425	$720

Source: Previous tables and ERG estimates.

Table 4-57. Aggregate Costs for Establishments with Class I Devices (only) in Other (non-Tier 1) Countries

Cost Element	First-Year	Annualized and Recurring
Administration and planning	$1,640,083	$0
Barcode registration costs	$1,706,500	$0
Equipment and other investments	$0	$0
Incremental label materials cost	$0	$1,062,366
Label redesign and date stamp cost	$3,109,000	$0
Software (with training)	$0	$0
GUDID	$3,881,120	$1,274,020
Total	$10,336,703	$2,336,386
Annualized Investment Total (a)	-	$1,471,714
Total Annualized Costs	-	$3,808,100

(a) First-year costs are annualized at 7 percent over 10 years.
Source: See previous tables.

Planning and administrative costs, which are labor costs, are reduced to 28 percent of U.S. establishment costs based on the wage adjustment factor.

Barcode registration costs are applied to all these establishments (as was done for the Class I only establishments in the non-Tier 1 countries). The per-establishments cost used are the same as those for the U.S. establishments.

For equipment costs, manual line operating costs are assumed to apply to all establishments handling up to 25 listings. The costs for one manual line (shown in Table 4-9 in Section 4.2.4.1) are applied to establishments operating 1 line, which includes those with 1 listing and those with 2-3 listings. Because automated lines are assumed to be equivalent to several lines, the costs for establishments with 4-10 listings (which in Tier 1 countries would be equated to those operating an automated line) are assigned a cost for 2.5 manual lines. For establishments operating 11-25 lines, the 1-line cost is multiplied by 4.5. Manual lines, where labels are applied by hand, do not pose the problems that automated lines do in changing labels during production processes. The last three sizes are computed similarly to the Tier 1 establishments that are subject to variable barcoding requirements (those establishments with 26-50 listings are assumed to operate 2-3 automated lines, those with 51-100 listings are assumed to operate 4-5 automated lines, and those with 101+ listings are assumed to operate 6+ lines. Table 4-53 in Section 4.6.1.2 shows the results of those calculations.

Table 4-58. Costs for Establishments with Other Than Only Class I Devices in Other (non-Tier 1) Countries

Cost	Establishment Costs by Size Class						
	1 Listing	**2-3 Listings**	**4-10 Listings**	**11-25 Listings**	**26-50 Listings**	**51-100 Listings**	**101+ Listings**
Other Countries, Other Devices	182	230	370	201	84	42	18
Planning and Administration							
Per establishment cost	$1,115	$1,172	$5,922	$9,744	$21,613	$33,532	$51,475
Total cost	$202,945	$269,507	$2,191,116	$1,958,518	$1,815,487	$1,408,361	$926,543
Barcode Registration							
Per establishment cost	$500	$500	$500	$2,000	$2,000	$2,000	$10,000
Total cost	$91,000	$115,000	$185,000	$402,000	$168,000	$84,000	$180,000
Equipment First Year							
Per establishment cost	$290	$290	$725	$1,304	$16,965	$27,180	$35,055
Total cost	$52,744	$66,654	$268,065	$262,124	$1,425,062	$1,141,573	$630,983
Equipment Recurring Year							
Per establishment cost	$26	$26	$66	$119	$5,441	$10,265	$16,172
Total cost	$4,822	$6,094	$24,509	$23,966	$457,069	$431,150	$291,102
Incremental Label Materials							
Per establishment cost	$1,097	$1,097	$2,354	$5,199	$20,421	$31,086	$87,955
Total cost	$199,587	$252,225	$870,880	$1,044,988	$1,715,395	$1,305,593	$1,583,196
Label Redesign							
Per establishment cost	$350	$700	$1,400	$2,800	$5,600	$14,000	$21,000
Total cost	$63,700	$161,000	$518,000	$562,800	$470,400	$588,000	$378,000
Software First Year							
Per establishment cost	$315	$945	$1,575	$6,300	$45,940	$95,792	$213,399
Total cost	$57,330	$217,350	$582,750	$1,266,300	$3,858,960	$4,023,269	$3,841,173
Software Recurring							
Per establishment cost	$79	$236	$394	$1,575	$7,274	$14,478	$26,722
Total cost	$14,333	$54,338	$145,688	$316,575	$610,999	$608,058	$480,991
GUDID First Year							
Per establishment cost	$627	$1,208	$1,715	$5,521	$2,067	$3,117	$8,251

Cost	Establishment Costs by Size Class						
	1 Listing	**2-3 Listings**	**4-10 Listings**	**11-25 Listings**	**26-50 Listings**	**51-100 Listings**	**101+ Listings**
Total cost	$114,023	$277,725	$634,550	$1,109,771	$173,607	$130,904	$148,523
GUDID Recurring							
Per establishment cost	$186	$389	$567	$1,899	$637	$1,004	$2,734
Total cost	$33,793	$89,476	$209,661	$381,666	$53,471	$42,171	$49,211
Date Stamp							
Per establishment cost	$15	$15	$15	$15	$45	$75	$120
Total cost	$2,730	$3,450	$5,550	$3,015	$3,780	$3,150	$2,160

Source: Previous tables and ERG estimates.

The labeling based costs (materials, coordination time, redesign costs and date stamps) are all estimated the same way as for Tier 1 establishments that label a mix of devices, except that the identified labor components are adjusted by the 28 percent factor rather than the 77 percent factor.

For software costs, we assume that all but the largest non-Tier 1 country establishments do not rely on software to handle UDI organizational tasks, but use more labor to handle these tasks up to the largest three sizes. A total of 1.5 hours per UDI initially is expected to ensure that all process records and other forms under conforming regulations contain the appropriate spaces to record UDIs, including the UDI production identifier. This is multiplied by the calculated wage rate for non-Tier 1 countries ($75*0.28, or $21/hour). Recurring costs are assumed to be 25 percent of these initial costs, since production number changes and other UDI changes will continue to need to be accounted for, but are assumed to entail relatively little incremental time, since other related information is being recorded at the same time. These costs are shown in Table 4-59 and range from $315 to $6,300 per establishment. For the largest establishments, software costs, as was done for Tier 1 establishments, are broken out so that the labor component can be adjusted downward by the 28 percent wage rate factor, leaving the software and maintenance contract costs unchanged from costs estimated for U.S. establishments. The results of the adjustment to labor using the 28 percent factor were shown in Table 4-54 in Section 4.6.1.2

Table 4-59. Derivation of Costs Assuming Small Non-Tier 1 Establishments Use Labor in Place of Software

Item	1 Listing	2-3 Listings	4-10 Listings	11-25 Listings
Average listings assumed	1	3	5	20
Number of UDIs (approx. 10 per avg. listings)	10	30	50	200
First-year costs (1.5 hours per UDI @ $21/hour)	$315	$945	$1,575	$6,300
Recurring-year costs (25 percent of first-year costs)	$79	$236	$394	$1,575

Source: ERG estimates.

GUDID costs per establishment are the same as those presented in Table 4-56 for non-Tier 1, Class I only establishments.

Table 4-60 presents the aggregate results of all of these costs with their associated adjustments and assumptions. The first-year cost to this group of establishments is $33.0 million. The recurring year costs are $11.3 million per year and the annualized costs are $16.0 million per year.

4.6.3 Direct Marking Costs

Direct marking costs apply to a subset of establishments in both Tier 1 and non-Tier 1 establishments, regardless of whether the establishment is considered a Class I only establishment or not. Thus this section discusses costs to Tier 1 establishments and non-Tier 1 establishments that are identified as labeling multiple use devices, regardless of other classes of devices labeled at those establishments.

As Table 4-61 shows, a total of 350 establishments in Tier 1 countries list multi-use devices. All assumptions remain the same for direct marking that were used to estimate costs for U.S. establishments, except for the labor adjustment factors. Tables 4-61 to 4-63 present the costs using the 77 percent wage adjustment factor for the Tier 1 establishments with multi-use devices. These tables present the cost estimates for requesting exemptions, for updating marking software where marking is assumed to already be done, and for purchasing, installing and operating the laser marking equipment among those establishments assumed to perform no marking.

Table 4-60. Aggregate Costs for Establishments with Other Than Class I Only Devices in Other (non-Tier 1) Countries

Cost Element	First-Year	Annualized and Recurring
Administration and planning	$8,772,479	$0
Barcode registration costs	$1,225,000	$0
Equipment and other investments	$3,847,204	$1,238,712
Incremental label materials cost	$0	$6,971,865
Label redesign cost	$2,765,735	$0
Software (with training)	$13,847,132	$2,230,981
GUDID	$2,589,102	$859,448
Total	$33,046,652	$11,301,007
Annualized Investment Total (a)	-	$4,705,100
Total Annualized Costs	-	$16,006,106

Source: ERG estimates.
(a) First-year costs are annualized at 7 percent over 10 years.

A total of 318 non-Tier 1 countries list multi-use devices, as can be seen in Table 4-63. Tables 4-64 to 4-66 present the same information for the non-Tier 1 multi-use establishments as was presented for those in the Tier 1 countries.

Table 4-67 presents the aggregate costs of direct marking to both establishment groups. First-year costs are estimated to be $18.1million and recurring year costs are estimated to be $1.2 million per year.

4.6.4 Total Costs to Foreign Establishments

Table 4-68 presents the total costs to all foreign establishments. As the table shows, when the aggregate costs across the four groups of establishments and the aggregate costs of direct marking are

Table 4-61. Costs for Tier 1 Establishments to Document Exceptions to the Direct Part Marking Requirements

Establishment Size	Estimated Estab. with Multi-Use Items	Number of Multi-Use Estab. Document-ing Exception	Assumed Products per Estabs. Affected	Cost per Estab. (a)	Total First Year Costs for Multi-Use Estabs.	New Products	Recurring Costs per Estab. (a)	Aggregate Recurring Costs
1 listing	21	1	1	$578	$606	0.3	$144	$152
2-3 listings	42	2	1	$578	$1,213	0.3	$144	$303
4-5 listings	81	4	2	$1,155	$4,678	1	$289	$1,169
6-10 listings	100	5	4	$2,310	$11,550	1	$578	$2,888
11-25 listings	54	3	10	$5,775	$15,593	3	$1,444	$3,898
26-100 listings	29	1	30	$17,325	$25,121	8	$4,331	$6,280
101+ listings	23	1	50	$28,875	$33,206	13	$7,219	$8,302
Total	350	18			$91,967			$22,992

(a) Assuming 10 hours per exception at a fully loaded wage rate of $58.

Source: ERG estimates. See ERG, 2012.

Table 4-62. Cost of Software Upgrades for Tier 1 Establishments Already Marking on Devices

Estab. Size	Total Number of Multi-Use Item Estabs.	Assumed Baseline Com-pliance Multi-Use Items	Aggregate Cost of Software Upgrade (a)	Per Estab. Cost of Redesign to Include Barcode (b)	Aggregate Cost of Redesign	Total Cost for Estabs. Already Marking
1 listing	21	75%	$7,560	$1,250	$15,750	$23,310
2-3 listings	42	75%	$15,120	$2,500	$63,000	$78,120
4-5 listings	81	75%	$29,160	$5,000	$243,000	$272,160
6-10 listings	100	75%	$36,000	$10,000	$600,000	$636,000
11-25 listings	54	75%	$19,440	$20,000	$648,000	$667,440
26-100 listings	29	75%	$10,440	$50,000	$870,000	$880,440
101+ listings	23	75%	$8,280	$75,000	$1,035,000	$1,043,280
Total	350		$126,000		$3,474,750	$3,600,750

Source: Table 4-11 and ERG estimates. See ERG, 2012.

(a) Design changes and software upgrades to allow barcodes to be printed are assumed to cost $594 ($600 in 2010; adjusted to 2012 dollars using the PPI ratio of 2012 to 2010 (BLS, 2013b)) among the 80 percent of establishments with DM equipment not currently barcoding.

(b) Redesign costs are assumed the same as redesign costs for main label (see ERG, 2012).

Table 4-63. Costs to Install and Operate Marking Equipment for Tier 1 Establishments Not Currently Marking Devices

Estab. Size	Total Number of Multi-Use Item Estabs.	Multi-Use Item Estab. Needing Equipment (a)	Assumed No. of Lines (b)	Capital Cost plus Installation for YAGs/High Speed Lasers per Estab. by Size (c)	Capital Cost plus Installation Assuming CO_2 Lasers	One Time Costs for Multi-Use Items (d)	Total O&M Costs (e)
1 listing	21	3	1	$79,647	$17,378	$59,063	$5,906
2-3 listings	42	3	1	$79,647	$17,378	$66,938	$6,694
4-5 listings	81	17	1	$79,647	$17,378	$334,688	$33,469
6-10 listings	100	18	1	$79,647	$17,378	$362,250	$36,225
11-25 listings	54	15	2	$159,294	NA	$2,393,141	$239,314
26-100 listings	29	6	4-6+	$530,376	NA	$3,028,316	$302,832
101+ listings	23	2	4-6+	$678,809	NA	$1,106,422	$110,642
Total	350	64				$7,350,816	$735,082

(a) Subtracts those applying for exceptions as calculated in Table 4-11 and assumes a 75 percent baseline compliance rate among multi-use device establishments.
(b) Assumptions about numbers of lines are the same as those used in Table 4-9.
(c) Includes engineering costs assumed at 75% of capital expenditures. Also assumes that two largest sizes install 1-2 fully automated lasers at $150,000 per laser. Only smaller operations are assumed to use CO_2 lasers due to high cost of materials.
(f) O&M assumed at 10 percent of one-time costs.
Source: ERG estimates and discussions with vendors (see ERG, 2012).

Table 4-64. Costs for Non-Tier 1 Establishments to Document Exceptions to the Direct Part Marking Requirements

Establishment Size	Estimated Estab. with Multi-Use Items	Number of Multi-Use Estab. Document-ing Exception	Assumed Products per Estabs. Affected	Cost per Estab. (a)	Total First Year Costs for Multi-Use Estabs.	New Products	Recurring Costs per Estab. (a)	Aggregate Recurring Costs
1 listing	15	1	1	$210	$158	0.3	$53	$39
2-3 listings	17	1	1	$210	$179	0.3	$53	$45
4-5 listings	85	4	2	$420	$1,785	1	$105	$446
6-10 listings	92	5	4	$840	$3,864	1	$210	$966
11-25 listings	73	4	10	$2,100	$7,665	3	$525	$1,916
26-100 listings	28	1	30	$6,300	$8,820	8	$1,575	$2,205
101+ listings	8	0	50	$10,500	$4,200	13	$2,625	$1,050
Total	318	16			$26,670			$6,668

(a) Assuming 10 hours per exception at a fully loaded wage rate of $75.

Source: ERG estimates. See ERG. 2012.

Table 4-65. Cost of Software Upgrades for Non-Tier 1 Establishments Already Marking on Devices

Estab. Size	Total Number of Multi-Use Item Estabs.	Assumed Baseline Com-pliance Multi-Use Items	Aggregate Cost of Software Upgrade (a)	Per Estab. Cost of Redesign to Include Barcode (b)	Aggregate Cost of Redesign	Total Cost for Estabs. Already Marking
1 listing	15	75%	$5,400	$1,250	$11,250	$16,650
2-3 listings	17	75%	$6,120	$2,500	$25,500	$31,620
4-5 listings	85	75%	$30,600	$5,000	$255,000	$285,600
6-10 listings	92	75%	$33,120	$10,000	$552,000	$585,120
11-25 listings	73	75%	$26,280	$20,000	$876,000	$902,280
26-100 listings	28	75%	$10,080	$50,000	$840,000	$850,080
101+ listings	8	75%	$2,880	$75,000	$360,000	$362,880
Total	318		$114,480		$2,919,750	$3,034,230

Source: Table 4-11 and ERG estimates. See ERG, 2012.
(a) Design changes and software upgrades to allow barcodes to be printed are assumed to cost $600 among the 80 percent of establishments with DM equipment not currently barcoding.
(b) Redesign costs are assumed the same as redesign costs for the main label (see ERG, 2012).

Table 4-66. Costs to Install and Operate Marking Equipment for Non-Tier 1 Establishments Not Currently Marking Devices

Estab. Size	Total Number of Multi-Use Item Estabs.	Multi-Use Item Estab. Needing Equipment (a)	Assumed No. of Lines (b)	Capital Cost plus Installation for YAGs/High Speed Lasers per Estab. by Size (c)	Capital Cost plus Installation Assuming CO_2 Lasers	One Time Costs for Multi-Use Items (d)	Total O&M Costs (e)
1 listing	15	3	1	$44,275	$9,660	$31,500	$3,150
2-3 listings	17	3	1	$44,275	$9,660	$35,700	$3,570
4-5 listings	85	17	1	$44,275	$9,660	$178,500	$17,850
6-10 listings	92	18	1	$44,275	$9,660	$193,200	$19,320
11-25 listings	73	15	2	$88,550	NA	$1,317,358	$131,736
26-100 listings	28	6	4-6+	$294,831	NA	$1,672,223	$167,222
101+ listings	8	2	4-6+	$377,344	NA	$611,142	$61,114
Total	318	64				$4,039,623	$403,962

(a) Subtracts those applying for exceptions as calculated in Table 4-64 and assuming a 75 percent baseline compliance rate among multi-use device establishments.

(b) Assumptions about numbers of lines are the same as those used in Table 4-9.

(c) Includes engineering costs assumed at 75% of capital expenditures. Also assumes that two largest sizes install 1-2 fully automated lasers at $150,000 per laser. Only smaller operations are assumed to use CO_2 lasers due to high cost of materials.

(f) O&M assumed at 10 percent of one-time costs.

Source: ERG estimates and discussions with vendors (see ERG, 2012).

Table 4-67. Aggregate Costs of DM for Foreign Establishments

Estab. Size	Number of Establish-ments	First-Year Exception Costs	Recurring Exception Costs	Upgrade Costs	First-Year Equipment Costs	Recurring Year Equipment Costs	Total First-Year Costs	Total Recurring Year Costs
1 listing	36	$764	$191	$39,960	$90,563	$9,056	$131,286	$9,247
2-3 listings	59	$1,391	$348	$109,740	$102,638	$10,264	$213,769	$10,612
4-5 listings	166	$6,463	$1,616	$557,760	$513,188	$51,319	$1,077,410	$52,934
6-10 listings	192	$15,414	$3,854	$1,221,120	$555,450	$55,545	$1,791,984	$59,399
11-25 listings	127	$23,258	$5,814	$1,569,720	$3,710,499	$371,050	$5,303,476	$376,864
26-100 listings	57	$33,941	$8,485	$1,730,520	$4,700,539	$470,054	$6,465,001	$478,539
101+ listings	31	$37,406	$9,352	$1,406,160	$1,717,564	$171,756	$3,161,130	$181,108
Total	668	$118,637	$29,659	$6,634,980	$11,390,439	$1,139,044	$18,144,056	$1,168,703

Source: Tables 4-60 to 4-65.

summed, first-year costs are estimated to be $230.4 million, recurring year costs are estimated to be $69.5 million per year, and annualized costs are estimated to be $102.3 million per year. As noted earlier, there is much uncertainty in these estimates. The uncertainty of these estimates is explored in Section 7.

4.7 Total Costs for All Affected Entities under the Selected Option (Immediate Implementation Scenario)

The total costs for all affected entities combines the costs to U.S. industry, the cost to foreign industry, and the cost for issuing agencies to comply with the requirements of the UDI rule. As Table 4-69 shows, these costs total $208.5 million, assuming that all costs are incurred immediately in the first year. Section 4.8, below, presents the costs for U.S. and foreign entities arrayed over the years in which costs are incurred, which leads to a smaller cost estimate for these entities because of the time value of money.

Table 4-68. Total Aggregate Cost for All Foreign Establishments under the Selected Option

Cost Element	First-Year	Annualized and Recurring
Administration and planning	$53,304,384	$0
Barcode registration costs	$4,404,000	$0
Direct marking	$18,144,056	$1,168,703
Equipment and other investments	$29,836,515	$12,786,768
Incremental label materials cost	NA	$37,658,031
Label redesign and date stamp cost	$23,677,075	NA
Software (with training)	$81,144,681	$11,511,761
GUDID	$19,839,834	$6,404,385
Total	$230,350,545	$69,529,648
Annualized Investment Total (a)	-	$32,796,735
Total Annualized Costs	-	$102,326,384

(a) First-year costs are annualized at 7 percent over 10 years.
Source: See previous tables.

Table 4-69. Costs of the Final Rule for All Affected Entities

Entity	One-Time Costs	Recurring Costs	Annualized One- Time Costs	Total Annualized Costs
Total Costs to Domestic Industry	$356,590,521	$55,199,178	$50,770,468	$105,969,646
Total Costs to Issuing Agencies	$790,500	$82,200	$112,549	$194,749
Total Costs to Foreign Industry (a)	$230,350,545	$69,529,648	$32,796,735	$102,326,384
Total Non-Federal Costs	**$587,731,566**	**$124,811,026**	**$83,679,753**	**$208,490,779**

Source: See previous tables.

4.8 Timing of Investments

This section presents the costs associated with the high-cost option and the selected option for U.S. industry, computed using a cost timing array that accounts for FDA's implementation schedule for the various Classes of devices and LS/LS devices. This array calculates the present value of costs incurred out over several years, ranging from 1 to 7 years. The present value of these costs is then annualized to estimate an average aggregate cost per year of the rule for the U.S. medical device industry. Costs to foreign establishments (for the selected option only) are also arrayed in this way. Given that the calculations in Section 4.6 already break out costs for Class I only establishments from those labeling a mix of devices, including Class II and Class III devices, arraying foreign costs is simpler than arraying those for U.S. establishments.

Also for simplicity, we are not arraying the costs of the static option for either U.S. or foreign establishments.

4.8.1 High-Cost Option (U.S. Only)

ERG generally follows the same methodology used in the economic report for the proposal with a few changes. First, we have broken out establishments with any LS/LS devices (except those who are already in the Class III category because they label any Class III device). These are almost all establishments previously identified as labeling Class I and/or Class II devices. Additionally, we have further modified the table to account for the fact that many Class I only establishments are likely to be those that are excepted from UDI requirements (i.e., they label custom devices only). This change reduces the percentage of Class I only devices and thus moves more of the costs a little earlier in the timing array table. Table 4-70 shows the percentages of Class I only establishments, Class I & II establishments without LS/LS devices, establishments with any LS/LS devices (except those that also label Class III devices) and establishments that label any Class III devices (and may include LS/LS devices) for the high cost option. This option excepts an estimated 1,740 custom device establishments. We removed 50 percent of these from the Class I only establishment totals and 50 percent from the Class I&II, no LS/LS device establishment totals, which reduces the percentages of both types of establishments. Originally, for example, Class I only establishments were estimated to make up 43.5 percent of all establishments. Class I only establishments not exempted from the rule now make up 41 percent of affected establishments.

As before, these distributions determine what portion of regulatory costs are incurred in each year, with Class III establishments incurring costs in the first year, LS/LS establishments incurring costs in Year 2, Class II establishments (without any LS/LS devices) incurring costs in Year 3, and Class I only establishments incurring costs in Year 5.[16] All multi-use devices are assumed Class I (virtually all

[16] As before, we assume that the first-year costs are incurred in the year of compliance, with half the recurring costs also being incurred in that year.

devices in the list provided by FDA are Class I) and thus costs for direct marking of these devices are incurred in Year 7. Note that costs for direct marking of implants have also been removed from Year 3, since these no longer apply, as shown in Table 4-71.

Table 4-70. Adjustments to Percentages of Establishments by Class to Account for Exceptions (High-Cost Option)

	Class I Only (No LS/LS)		Class I & II Only (No LS/LS)		Class I & II Only (With LS/LS)		Any Class III (May Have LS/LS)		
Type of Labeler	**No. of Estabs.**	**Percent**	**No. of Estabs.**	**Percent**	**No. of Estabs.**	**Percent**	**No. of Estabs.**	**Percent**	**Total**
Manufacturer	1,019	16.7%	1,503	24.7%	536	8.8%	359	5.9%	3,417
Reprocessor	8	0.1%	12	0.2%	1	0.0%	-	0.0%	21
Specification Developer	646	10.6%	475	7.8%	161	2.6%	64	1.1%	1,346
Repackager/Relabeler	828	13.6%	402	6.6%	59	1.0%	21	0.3%	1,310
All Labelers	2,501	41.0%	2,392	39.3%	757	12.4%	444	7.3%	6,094

Source: FDA, 2010.
Note: One R/R moves from Class I Only to Class I & II (with LS/LS).

Table 4-71 has changed somewhat from the version seen in ERG (2012). These changes were made to account for the LS/LS establishments, costs for which have been added as a separate line. Additionally, we have removed the line for label changes, since date changes are now assumed to be made at the same time the label is changed to accommodate UDI. Labeling costs are, therefore, added to the total first year costs that are distributed by type of establishment (Class III, LS/LS, etc.). The only other differences in this table from that shown in ERG (2012) occurs because of changes to the costs, which have been presented in the previous sections of this report.

As the table shows, under the high-cost option, the costs of the rule are reduced when timing assumptions are made. Assuming a discount rate of 7 percent over 10 years, the rule under the high-cost option would cost U.S. industry $108.0 million per year.

4.8.2 Selected Option (U.S. Only)

The timing array analysis uses a similar approach to that used for the high-cost option to array the costs of the selected option. This analysis is also similar to the one discussed in the economic report for the proposed rule (ERG, 2012), with some key differences.

The first difference is that ERG also recalculated the percentages of establishments by whether they were Class I, LS/LS, Class II without LS/LS or Class III devices to account for, not only the custom device establishments (as was done in Table 4-70), but also GMP-exempt devices. The result of this recalculation is shown in Table 4-72.

Table 4-71. Total Costs of the High-Cost Option to All U.S. Labelers with Timing of Outlays Occurring in Years Corresponding to Compliance Dates, Depending on Class (or Type) of Device Labeled

	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Year	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**
Industry Share	7.29%	12.42%	39.26%	0.00%	41.04%															
Class III	$38,425,227	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733	$5,993,733
LS/LS		$65,513,282	$10,219,045	$10,219,045	$10,219,045	$10,219,045	$10,219,045	$10,219,045	$10,219,045	$10,219,045	$10,219,045	$10,219,045	$10,219,045	$10,219,045	$10,219,045	$10,219,045	$10,219,045	$10,219,045	$10,219,045	$10,219,045
Class II			$207,045,266	$32,295,817	$32,295,817	$32,295,817	$32,295,817	$32,295,817	$32,295,817	$32,295,817	$32,295,817	$32,295,817	$32,295,817	$32,295,817	$32,295,817	$32,295,817	$32,295,817	$32,295,817	$32,295,817	$32,295,817
Class I					$216,437,951	$33,760,928	$49,251,513	$34,902,715	$34,902,715	$34,902,715	$34,902,715	$34,902,715	$34,902,715	$34,902,715	$34,902,715	$34,902,715	$34,902,715	$34,902,715	$34,902,715	$34,902,715
Reinvestment											$20,041,521		$107,989,004		$112,887,965		$10,668,380			
Total	$38,425,227	$71,507,015	$223,258,045	$48,508,595	$264,946,546	$82,269,523	$97,760,108	$83,411,310	$83,411,310	$83,411,310	$103,452,831	$83,411,310	$191,400,314	$83,411,310	$196,299,275	$83,411,310	$94,079,690	$83,411,310	$83,411,310	$83,411,310
PV at 7%	$38,425,227	$66,828,986	$195,002,223	$39,597,463	$202,126,452	$58,657,033	$65,141,688	$51,944,372	$48,546,142	$45,370,226	$52,590,174	$39,628,113	$84,984,029	$34,612,728	$76,128,243	$30,232,097	$31,868,046	$26,405,885	$24,678,397	$23,063,922
PV at 3%	$38,425,227	$69,424,287	$210,442,120	$44,392,236	$235,401,575	$70,966,414	$81,872,552	$67,821,028	$65,845,659	$63,927,824	$76,978,622	$60,258,105	$134,244,330	$56,799,044	$129,776,946	$53,538,546	$58,627,353	$50,465,214	$48,995,354	$47,568,305

NPV over 20 yrs. at 7%	$1,235,831,446
Annualized (7%, 20 yrs.)	$109,022,192
NPV over 20 yrs. at 3%	$1,665,770,739
Annualized (3%, 20 yrs)	$108,704,814
NPV over 10 yrs. at 7%	$811,639,812
Annualized (7%, 10 yrs.)	**$107,999,299**
NPV over 10 yrs. at 3%	$948,518,921
Annualized (3%, 10 yrs.)	$107,956,654

Source: ERG calculations. Total first-year and annual costs from Table 4-45. After 10 years, reinvestments in equipment and software are assumed. First-year costs for other items do not recur after 10 years. Half of recurring costs are assumed incurred in first year of implementation.

Table 4-72. Adjustments to Percentages of Establishments by Class to Account for Exceptions (Selected Option)

Type of Labeler	Class I Only (No LS/LS)		Class I & II Only (No LS/LS)		Class I & II Only (With LS/LS)		Any Class III (May Have LS/LS)		Total
	No. of Estabs.	Percent	No. of Estabs.	Percent	No. of Estabs.	Percent	No. of Estabs.	Percent	
Manufacturer	620	11.4%	1,503	27.8%	536	9.9%	359	6.6%	3,018
Reprocessor	7	0.1%	12	0.2%	1	0.0%	-	0.0%	20
Specification Developer	496	9.2%	475	8.8%	161	3.0%	64	1.2%	1,196
Repackager/Relabeler	699	12.9%	402	7.4%	59	1.1%	21	0.4%	1,181
All Labelers	1,822	33.6%	2,392	44.2%	757	14.0%	444	8.2%	5,415

Source: FDA, 2010 and ERG estimates.
Note: One R/R moves from Class I Only to Class I & II (with LS/LS).

The second difference is that ERG has refined the analysis to account for the fact that Class I only establishments, which are subject only to static barcoding requirements, are not expected to incur software- and equipment-related costs. They are also expected to face lower costs in a few other cost categories as well, but the two major cost differences are represented in the software and equipment categories. Thus, ERG is estimating the costs attributable to Class I only establishments based on the overall percentage of Class I only establishments shown in Table 4-72 to distribute costs that do not include software and equipment. We then used only the counts of Class II without LS/LS, LS/LS, and Class III establishments as a percentage of the sum of these establishments to distribute the remaining costs. The results of this redistribution of percentages can be seen in Table 4-73.

Table 4-73. Redistribution of Percentages across All Establishments Not Considered Class I Only

	Class I & II Only (No LS/LS)		Class I & II Only (With LS/LS)		Any Class III (May Have LS/LS)		
Type of Labeler	**No. of Estabs.**	**Percent**	**No. of Estabs.**	**Percent**	**No. of Estabs.**	**Percent**	**Total**
Manufacturer	1,503	41.8%	536	14.9%	359	10.0%	2,398
Reprocessor	12	0.3%	1	0.0%	-	0.0%	13
Specification Developer	475	13.2%	161	4.5%	64	1.8%	700
Repackager/Relabeler	402	11.2%	59	1.6%	21	0.6%	482
All Labelers	2,392	66.6%	757	21.1%	444	12.4%	3,593

Source: FDA, 2010, and ERG estimates.
Note: One R/R moves from Class I Only to Class I & II (with LS/LS).

The total first-year costs without equipment and software are $177.6 million. We distribute these costs assuming that 33.6 percent of these costs are incurred by Class I only establishments, given the percentage of these establishments calculated in Table 4-73. The amount remaining undistributed ($11.8 million) is added to the first year costs of software and equipment ($179.0 million, for a total of $296.8 million) to calculate the first-year costs attributable to all other establishments. These costs are then distributed based on the percentages shown in Table 4-72. We use the same approach for recurring year costs. Direct marking costs are assumed to apply only to Class I establishments, thus they do not need to be distributed by percentages.

These costs are then entered into the spreadsheet in the year in which they are expected to be incurred (i.e., in the first year for Class III establishments, second year for LS/LS establishments, third year for Class II establishments, fifth year for Class I, and seventh year for direct marking). Additionally, for a 20-year analysis, we add in first-year software and equipment costs to represent reinvestments made after a presumed 10-year equipment life. For more details on the methodology, refer to ERG (2012).

Table 4-74 presents the results of this arraying of costs. The net present value of costs over 10 years is $620.4 million, which, annualized at 7 percent, is $82.6 million per year. The table also presents

Table 4-74. Total Costs of the Final Rule under the Selected Option to All U.S. Labelers with Timing of Outlays Occurring in Years Corresponding to Compliance Dates, Depending on Class (or Type) of Device Labeled

	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Year	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**
Industry Share	8.20%	13.98%	44.18%	0.00%	33.64%															
Class III	$39,714,421	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079	$6,073,079
L8/L8		$67,711,299	$10,354,327	$10,354,327	$10,354,327	$10,354,327	$10,354,327	$10,354,327	$10,354,327	$10,354,327	$10,354,327	$10,354,327	$10,354,327	$10,354,327	$10,354,327	$10,354,327	$10,354,327	$10,354,327	$10,354,327	$10,354,327
Class II			$213,991,781	$32,723,354	$32,723,354	$32,723,354	$32,723,354	$32,723,354	$32,723,354	$32,723,354	$32,723,354	$32,723,354	$32,723,354	$32,723,354	$32,723,354	$32,723,354	$32,723,354	$32,723,354	$32,723,354	$32,723,354
Class I					$62,772,610	$6,048,418	$21,539,003	$7,190,205	$7,190,205	$7,190,205	$7,190,205	$7,190,205	$7,190,205	$7,190,205	$7,190,205	$7,190,205	$7,190,205	$7,190,205	$7,190,205	$7,190,205
Reinvestment (a)											$22,117,265	$37,708,940	$119,173,658		$0		$10,668,380			
Total	$39,714,421	$73,784,378	$230,419,186	$49,150,760	$111,923,370	$55,199,178	$70,689,763	$56,340,965	$56,340,965	$56,340,965	$78,458,229	$94,049,905	$175,514,623	$56,340,965	$56,340,965	$56,340,965	$67,009,345	$56,340,965	$56,340,965	$56,340,965
PV at 7%	$39,714,421	$68,957,363	$201,257,041	$40,121,661	$85,385,803	$39,356,251	$47,103,574	$35,086,321	$32,790,955	$30,645,752	$39,884,185	$44,682,432	$77,930,592	$23,379,497	$21,849,998	$20,420,558	$22,698,383	$17,836,107	$16,669,259	$15,578,746
PV at 3%	$39,714,421	$71,635,318	$217,192,183	$44,979,908	$99,442,465	$47,615,296	$59,201,563	$45,810,360	$44,476,078	$43,180,658	$58,380,291	$67,943,652	$123,102,425	$38,365,456	$37,248,015	$36,163,121	$41,758,008	$34,087,210	$33,094,379	$32,130,465
NPV over 20 yrs. at 7%	$921,348,899																			
Annualized (7%, 20 yrs.)	$81,279,269																			
NPV over 20 yrs. at 3%	$1,215,521,273																			
Annualized (3%, 20 yrs)	$79,322,449																			
NPV over 10 yrs. at 7%	$620,419,141																			
Annualized (7%, 10 yrs.)	**$82,554,886**																			
NPV over 10 yrs. at 3%	$713,248,250																			
Annualized (3%, 10 yrs.)	$81,179,081																			

Source: ERG calculations. Total first-year and annual costs from Table 4-47. After 10 years, reinvestments in equipment and software are assumed. First-year costs for other items do not recur after 10 years. Half of recurring costs are assumed incurred in first year of implementation.

results for a 20-year analysis at a 7 percent discount rate and over both 20 years and 10 years at a 3 percent discount rate.

4.8.3 Selected Option (Foreign)

The timing array for foreign costs is simplified because the costs for foreign establishments are already broken out by costs for Class I only establishments and costs for all other establishments. The first-year costs and a half-year of recurring costs for the Class I only establishments are simply inserted in Year 5, with the annual recurring costs arrayed following that year. The costs for the other establishments, however, do need to be distributed. Table 4-75 presents the distribution of establishments among the remaining (non-Class I only) establishments. These percentages are then used to distribute the costs to the relevant establishments. The array is then populated in the same manner as in the other two arrays.

Table 4-75. Distribution of Percentages across All Foreign Establishments Not Considered Class I Only

	Class I & II Only (No LS/LS)		Class I & II Only (With LS/LS)		Any Class III (May Have LS/LS)		
Type of Labeler	**No. of Estabs.**	**Percent**	**No. of Estabs.**	**Percent**	**No. of Estabs.**	**Percent**	**Total**
Manufacturer	2,284	32.2%	482	6.8%	180	2.5%	2,946
Reprocessor	0	0.0%	0	0.0%	0	0.0%	0
Spec. Developer	122	1.7%	27	0.4%	5	0.1%	154
Relabeler/Repackager	54	0.8%	12	0.2%	4	0.1%	70
All Labelers	2,460	77.6%	521	16.4%	189	6.0%	3,170

Source: FDA, 2010, and ERG estimates.

Table 4-76 presents the results of this cost array. As the table shows, under the selected option, foreign establishments are expected to incur costs of $74.7 million per year over 10 years, assuming a 7 percent discount rate.

4.9 Costs to All Affected Entities under the Selected Option

Table 4-77 presents the costs to all affected entities under both an immediate implementation scenario and after the timing assumptions are considered. As the table shows, the selected option is expected to cost a total of $208.5 million per year for all affected entities (U.S., foreign, and issuing agencies), under an immediate implementation scenario. These costs drop to $157.4 million per year when we account for the fact that many establishments will not need to immediately implement the final rule.

Table 4-76. Total Costs of the Final Rule under the Selected Option to All Foreign Labelers with Timing of Outlays Occurring in Years Corresponding to Compliance Dates, Depending on Class (or Type) of Device Labeled

	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Year	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**
Industry Share	5.96%	16.44%	77.60%																	
Class III	$13,152,116	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896	$3,800,896
LS/LS		$36,255,303	$10,477,602	$10,477,602	$10,477,602	$10,477,602	$10,477,602	$10,477,602	$10,477,602	$10,477,602	$10,477,602	$10,477,602	$10,477,602	$10,477,602	$10,477,602	$10,477,602	$10,477,602	$10,477,602	$10,477,602	$10,477,602
Class II			$171,186,266	$49,471,978	$49,471,978	$49,471,978	$49,471,978	$49,471,978	$49,471,978	$49,471,978	$49,471,978	$49,471,978	$49,471,978	$49,471,978	$49,471,978	$49,471,978	$49,471,978	$49,471,978	$49,471,978	$49,471,978
Class I					$25,793,276	$4,610,470	$23,338,878	$5,779,173	$5,779,173	$5,779,173	$5,779,173	$5,779,173	$5,779,173	$5,779,173	$5,779,173	$5,779,173	$5,779,173	$5,779,173	$5,779,173	$5,779,173
Reinvestment											$6,616,860	$18,240,127	$86,124,209		$0		$11,059,689			
Total	$13,152,116	$40,056,199	$185,464,764	$63,750,475	$89,543,752	$68,360,945	$87,089,353	$69,529,648	$69,529,648	$69,529,648	$76,146,508	$87,769,775	$155,653,857	$69,529,648	$69,529,648	$69,529,648	$80,589,338	$69,529,648	$69,529,648	$69,529,648
PV at 7%	$13,152,116	$37,435,700	$161,992,108	$52,039,378	$68,312,499	$48,740,409	$58,031,313	$43,299,571	$40,466,888	$37,819,522	$38,709,024	$41,698,788	$69,112,174	$28,852,332	$26,964,796	$25,200,744	$27,298,397	$22,011,306	$20,571,314	$19,225,527
PV at 3%	$13,152,116	$38,889,513	$174,818,328	$58,340,716	$79,558,463	$58,968,752	$72,935,962	$56,533,967	$54,887,346	$53,288,686	$56,660,153	$63,406,753	$109,172,484	$47,346,307	$45,967,289	$44,628,435	$50,220,611	$42,066,581	$40,841,340	$39,651,787
NPV over 20 yrs. at 7%	$880,933,905																			
Annualized (7%, 20 yrs.)	$77,713,952																			
NPV over 20 yrs. at 3%	$1,201,335,589																			
Annualized (3%, 20 yrs)	$78,396,720																			
NPV over 10 yrs. at 7%	$561,289,503																			
Annualized (7%, 10 yrs.)	**$74,686,914**																			
NPV over 10 yrs. at 3%	$661,373,849																			
Annualized (3%, 10 yrs.)	$75,274,943																			

Source: ERG calculations. Total first-year and annual costs from tables in Section 4.6. After 10 years, reinvestments in equipment and software are assumed. First-year costs for other items do not recur after 10 years. Half of recurring costs are assumed incurred in first year of implementation.

Table 4-77. Comparisons of Total Costs of the Rule under the Immediate Implementation Scenario and under the Timing Assumptions Given Implementation Dates

Entity	One-Time Costs	Recurring Costs	Immediate Implementation		With the Provided Additional Implementation Time
			Annualized One-Time Costs	Total Annualized Costs	
Domestic Industry	$356,590,521	$55,199,178	$50,770,468	$105,969,646	**$82,554,886**
Issuing Agencies	$790,500	$82,200	$112,549	$194,749	$194,749
Foreign Industry (a)	$230,350,545	$69,529,648	$32,796,735	$102,326,384	**$74,686,914**
Total Non-Federal Costs	**$587,731,566**	**$124,811,026**	**$83,679,753**	**$208,490,779**	**$157,436,549**

Source: See previous tables.

The difference between these two implementation scenarios among the U.S. establishments is $23.4 million per year. The rule is estimated to cost $106.0 million under the immediate implementation scenario, but $82.6 million per year when implementation dates are considered.

For foreign establishments, the difference is $27.6 million per year, with the rule estimated to cost these establishments $102.3 million under the immediate implementation scenario, but $74.7 million per year when implementation dates are considered.

Note, however, especially for the foreign establishments, these cost estimates are subject to considerable uncertainty. Section 7 discusses the uncertainty of the estimates and estimates bounding ranges.

5.0 IMPACTS OF THE HIGH-COST AND SELECTED OPTION

The general methodology for identifying impacts on medical device firms and establishments in the U.S. is identical to that presented in the economic report for the proposal (ERG, 2012). Basically, for firm-level impacts, ERG reorganizes the costs presented in Section Four, presenting them on a per-establishment basis first, then makes a number of assumptions to distribute establishment costs to firms based on a presumed number and size of firms owned by firms of various sizes. Costs, such as software costs, that were estimated on the basis of per-firm costs are then added in to create a total average cost per firm by size of firm. These costs are applied to all affected firms. Another set of per-establishment costs for direct marking of multi-use devices is also distributed to a small number of firms, which are assigned both the general costs and the DM costs. All costs are annualized to create a per-firm annualized cost. These annualized costs are then compared to revenues. Impacts are identified whenever the annualized cost per firm exceeds 1 percent or 3 percent of revenues estimated for a firm's size class.

To estimate average costs per-establishment by size, the per establishment costs are used as prepared for the beginning of the process to develop the per-firm costs, but then those costs computed on a per-firm basis are redistributed to facilities to create a per-establishment cost, and the costs are summed and annualized. The revenues per establishment by size are also estimated and the same impact analysis using 1 percent or 3 percent of revenues is used to determine numbers of establishment experiencing impacts that could result in facility closures. See Section Five in ERG (2012) for more details.

ERG made no methodology changes to the impact analysis, so the changes that are seen reflect only:

- Changes to costs as presented in Section Four, including, a change in the way costs for planning and administration were estimated, and the addition of GMDN costs.

- The elimination of any analysis of DM for implants, which are no longer required to be marked.

We focus on the high-cost option first in Section 5.1. Impacts from the selected option will be discussed in Section 5.2.

5.1 The High-Cost Option

We will not reproduce all tables presented in the economic report for proposal, since some were used as a way of showing the steps taken to calculate costs per firm. Impacts on firms are presented first in Section 5.1.1, with impacts on establishment presented in Section 5.1.2

5.1.1 Impacts on Firms

Firm impacts are first presented for initial labelers in Section 5.1.11; Section 5.1.1.2 then presents the impacts for the R/Rs. Section 5.1.1.3 presents a summary of all U.S. industry impacts.

5.1.1.1 Initial Labelers

Table 5-1 shows the annualized costs per establishment that will be used to compute the costs per firm, based on the costs shown in Section Four. As the table shows, the costs per establishment (not including firm-based costs) range from $2,300 to $124,000 (without DM).

The cost per establishment in Table 5-1 is distributed across firms, based on the detailed assumptions shown in Table 5-2. The costs for GMDN and software are already based on the size of firms, so they are pulled in directly without the need for any distribution. As Table 5-2 shows, the costs per firm range from $2,500 to $567,000, unless the firm must directly mark their devices. In this situation, the total costs rise to $8,300 to $770,000 per firm.

Table 5-3 then presents firm-level revenues, estimated using SBA data from 2007, but updated using the PPI for each of the 6-digit NAICs industries (SBA, 2013a). The size categories do not align to the size categories presented in Table 5-3, so (as was done in the economic report for the proposal), the costs per firm are redistributed on the basis of the size categories found in the SBA data. Table 5-4 presents the results of the redistribution.

Costs and revenues can now be compared. Table 5-5 presents the costs of the high-cost option as a percent of revenues by size of firm and industry for all firms except those that will need to direct mark devices. As the table shows, costs as a percentage of revenues are less than 1 percent for all size categories and industry types. The highest percentage found is in NAICS 339114 in the 5-19 size group, which is estimated to experience in the high-cost option, on average, costs as a percent of revenues of 0.998 percent, which is very close to but still below 1 percent.

The impacts on firms estimated to direct mark devices are shown in Table 5-6. As the table shows, costs exceed 1 percent of revenues in the 1-4 employee and the 5-9 employee size groups, in which 19 and 13 establishments, respectively, are expected to be incrementally affected by the DM requirements.

5.1.1.2 Repackagers/Relabelers

Table 5-7 and Table 5-8 present information similar to that seen for the initial labelers. Table 5-7 presents the costs that were estimated on a per-establishment basis organized by annualized cost per establishment by size. Table 5-8 then arrays these costs, using the assumptions in the table footnotes (unchanged from ERG, 2012) to create costs per firm, calculated to match the revenue categories reported by SBA. Costs that were estimated already on a firm basis (software) are then added in. Revenues by size are also shown. These revenues are from SBA, 2013a (see Table 5-3), updated to 2012 using the PPI for NAICS 423 (only available at that level of disaggregation). Table 5-8 also shows the impact calculation. Costs as a percentage of revenues are well below 1 percent for the R/Rs.

Table 5-1. Annualized Costs for Initial Labelers (Excluding Firm-Level Costs) under the High-Cost Option

Estab. Size	No. of Initial Labelers	No. of Affected DM Estabs.	Annualized Cost of Planning, Labeling and GUDID (a)	Annualized Cost of Equipment	Annualized Cost of DM, Multi-Use Items (a)	Per-Estab. Costs of Planning, Labeling, and GUDID	Wtd. Avg. Per-Estab. Costs of Equipment (b)	Total Per-Estab. Costs Applicable to All Estabs.	Per Estab. Costs of DM, Multi-Use
1-4	1,162	19	$2,532,485	$116,617	$109,466	$2,179	$100	$2,279	$5,817
5-9	721	13	$2,555,721	$72,356	$77,680	$3,544	$100	$3,645	$5,817
10-49	1,725	38	$12,501,204	$21,740,295	$218,640	$7,248	$12,604	$19,852	$5,817
50-99	472	12	$4,644,976	$5,687,513	$67,811	$9,837	$12,044	$21,881	$5,817
100-249	396	13	$8,741,054	$7,096,672	$619,870	$22,078	$17,924	$40,002	$48,112
250-499	195	6	$7,154,611	$7,105,615	$872,762	$36,702	$36,451	$73,153	$158,621
500+	113	4	$9,171,210	$4,842,069	$729,877	$81,060	$42,796	$123,856	$202,825
Total	**4,784**	**103**	**$47,301,262**	**$46,661,137**	**$2,696,107**				

(a) Includes costs to UPC establishments.
(b) Cost of equipment per establishment is the weighted average of costs to those currently printing variable barcodes (3 percent of all establishments) and to those that are not.
Source: ERG (2012); Section 4 of this report. Costs are annualized at 7 percent over 10 years.

Table 5-2. Assignment of Establishment Costs to Initial Labeler Firms (Includes Software and Computer-Related Costs)

Cost Element	Employment Size by Firm						
	Smallest (1-4)	**Small (5-19)**	**Medium (20-99)**	**Large (100-199)**	**Larger (200-499)**	**V. Large (500-999)**	**Largest (1000+)**
No. of Firms (adjusts double counting)	1,162	1,403	980	172	96	36	89
Planning, labeling, equip. & GUDID	$2,279	$10,128	$20,664	$40,754	$74,869	$143,618	$340,329
Software first year	$909	$11,265	$28,530	$79,060	$194,792	$555,399	$914,357
Software recurring	$63	$1,838	$4,425	$10,676	$25,188	$58,222	$96,334
Software annualized	$192	$3,442	$8,487	$21,932	$52,922	$137,298	$226,518
Total costs per firm annualized	$2,471	$13,569	$29,151	$62,686	$127,791	$280,916	$566,847
No. of firms with multi-use estabs.	19	13	19	12	22	15	4
Add multi-use DM cost to total	$8,288	$19,386	$34,968	$68,503	$158,066	$343,165	$769,672

Source: See previous tables; software costs are from Table 4-19 and are on a firm basis already.

Assumptions for assigning establishment costs to firms:

Costs for planning, labeling, equipment and GUDID use the weighted average costs for facilities needing variable printing equipment and those not needing it (3 percent).

Most firms are single facility firms (3,901 firms and 4,784 facilities are affected). Number of firms excludes those assumed using variable barcodes.

The largest numbers of facilities are in the 10-49 size; these are assumed common extra facilities among those with multiple facilities.

Small firms (5-19 employees) are assumed to incur costs for one facility weighted at 60 percent 5-9 employee size and 40 percent 10-49 employee size; approximated based on numbers of establishments in each size, assuming single facility firms only.

Medium firms (20-99 employees) are assumed to incur costs for one facility weighted at 60 percent (10-49 employees size) and 40 percent (50-99 employees size).

Large firms (100-199 employees) are assumed split between single-facility firms and firms with two establishments; 20 percent are assumed to have two establishments with 50-99 employees in each facility and 80 percent are assumed single facility firms with 100-249 employees.

Larger firms (200-499 employees) are assumed split between single-facility firms and firms with three establishments; 20 percent are assumed to have three establishments--a 10-49 employee size, a 50-99 employee size and a 100-199 employee size--and 80 percent are assumed to be single facility firms with 250-499 employees.

Very large firms (500-999 employees) are all assumed to be multi-facility firms with five facilities--two 100-249 employee, two 50-99 employee and one 10-49 employee establishments.

Largest firms (1,000+ employees) are all assumed to be multi-facility firms with eight facilities--one 500+ employee, one 250-499 employee, one 100-249 employee, two 50-99 employee and three 10-49 employee establishments.

Firms affected by DM costs are assumed to own only one such establishment.

Firms with multi-use items--affected establishments are distributed so that not all medium firms (20-99 employees) own all 10-49 establishments with multi-use items. The 10-49 employee establishments are distributed to firms with 100-199 employees and over 500 employees. Costs for two sizes of establishment at those firms are evaluated. Only 25 percent of 100-199 employee and over 500 employee firms are assigned the costs of the 10-49 employee establishments. Costs shown in this table are averages between the two sets of costs in these firm sizes.

Table 5-3. Estimated Revenues by Firm Size and Industry (2007)

Industry	Firm Revenues by Employment Size			
	0-4 Employees	**5-19 Employees**	**20-499 Employees**	**500+ Employees**
NACIS 325413, In vitro diagnostic substances manufacturing	$992,287	$3,854,924	$31,593,697	$460,657,189
NAICS 334510, Electromedical and electrotherapeutic apparatus mfg.	$492,502	$1,980,909	$19,963,072	$311,222,887
NAICS 334517, Irradiation apparatus manufacturing	$608,750	$2,343,989	$19,029,121	$819,261,670
NAICS 339112 Surgical and medical instrument manufacturing	$455,237	$1,773,623	$16,339,018	$246,856,926
NAICS 339113 Surgical appliance and supplies manufacturing	$390,874	$1,730,316	$14,586,060	$249,299,028
NAICS 339114, Dental equipment and supplies manufacturing	$431,625	$1,359,920	$21,165,205	$218,812,685
NAICS 339115, Ophthalmic goods manufacturing	$1,830,257	$1,733,399	$9,046,649	$239,601,440
Reprocessors (a)	$455,237	$1,773,623	$16,339,018	$246,856,926
Specification Developers (b)	$633,160	$1,847,394	$17,542,648	$316,789,711

(a) Reprocessors are assumed to have revenues similar to those for surgical and medical instrument manufacturing.

(b) Specification developers are assumed to have revenues similar to the average medical device manufacturer. The average revenues have been updated using PPI for NAICS 325413 (this PPI is roughly centered in the range of PPIs for all these groups of device manufacturers).

Source: Based on estimated receipts reported for 2007 (SBA, 2013a) and inflated using the 2012 PPI for the NAICS.

Table 5-4. Costs per Firm Consolidated to Match Firm Sizes for Which Revenue Data Are Available

Cost Element	Employment Size by Firm			
	Smallest (1-4)	**Small (5-19)**	**Medium (20-499)**	**Largest (500+)**
Number of firms (adjusts double counting)	1,162	1,403	1,248	125
Planning, labeling, equipment & GUDID/firm (a)	$2,279	$10,128	$27,595	$283,348
Aggregate costs excluding software and DM	$2,648,172	$14,204,936	$34,433,579	$35,499,450
Aggregate software costs, first year	$909	$11,265	$60,220,778	$101,528,800
Aggregate software costs, recurring	$63	$1,838	$8,586,341	$10,686,156
Aggregate software costs, annualized	$192	$3,442	$17,160,425	$25,141,573
Total costs per firm annualized	**$2,471**	**$13,569**	**$41,348**	**$484,022**
Number of affected firms with multi-use estabs.	19	13	53	18
Add multi-use (a)	$8,288	$19,386	$94,394	$426,140

(a) Annualized.
Source: See Table 5-2.

Table 5-5. Impacts of the High-Cost Option on Initial Labelers.

	No. of Affected Firms (No DM) by Size (a)				Compliance Costs as Percentage of Revenues			
NAICS	**1-4**	**5-19**	**20-499**	**500+**	**1-4**	**5-19**	**20-499**	**500+**
325413	10	32	52	10	0.25%	0.35%	0.13%	0.11%
334510	38	91	134	19	0.50%	0.68%	0.21%	0.16%
334517	12	32	31	4	0.41%	0.58%	0.22%	0.06%
339112	57	201	226	22	0.54%	0.77%	0.25%	0.20%
339113	140	388	418	34	0.63%	0.78%	0.28%	0.19%
339114	66	189	85	1	0.57%	0.998%	0.20%	0.22%
339115	50	95	81	6	0.14%	0.78%	0.46%	0.20%
Reprocessors	0	11	6	1	NA	0.77%	0.25%	0.20%
Spec. Dev.	769	351	163	8	0.39%	0.73%	0.24%	0.15%
Total	1,143	1,389	1,195	107	NA	NA	NA	NA

(a) With DM firms removed from counts. DM firms are found only in NAICS 339112 and NAICS 339113. Excepted firms (custom operations) and those assumed to be using UPCs only are also excluded from count, as are those assumed to be using variable barcodes.
Source: Tables 5-3 and 5-4.

Table 5-6. Impacts of the High-Cost Option on Firms Required to Direct Part Mark

DM Type	Number of Affected Firms (with DPM) by Size (a)				Compliance Costs as Percentage of Revenues			
	1-4	5-19	20-499	500+	1-4	5-19	20-499	500+
Multi-Use Items	19	13	53	18	1.82%	1.09%	0.58%	0.17%

Source: Table 5-3 and Table 5-4. Totals might not add due to rounding.

Table 5-7. Aggregate Costs and Annualized Cost per Establishment for R/Rs

Estab. Size	No. of R/Rs	Costs of Planning, Labeling & GUDID (a)		Costs of Equipment		Total Annualized Costs	Total Annualized Costs per Establishment
		First Year	Rec. Yr.	First Year	Rec. Year		
1-4	736	$2,847,355	$409,022	$0	$0	$814,421	$1,106
5-9	212	$1,373,964	$184,376	$0	$0	$379,997	$1,789
10-49	272	$5,091,444	$383,897	$8,511,459	$2,742,562	$5,063,207	$18,596
50-99	47	$1,330,578	$101,703	$1,473,058	$474,649	$975,526	$20,702
100-249	28	$1,644,124	$165,451	$670,456	$451,398	$946,393	$34,210
250-499	10	$1,069,804	$88,363	$402,360	$353,480	$651,446	$67,420
500+	4	$732,759	$166,485	$206,456	$202,707	$502,915	$115,136
Total	**1,310**	**$14,090,028**	**$1,499,297**	**$11,263,789**	**$4,224,795**	**$9,333,905**	

Source: Previous tables in Section Four. Costs are annualized using 7 percent over 10 years.

Table 5-8. Annualized Costs per R/R Firm, Revenues per Firm and Impacts of the High-Cost Option

Cost Element	Employment Size by Firm					
	Smallest (1-4)	**Small (5-19)**	**Medium (20-199)**	**Large (200-499)**	**Medium/ Large (20-499)**	**Largest (500+)**
Number of Firms	727	318	131	13	144	24
Cost of Planning, Labeling, GUDID & Equipment/Estab.	$1,106	$3,469	$19,482	$51,213	$21,770	$102,637
Aggregate Cost of Planning, Labeling, GUDID & Equip.	$803,741	$1,101,821	$2,543,011	$666,191	$3,124,851	$2,470,722
Per Firm Cost of Software, First Year	$909	$11,265	$28,530	$79,060	$33,109	$194,792
Per Firm Cost of Software, Recurring Year	$63	$1,838	$4,425	$10,676	$4,992	$25,188
Annualized Per Firm Cost of Software	$192	$3,442	$8,487	$21,932	$9,706	$52,922
Per Firm Cost of Registration	$500	$500	$4,000	$4,000	$4,000	$20,000
Annualized Per Firm Cost of Registration	$71	$71	$570	$570	$570	$2,848
Total Annualized Cost per Firm, including Software and Registration	$1,369	$6,982	$28,539	$73,715	$32,046	$158,406
Total Revenues per Firm	$807,452	$2,804,152	NA	NA	$25,144,926	$462,879,102
Impacts (Compliance Costs as a Percentage of Revenues)	0.17%	0.25%			0.13%	0.03%

Source: Table 5-7, Table 4-19, and Table 4-23; SBA, 2013a.

Assumptions used to assign establishment costs to firms:

Small firms (5-19 employees) are assumed to own one facility; 90 percent are assumed to own establishments in the 5-9 employee size class and 10 percent are assumed to own establishments in the 10-49 size class.

Medium firms (20-199 employees) are assumed to own one facility; 90 percent are assumed to own an establishment in the 10-49 employee size class, 5 percent are assumed to own an establishment in the 50-99 employee size class and 5 percent are assumed to own an establishment in the 100-249 employee size class.

Large firms (200-499 employees) are assumed to own one or two facilities; 20 percent are assumed to own two establishments (a 10-49 employee and a 100 to 249 employee size establishment), 40 percent are assumed to own one 250-499 employee size establishment, and 40 percent are assumed to own one 100-249 employee size establishment.

The largest firms (500+ employees) are assumed to own one to four establishments; 50 percent are assumed to own one 500+ establishment, 30 percent are assumed to own two establishments: a 50-99 employee size establishment and a 250-500 employee size establishment; and 20 percent are assumed to own four establishments: three 50-99 employee size establishments and one 100-249 employee size establishment.

5.1.1.3 Impacts on U.S. Industry under the High-Cost Option

Table 5-9 combines the results of the impacts to initial labelers, with and without DM requirements, and R/Rs. As the table shows, no firms without DM requirements are expected to experience impacts exceeding 1 percent of revenues. A total of 32 firms, estimated to have incremental costs associated with DM, are, however, expected to experience impacts exceeding 1 percent of revenues under the high-cost option.

5.1.2 Impacts on Establishments

The only change of note for this analysis (other than the change of costs), was the updates to revenues. The previous analysis in ERG (2012) used the value of shipments from 2007 and the total employment by NAICS, and then computed average revenues per employee to construct revenues by establishment size group. Shipments were updated to 2012 dollars using the appropriate PPIs by NAICs, but we did not update the employment figures for each of the NAICs, first, because employment figures are only available through 2010 (U.S. Census, 2010), and, second, because employment declined in nearly all the affected NAICS between 2007 and 2010, according to Census. Thus, computing the revenue per employee using the original 2007 employment figure is likely to lead to a conservative estimate of revenues per employee. Table 5-10 shows the results of this update.

Table 5-11 presents the per-establishment impacts for all establishments (initial labelers and R/Rs). As the table shows, impact results are similar to the firm level impacts, with only the smallest establishments (1-4 employees size) that are expected to face incremental costs for DM experiencing costs that exceed 1 percent of revenues. The difference between the firm-level results and the establishment-level results most likely reflects the fact that not all of the smaller establishments are single-facility firms, and those smaller establishments owned by a larger firm with multiple establishments might earn higher revenues on average

5.2 The Selected Option

Because DM will still be required, the impacts on firms shown in Section 5.1 could still occur. However, some multi-use device manufacturers, if they manufacture Class I devices only, could face substantially reduced costs. To the extent that this situation occurs, this alternative could possibly reduce the number of firms estimated to have costs exceeding 1 percent of revenues. We do not, however, have any information on whether firms that manufacturer only Class I devices and that require DM are among the groups of firms considered likely to face costs exceeding 1 percent of revenues. However, because the group of firms with costs exceeding 1 percent of revenues are among the smallest size groups and thus might specialize in a few multi-use devices, which are virtually all Class I devices according to the list of affected devices provided by FDA, it may be likely that their costs will be somewhat reduced. However, the cost differences between static and variable requirements for this size group are not large.

The cost of static requirements for a firm with 1-4 employees (assuming at this size, the firms are single establishment firms), combined with the costs for DM are estimated to be $7,344 (see Table 5-12).

Table 5-9. Number of Firms with Costs Exceeding 1%, 3%, and 5% of Revenues, with and without DPM Considered

	No. of Firms with Costs >1% of Revenues					No. of Firms with Costs >3% of Revenues					No. of Firms with Costs >5% of Revenues				
NAICS	**1-4**	**5-19**	**20-499**	**500+**	**Total**	**1-4**	**5-19**	**20-499**	**500+**	**Total**	**1-4**	**5-19**	**20-499**	**500+**	**Total**
325413	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
334510	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
334517	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
339112 (no DPM)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
339112	19	13	0	0	32	0	0	0	0	0	0	0	0	0	0
339113	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
339114	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
339115	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Reprocessors	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Spec. Dev.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
R/Rs	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total with DPM	19	13	0	0	32	0	0	0	0	0	0	0	0	0	0
Total without DPM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
All Firms	1,889	1,720	1,432	193	5,234	1,889	1,720	1,432	193	5,234	1,889	1,720	1,432	193	5,234
% of All Firms with DPM	1.0%	0.8%	0.0%	0.0%	0.6%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
% of all Firms without DPM	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: Tables 5-5, 5-6 and 5-8. The line "All Firms" excludes excepted firms, but includes those assumed using variable barcodes.

Table 5-10. Average Revenues per Employee by Type of Establishment

NAICS	Industry	2007 Employment	2007 Value of Shipments/ Receipts ($000)	Revenue/Employee ($)
Initial Labelers				
325413	In vitro diagnostic substances manufacturing	30,548	$14,488,271	$474,279
334510	Electromedical and electrotherapeutic apparatus manufacturing	62,023	$21,245,690	$342,545
334517	Irradiation apparatus manufacturing	15,533	$11,037,955	$710,613
339112	Surgical and medical instrument manufacturing	108,455	$30,430,980	$280,586
339113	Surgical appliance and supplies manufacturing	107,322	$33,691,746	$313,931
339114	Dental equipment and supplies manufacturing	16,391	$5,700,772	$347,799
339115	Ophthalmic goods manufacturing	24,230	$6,307,790	$260,330
Repackagers/Relabelers				
423450	Hospital equipment and supplies	181,685	$151,295,784	$832,737
423460	Ophthalmic goods	22,501	$9,389,520	$417,293

Source: U.S. Census Bureau (2010).

Table 5-11. Impacts of the High-Cost Option on Establishments

	Initial Labelers Costs and Shipments			R/R Costs and Receipts		Costs as Percent of Shipments, Initial Labelers			Initial Labeler Impacts with DM	
Estab. Size	Annualized Per Estab., without DM	Annualized Cost Per Estab., Plus DM Multi-Use	Estimated Shipments per Estab.	Annual Cost per Estab.	Estimated Receipts per Estab.	No DM	With Multi-Use DM	Cost as a Percent of Receipts, R/Rs	No. of Multi-Use Estabs.	No. Estabs. With Costs>1% of Shipments
1-4	$2,279	$8,097	$584,460	$1,106	$928,066	0.4%	1.4%	0.1%	19	19
5-9	$3,645	$9,462	$1,636,488	$1,789	$2,598,585	0.2%	0.6%	0.1%	13	0
10-49	$19,852	$25,669	$7,013,520	$18,596	$11,136,794	0.3%	0.4%	0.2%	38	0
50-99	$21,881	$28,332	$17,533,800	$20,702	$27,841,986	0.1%	0.2%	0.1%	12	0
100-249	$40,002	$90,106	$40,912,200	$34,210	$64,964,634	0.1%	0.2%	0.1%	13	0
250-499	$73,153	$238,206	$87,669,000	$67,420	$139,209,930	0.1%	0.3%	0.0%	6	0
500+	$123,856	$337,380	$175,338,000	$115,136	$278,419,859	0.1%	0.2%	0.0%	4	0
Total										19

Source: Tables 5-1, 5-8, and 5-10.

Table 5-12. Estimated Costs to and Impacts on Class I Direct Marking Firms under the Selected Option

	First-Year Per-Firm Cost					Recurring Per-Firm Costs					
Size of Firm	Planning and Administrative	Label Redesign	GUDID	Total	First-Year Annualized	Label Materials	GUDID Recurring	DM (Annualized)	Total Annualized	Estimated Revenues	Costs as % of Revenues
1-4 employees	$2,250	$1,250	$2,238	$5,738	$817	$47	$663	$5,817	$7,344	$455,237	1.6%
5-9 employees	$4,500	$2,500	$4,313	$11,313	$1,611	$47	$1,389	$5,817	$8,864	$1,773,623	0.5%
10-49 employees	$9,000	$5,000	$6,125	$20,125	$2,865	$254	$1,317	$5,817	$10,253	$1,773,623	0.6%

Source: Tables 4-4, 4-14, 4-17, 5-1, and 5-3.

As a percentage of the $455,000 average revenues in the 339112 NAICS, this cost is 1.6 percent of revenues. Thus, the selected option does not reduce the cost impacts to this group of firms to below 1 percent of revenues.

For the firms in the 5-19 size group (again assuming single establishment firms), total costs are expected to range between $8,864 and 10,253 per year per firm (see Table 5-12). Compared to the $1.8 million average revenues in this firm size group, this is no more than 0.6 percent of revenues. Thus, costs as a percentage of revenues might drop below 1 percent for some or all of the affected DM firms, and the selected option could mitigate some of the impacts seen under the high-cost option.

Because firms in the 1-4 employee size group are assumed to be single-facility firms, the selected option will not change the results of the establishment impact analysis.

6.0 SMALL BUSINESS IMPACTS OF THE SELECTED OPTION

The Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) requires all notice and comment rulemaking to be accompanied by a Regulatory Flexibility Analysis (RFA) unless the agency can certify that the rule will have no significant impact on a substantial number of small entities. FDA has decided to perform a Final Regulatory Flexibility Analysis (FRFA), regardless of whether the final rule is ultimately certified.

When an RFA is prepared for a final rulemaking, the analysis is a FRFA, and this FRFA must address the following (as cited in 5 USC 604):

- A succinct statement of the objectives of, and legal basis for, the rule;
- A summary of the significant issues raised by the public comments in response to the IRFA, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- A description and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
- A description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
- A description of the steps the agency has taken to minimize the significant adverse economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives to the rule considered by the agency was rejected.

This section addresses each of these major areas in the following sections. Additionally, because revised information is available, we also present an estimate of the total costs of the selected option to small entities at the end of the required information.

6.1 Objectives and Legal Basis of the Final Rule

The primary objectives of the rule are discussed in the Preamble to the final rule.

6.2 Summary of Public Comments and Any Changes Made to the Rule

Only three comments were received that were specifically addressed to the issue of small business impacts. The first commenter is a manufacturer of Class I durable medical equipment for children with physical disabilities, sold at retail, who believed the rule will have a major impact on his small firm.

The second comment was from a commenter who simply stated that the rule will have a significant impact on his small firm.

The third commenter also stated that the rule will have a significant impact on a substantial number of small businesses.

The specific responses to these commenters, to the extent their comments were sufficiently detailed for FDA to develop a response, are discussed in the preamble of the final rule. However, these comments, by themselves, did not contribute to any changes made to the final rule.

6.3 Estimate of Small Entities Affected by the Final Rule

ERG estimated the number of small entities affected by the final rule in the economic analysis for the proposal (see ERG, 2012). These estimates are unchanged. As Table 3-6 in Section Three of ERG (2012) showed, ERG identified a total of 6,569 domestic firms that are considered labelers. For all relevant initial labeling NAICS, small entities are those with fewer than 500 employees, while for R/Rs, small entities are those with fewer than 100 employees (SBA, 2013b).

Many of these small entities, however, are expected not to be affected by the rule because FDA has offered exceptions to labelers of certain devices such as custom devices and GMP-exempt devices. Additionally, labelers who label only with UPCs on Class I devices have much-reduced requirements and, therefore, cost. These latter devices are considered to be in compliance with UDI labeling requirements already. Therefore, many of the smallest labelers are considered very likely to be unaffected or only very minimally affected by the final rule. An estimated 1,652 small businesses are estimated to meet the custom device exception and GMP-exempt exception out of 6,344 small businesses estimated to be currently registered with FDA as labelers. Thus, 26 percent of all small firms are considered likely to be unaffected by the UDI rule.

Table 6-1 presents the counts of firms, both initial labelers and R/Rs, by size, after the exceptions and exclusive UPC use are considered. The numbers of firms are presented here for ease of seeing counts that have been summarized previously and to provide a sense of how many firms are more highly affected (some firms will have minimal costs because they are already meeting many of the more expensive aspects of the rule). However, there are additional observations that can be made based on this table. Before GMP-exempt firms are considered, 4,127 initial labeling firms and 1,212 R/R firms are expected to be affected by the rule, for a total of 5,339 firms (this total does not include those labeling custom devices). The GMP-exempt exception lowers this estimate to 4,611 firms (including both large

Table 6-1. Number of Small Entities Affected under the Final Rule

Type of Firm	Employment Size by Firm							Total Firms	Total Small
	Smallest (1-4)	Small (5-19)	Medium (20-99)	Large (100-199)	Larger (200-499)	V. Large (500-999)	Largest (1000+)		
No. of initial labeling firms (includes those using UPCs, static and variable barcodes, and GMP-exempt)	1,211	1,458	988	189	111	44	125	4,127	3,957
UPC firms	49	56						104	104
Initial labelers excluding UPC firms	1,162	1,403	988	189	111	44	125	4,022	3,853
Initial labelers currently using variable barcodes	-	-	8	17	15	8	36	85	41
Initial labelers also excluding those using variable barcodes	1,162	1,403	980	172	96	36	89	3,937	3,812
GMP exempt initial labelers	102	63	191	32	15	8	-	410	402
Initial labelers excluding GMP-exempt	1,060	1,339	789	141	81	28	89	3,527	3,410
Estimated affected initial labelers currently using static barcoding for Class I (after removing less affected)	15	49	32	37	43	NA	NA	NA	175
Total highly affected initial labelers excluding static barcoders	**1,045**	**1,290**	**757**	**104**	**38**	**NA**	**NA**	**NA**	**3,234**
No. of R/R Firms	727	318	112	18	13	24	NA	1,212	1,157
GMP exempt R/Rs	73	34	18	2	2	-	-	129	125
R/Rs excluding GMP-exempt	654	283	94	16	11	24	NA	1,083	1,032
Estimated Affected R/Rs currently using Static for Class I	33	14	5	NA	NA	NA	NA	NA	52
Total highly affected R/Rs excluding static barcoders	**622**	**269**	**90**	**NA**	**NA**	**NA**	**NA**		**980**
Total Labeling Firms Most Affected by Rule (excludes GMP-exempt, UPC firms, and static Class I only and variable barcoders)	**1,667**	**1,560**	**846**	**104**	**38**	**NA**	**NA**	**NA**	**4,215**

Source: From Tables 5-2, 4-19 and 5-8; see assumptions in ERG, 2012, Section 7 (all counts exclude firms assumed to label custom devices).

and small initial labelers and R/Rs). Of these, 4,442, or 96 percent, are small firms. Additionally, among initial labelers, 104 are estimated to use UPCs, 41 are estimated to use variable barcodes, and 227 are estimated to be Class I only labeling firms (initial labelers and R/Rs) that currently use static barcodes. These small firms will have .much lower costs than the average small firm. The total highly affected small firms, 4,215 firms, are just 66 percent of the 6,344 small firms that are estimated to have registered devices that they label. Conversely, as noted in Section 5, there are 85 small firms that are estimated to have much higher costs than the average small firm because they must incrementally meet DM requirements.

6.4 Recordkeeping, Reporting and Other Compliance Requirements of the Final Rule

6.4.1 Recordkeeping and Reporting Requirements

The primary recordkeeping and reporting requirements of the final rule are organized by cost category as follows:

- Administrative and Planning Costs—these costs include costs for creating and revising SOPs. Costs for SOP revisions total 15 percent to 38 percent of total administrative and planning costs, depending on the size of the establishments (with the smallest establishments having the higher percentages). All affected small entities will need to consider whether the requirements affect their SOPs and revise existing SOPs or create new ones. This is considered a managerial task primarily, although some clerical work might be required. Medical device labelers of all sizes routinely create and revise SOPs. Additionally a certain number of labelers are expected to file for exceptions. Hours for this task are estimated to range from 4 to 120 hours, depending on size, for initial labelers but will only affect a subset of small labelers.

- Barcode Registration Costs—only a fraction of small entities are expected to need to register. ERG estimates that 474 small entities will need to register. The time needed to fill out the web-based form is considered a minimal portion of the overall planning effort. The registration form asks for identifying information, the type of applicant (e.g., manufacturer), the revenue class to which the applicant belongs, a check off box for each revenue class for identifying the appropriate fee, and credit card information. ERG assumes a manager would be completing this form.[17]

- Equipment Costs—a portion of this cost category is the labor to operate verifiers. ERG assumes that a part of the task of operating the verifiers is to indicate in records the outcome of the verification task and what was done to correct any problems found. Most small entities were assumed to need to meet this requirement incrementally. The labor

[17] HIBCC's form is used as the basis for detailing these requirements.

category assumed for this task was a quality control inspector. Maintaining records of this type is routine in the medical device labeling industries.

- Direct Marking—only a relatively small fraction of small entities are expected to need to do DM. ERG estimates, however, that 25 small entities might need to file exceptions for DM, which is expected to require 10 hours per exception (note, however, that submission of an exception notification to FDA is no longer required, so this estimate might overstate the level of effort needed). The submission would document the reason for the exception. It is assumed that this is not a routine staff function and, therefore, is a management-level task.

- Software—integration of variable barcoding into IT systems requires acquisition of software modules, testing, verification, and validation of those software systems. Even the smallest facilities will require some testing, so all small entities are expected to need to document testing, verification, and in some cases, validation outcomes, both on a one-time basis, and to a more limited extent, on a recurring basis. This task is likely to be performed by inspection or QA workers. However, except for the very smallest entities, this software installation should automate all UDI-related recordkeeping tasks, which mostly involve ensuring that the UDI appear on all device records that FDA currently requires to be maintained. Personnel running the reports are assumed to be the same personnel who ordinarily run similar IT reports that currently do not contain the UDI. These might be IT staff, accounting staff, or clerical workers, depending on the size and sophistication of the operation. The incremental task of ensuring a UDI appears on device records, where this is assumed to be done manually (among the 1-9 employees size groups), is considered negligible for the very few products likely to be labeled by entities in this size group. This is judged to be a clerical task.

- GUDID—this is the major recordkeeping and reporting task in this final rule, because so much of the recordkeeping and reporting tasks associated with device records are assumed to become automated using the software discussed above. Adding a UDI to existing or future device records is considered a minimal task with automation. The GUDID task requires that firms input additional information on each device they manufacture. Currently all device manufacturers must list devices by type and provide some information on the device. The final rule requires them to provide UDI information for each device type, which could cover, for example, several dozens of individual products. For each product, the entities will need to provide the UDI assigned and a number of other relatively easily obtained information items. The exception is the task to locate the GMDN code, which will be a somewhat more time intensive activity for initial laborers. This task will involve initial time to train personnel and for them to learn to use the system. Hours for compiling the information are estimated to range from 19 to 137 hours for the smallest to largest of the initial labeler small firms). For the smallest firms, these tasks are made simpler by the relatively small number of products for which they

will need to provide data and by the (presumed) ease of use of FDA's web-based data entry system. Those entities with many more products are assumed to use an upload process, with an assumed upload function provided by FDA online. The software systems assumed to be used at the larger entities (within the small firm group) should automate much of the uploading. Because all of these entities already use similar web-based systems or upload similarly formatted data to FDA's FURLS system for the registration and listing process, all should have personnel familiar with using web-based or uploading systems, and SPL translation itself can be outsourced at a modest cost. Much of this work can be handled by whoever handles these tasks now (IT personnel, managers, or even trained technicians or clerical staff). A total of 30 to 146 hours per initial labeling small entity for uploading information (8 to 42 hours for small R/Rs) is assumed in the first year, followed by 9 to 48 hours per year to add or edit information for initial small labelers, and 2 to 10 hours per year for small R/Rs.

6.4.2 Other Compliance Tasks

Other compliance tasks include planning implementation of the UDI requirements, running new labeling equipment, running new direct marking lasers, applying supplemental labels, and designing new labels. All small entities either currently perform such tasks (planning for implementation of new FDA rules and designing labels), are assumed to have personnel that would be trained to perform such tasks with new equipment (running new printing/labeling equipment or DM lasers), or the tasks require little to no new skills (adding a supplemental label).

6.5 Description of Steps Taken to Minimize Impacts on Small Entities

The preamble to the final rule discusses the steps taken to minimize impacts on small entities.

6.6 Summary of Costs to Small Entities

The per-firm costs for initial labelers are shown in Table 6-2. The costs to the Class I only firms are based on an assumption that small Class I only initial labelers are generally single-facility firms and are assigned costs on the basis of their establishment size. The number of such establishments is equated to numbers of firms in this table. The costs for other firms, which will be affected by variable requirements are taken from the costs per firm (and numbers of firms) presented in Table 5-2 in the previous section of this report. As the table shows, the aggregate costs for small initial labeling firms are $34.6 million per year.

Similarly, small Class I only R/Rs are also assumed to be single facility firms and are assigned the costs per establishment on the basis of their establishment size. See the footnote to the table for more information on assumptions used to map establishment costs to firms. The costs to R/Rs that are subject to variable barcoding requirements are compiled from per-establishment costs shown previously in Table 5-7. As Table 6-3 shows, aggregate costs to small R/Rs are estimated to be $6.2 million.

In total, for the two labeling groups, costs to small entities are estimated to be $40.8 million per year. Note that small entities make up 96 percent of the highly affected firms (before adjustments for static barcoding) but are estimated to bear only 39 percent of the $106.0 million in total annualized costs.

Table 6-2. Per-Firm and Aggregate Costs of the Final Rule to Small Initial Labelers

Estab. Size	Total Small Firms	Not Class I Only or GMP-Exempt	Cost per Firm for Variable Barcoding	Number Class I Only Estabs.	Class I Only Costs per Firm	% Savings for Small Class I Only	Total Cost--No DM	Number affected by DM	Average Cost per Firm	Aggregate DM Costs	Total Costs to Small Initial Labeling Firms
1-4	1,162	704	$2,471	355	$1,819	26%	$2,387,304	19	$5,817	$109,466	$2,496,770
5-19	1,403	1,119	$13,569	221	$3,156	77%	$15,877,065	13	$5,817	$77,680	$15,954,745
10-49	735	56	$29,151	528	$4,772	84%	$4,151,626	38	$5,817	$218,640	$4,370,266
50-99	245	67	$29,151	138	$4,871	83%	$2,636,314	12	$5,817	$67,811	$2,704,125
100-249	172	31	$62,686	110	$10,152	84%	$3,046,453	13	$48,112	$619,870	$3,666,323
250-499	96	30	$127,791	51	$14,562	89%	$4,576,876	6	$158,621	$872,762	$5,449,638
Total	3,812	2,007		1,402			$32,675,637	100		$1,966,230	$34,641,867

Source: Table 5-2, Table 4-13, Table 4-6, Table 4-10, Table 4-20, and Table 6-24 in ERG (2012).
Note: Does not include counts or costs for certain groups of small firms, such as those owning UPC establishments, those already labeling with variable barcodes, etc. Also does not include costs to a small number of small firms. These costs include those for filing for exceptions to DM requirements. Class I only and GMP-exempt firms are assumed to own only one facility. Additionally, the table prorates costs across all Class I only firms, including those currently labeling with static barcodes. If the static barcoding firms had been removed, average costs would be higher and numbers of establishments would be lower, leaving the aggregate costs the same.

Table 6-3. Per-Firm and Aggregate Costs of the Final Rule to Small R/Rs

Estab. Size	Total Small Firms	Not Class I Only or Exempt	Cost per Firm for Variable Barcoding	Total Number of Class I Only and GMP-Exempt	Class I Only Cost per Firm	% Savings for Small Class I Only	Total Costs
1-4	727	261	$1,298	466	$1,029	21%	$818,194
5-19	318	97	$13,634	221	$7,437	45%	$2,962,836
20-99(a)	112	71	$25,614	41	$13,749	46%	$2,390,154
Total	1,157	429		728			$6,171,185

Source: Table 5-7, Table 6-1, Table 4-25, Table 4-27, and Table 4-29; see also Table 6-24 in ERG (2012) for numbers of Class I only and GMP-exempt R/Rs

(a) To map R/R establishments to firms to create counts of Class I only or GMP-exempt, the establishments determined to be Class I only or GMP-exempt in the 5-9 employees establishment size class plus half of the establishments in the 10-49 size class were included in the 5-19 employees firm size class. For the 20-99 employee firm size class, the proportion of Class I and GMP-exempt establishments to total establishments was calculated, which included half the establishments in the 10-49 establishment size group plus all of the establishments in the 50-99 size group. Costs for 5-19 are the average of the 5-9 employee size group and the 10-49 employee size group.

7.0 IMPACTS ON TRADE

The effect of the UDI regulation on foreign trade is difficult to assess because the numerous different device types each can define a separate market. However, there are some basic changes in the balance of trade that might occur in each market depending on whether or not foreign establishments can meet UDI requirements at lower costs than domestic establishments. In the trade scenarios explored below, we assume no shift in domestic demand for the good. A shift in the demand curve could theoretically occur if a regulatory requirement, for example, increased the safety of that good, causing consumers to demand more of the safer good (http://www.ers.usda.gov/media/321535/aer828d_1_.pdf). The increase in device safety conferred by use of UDI, however, is unlikely to be directly perceived by consumers.

We first discuss a theoretical case that assumes products that are not differentiated, that is, within each market, the different devices brands are perfect substitutes. Many products, particularly those among the Class I devices, might follow such a pattern. Such typically undifferentiated or minimally differentiated products might include latex gloves, catheters, basic surgical sponges, and other commodity supplies. However, there are a number of more sophisticated products that the U.S. both imports and exports (such as imaging devices, high-tech implantables, and other more innovative devices). These products, even of the same type, are not necessarily perceived as perfect substitutes for each other, and a certain amount of price insensitivity might appear to occur. This scenario will be discussed briefly after the perfect competition model is summarized.

In the case of perfect substitutes, trade takes place when foreign firms can supply a good at a lower price than can be achieved domestically, despite tariffs, transportation costs, and other barriers. That is, the world price of a good perceived by the importing country (including all tariffs, transportation costs, etc.) is lower than the domestic price. If the world price is higher than the domestic price, the entire quantity of a good demanded domestically would be met domestically and there would be no imports of that good. [18]

If domestic establishments cannot meet a regulatory requirement at an equal or lower cost than foreign establishments (which might be the case, on average, as shown by our cost analysis for foreign establishments), the world price would remain less than the domestic price and imports would continue. In this case, for any market in which this occurs, domestic quantity produced would always decline, while imports would increase to make up for some (but not all) of the domestic declines in production. The magnitude of the increase in imports would depend on how much more it costs domestic establishments to produce the good than foreign establishments. Thus, the result is 1) an unambiguous increase in price and imports and 2) an unambiguous decrease in U.S. market share, U.S. production, and total U.S. sales.

[18] We discuss world price and domestic price as driven by cost increases, but what also drives the differences between these prices is the relative elasticities of the supply curves, foreign and domestic. If the domestic supply curve elasticity is vastly different from that of the foreign supply curve for a particular device market, this could introduce even more complexity into all of the scenarios discussed here. We assume here, for simplicity, that over the per-unit incremental cost ranges considered, the elasticities are not vastly different.

For any market, however, where domestic establishments can meet a regulatory requirement at a lower cost than foreign establishments, this implies that the world price might rise to exceed the domestic price (which would also rise, but in this scenario not as much as the world price). Up to a point, trade might cease because domestic demand would be met entirely by domestic supply (as long as an equilibrium is reached in which domestic price remains below the world price). Thus, in the scenario of world price rising above domestic price, the domestic quantity produced would generally increase to replace imports (despite the shift upward in the domestic supply curve resulting from increased regulatory costs). Total quantity produced, however, would be smaller and both world price and domestic price would be higher in the post-regulatory scenario (as they would be regardless of what production cost increase scenario is considered). The result in this scenario is 1) an unambiguous increase in price, U.S. market share, and U.S. production and 2) an unambiguous decrease in imports and total U.S. sales.

If the world price rises more than the domestic price but remains below the domestic price, imports are not eliminated (although they decline) but some advantage would still accrue to domestic establishments. The result is either an increase in domestic production to replace a portion of the large relative decline in imports or a decline in domestic production that is less than it would have been had the world price not risen more than the domestic price had risen. The result in this scenario is 1) unambiguous increase in price and U.S. market share, 2) ambiguous change in U.S. production, 3) unambiguous decrease in imports and total sales.

It is likely that various combinations of these scenarios could occur in each of the relevant device markets. Whether the decline in total quantity is primarily due to reductions in imports or to declines in production at domestic establishments is dependent on the magnitude of the cost increases incurred by domestic producers relative to foreign producers (with elasticities of domestic supply and demand also contributing to the measure of the total production lost in the specific device market).

As noted earlier, however, there are device markets in which the devices are not perfect substitutes. For example, many doctors exhibit brand loyalty without much, if any, consideration of price; orthopedic surgeons often specialize in a particular brand of replacement joint. Furthermore, pricing signals in medical device markets are relatively poor. There is a disconnect between those who ultimately pay for the devices (private insurers or Medicare, for example) and those who use the devices (health care providers or patients). Furthermore, price increases for devices, if relatively small, can be lost amid the payment system because most payment systems in the U.S. pay for a procedure (in which a device or devices are used), not the device itself. Furthermore, as noted in CMS (2013), payments for procedures can vary widely for the same procedure depending on the setting (e.g., inpatient vs. outpatient), geographic region, or even hospital to hospital within a city. These complexities further make a quantitative analysis of even one non-commodity device market very difficult.

Overall, however, we can make some generalizations for some device markets, even though we have had to make broad assumptions regarding the incremental cost differences between foreign and domestic establishments. It would appear that costs to foreign firms might be, on average, somewhat less than those faced by domestic firms due to lower labor costs, even if capital costs are not substantially

different. Thus (while still considering all of the caveats noted above and realizing we do not have one "average" market for medical devices in the U.S.), the balance of trade in some medical devices, on average, might shift towards more imports. Alternatively, establishments in some countries could incur higher costs on average to meet the UDI requirements than those incurred by U.S. establishments, leading to lower levels of imports from those countries. For example, in countries, such as Hong Kong, which has a higher average per-capita GDP (adjusted for purchasing power parity) than the U.S., costs to produce a commodity item might increase more than the costs to produce its U.S. counterpart (although a higher incremental cost to produce an innovative high-tech device than a that for a similar U.S. device might still not result in a change in sales of that product).

As noted in the Executive Summary, however, the costs of this rule relative to the value of device shipments is estimated to be very small, so it is likely that any impacts on trade will be, on average, small. Nevertheless, it is possible that certain device markets could experience much higher price increases than average and/or much greater trade impacts than average.

8.0 UNCERTAINTY ANALYSIS

8.1 U.S. Industry

The cost estimate for U.S. entities presented in Section Four is associated with uncertainty, with some cost categories more uncertain than others. This section qualitatively discusses the uncertainty of the cost estimates for each of the major cost categories and presents an upper bound and lower bound estimate for each cost category, as well as total cost.

The maximum number of firms and establishments expected to be affected by the final rule is reasonably certain. (Although these data are several years old, given the economic conditions in the intervening years, however, substantial expansion is unlikely to have occurred.) All entities that will be affected by the final rule should be registered with FDA. If there are any that should be registered with FDA but are not, they are out of compliance with FDA's registration and listing requirements. Therefore, they will be unlikely to incur costs because if they did not know that registration and listing requirements apply to them, then they probably will not realize UDI applies to them. If the UDI rule somehow prompts more non-compliant device labelers to register and list, however, this would increase the cost of the rule overall.

More uncertain are the share of establishments involved in labeling only Class I devices with UPCs. These uncertainties are handled within bounding estimates ERG has made for each cost category. These bounding estimates depend on factors that ERG has developed based on our sense of the uncertainty in each cost category (see Table 8-1).

It is not as certain, however, how many establishments will meet a general exception to the final rule on the basis of labeling of devices such as custom devices. ERG estimated that 1,141 establishments in the 1-4 employee size group and 238 establishments in the 5-9 employee size group will meet an exception for this reason. However, at $2,179 and $3,544 per establishment (see Section Five),[19] respectively, if none of these establishments met such an exception, this would add only $3.3 million per year to the costs of the rule (a 3 percent increase).

Other, general uncertainties also include the following:

- If the date for UDI to appear on all labels (including on devices in inventories or held in consignment) within 3 years after the rule becomes effective for a device results in, at a minimum, filing an exception or in inventory losses or the need to repackage and/or relabel the devices in inventory, additional costs would be incurred. However, FDA believes this situation would arise only very rarely.

[19] Table 5-3 reports the cost for the 1-4 employee size group; the costs for the 5-9 employees size group is calculated as the annualized cost for software for this group in Table 5-3 ($3,195) plus the annualized cost for all other requirements except DM for this size group in Table 5-2 ($1,667). The number of establishments excludes any estimates of establishments assumed to be using UPCs exclusively beyond those estimated under the proposed rule.

- If many implantables are packaged in shelf packs, this could add costs to the total costs, although it is likely few implantables are managed in this fashion.

- Simplifications allowing a UDI to appear on kits or combination products, for example, in lieu of individually labeling devices held within those types of products, could contribute to lower costs than those estimated here.

Other uncertainties are discussed under specific cost items.

Table 8-1 presents ERG's bounding assumptions for each of the cost categories. The first category, Planning and Administrative Costs, is ERG's best estimate of the time needed for companies to undertake basic compliance preparations, although some entities might spend more or less time. The true overall average across most entities is unlikely to vary too widely (i.e., an order of magnitude) from the estimate. ERG has now made a careful assessment to include costs of dealing with shortened implementation times and the change to requirements to allow date format requirements to be met when UDI label changes are made have further reduced uncertainty in this estimate. We have lowered the uncertainty range from 50 percent lower and 50 percent higher than that estimated in Section Four to 25 percent lower and higher.

Table 8-1. Bounding Assumptions for the Major Cost Categories

Cost Element	Lower	Higher
Labeling and Database Requirements		
Administration and planning	25%	25%
Registration costs	10%	10%
Equipment and other investments	50%	50%
Incremental label cost	25%	25%
Label redesign cost	60%	60%
Software (with training)	50%	50%
Recordkeeping & Reporting (GUDID)	25%	25%
Direct Marking		
Multi-Use Devices	50%	50%

Source: See text.

Barcode registration costs are considered reasonably reliable. A plus or minus 10 percent factor is used to bound the estimate for this cost category. The only major uncertainty is whether HCT/P devices are currently registered with barcode registries at the same frequency as other devices. Because these devices are a very small portion of all devices and the costs for registration are small, this uncertainty should have little effect on the point estimate.

The cost estimates for equipment are somewhat less certain. The costs for smaller establishments are reasonably certain, but those for the largest establishments could vary widely and could become very expensive if certain types of device packages are being labeled. If establishments must create new levels of packaging and labeling for certain devices, or if larger carton sizes are needed to accommodate UDI on labeling, additional equipment for packaging and labeling might need to be purchased or additional re-engineering time might be needed to change lines to handle larger outer cartons than was estimated in Section Four. However, FDA is allowing shelf packs to be labeled on the outer packaging, rather than requiring each individual item within the shelf pack to be labeled for nearly all device types and has added substantial flexibility to how combination products and convenience kits must be labeled with UDI, minimizing the likelihood that new levels of labeling must be created. Additionally, with the option of using small 2-D barcodes, the need for larger packaging or labels is likely to be minimized. On the other hand, establishments will be able to judge which of several options (e.g., switching from outside printing to in-house printing) is the least expensive for them in complying with UDI requirements. ERG did not attempt to judge which options would be chosen on the basis of cost, which could result in equipment costs to be overstated. To account for these uncertainties, ERG has estimated uncertainty factors of plus or minus 50 percent for equipment costs.

It is possible that few establishments will need additional materials for labels. The lower bound of the material costs could be substantially smaller than our estimate because:

- The rule allows for shelf packs to be labeled in lieu of individual items,
- 2D barcodes (which are very small) can be used to represent UDI information, and
- Label redesign should solve many label size issues without the need to expand label area.

However, ERG is also uncertain that the approximation of label materials costs (2 percent of all packaging materials costs) and the potential cost increase associated with larger packaging/labeling areas (estimated at 10 percent). These uncertainties and assumptions could make costs too low or too high. An uncertainty factor of plus or minus 25 percent has been chosen for the label materials cost category.

Label redesign costs are more speculative, given the range of technical, regulatory, and marketing considerations at play. It is not known how many establishments might be able to integrate UDI requirements into usual label redesign cycles, which could reduce the incremental cost of label redesign, although the long lead times offered by the implementation schedule implies that many establishments might be able to do this. Alternatively, costs could be much higher at establishments with unusual packaging and labeling issues. It is also not certain whether FDA will grant all exceptions that might be requested on the basis of currently inadequate label size (thus, requiring the labeler to make a packaging size change to accommodate a larger label able to contain the UDI; see equipment discussion, above). Given the small number of comments addressing label size, however, redesigning very small packaging might not be a major issue. A plus or minus 60 percent factor is used to create the upper and lower bound estimate for the label redesign cost item.

Software costs are also considered highly speculative. ERG believes that costs could be overstated because it is not certain how much of the integration costs will be incurred as a result of complying with the rule and how much will be performed as a result of corporate preferences for integration. The integration will, however, yield benefits in terms of recordkeeping and reporting cost savings, so the lower bound factor reflects the judgment that some integration might be performed to reduce incremental costs of recordkeeping and reporting. ERG estimates that uncertainty factors of plus or minus 50 percent are reasonable for this cost item.

GUDID costs are considered reasonable estimates, so have been given factors of plus or minus 25%. The largest uncertainty involves the exact structure of the data entry site and uploading functions that have yet to be designed, as well as whether updates to GMDN codes will be required. The site may be easier or harder to use to input or upload data than has been estimated here.

ERG believes the uncertainty is significant for direct marking of multi-use devices, due mainly to the issue of whether the wording change from "sterilized" to "reprocessed" has broadened the scope of devices that must be marked. FDA did not provide a revised multi-use device list, nor did FDA provide any information as to what types of devices might additionally be required to be directly marked under this revised definition of multi-use devices. Additionally, whether such additional devices might be subject to 510(k) premarket notification or PMA supplement requirements prior to marking is not known (the original list of multi-use devices provided by FDA were nearly all Class I devices and were thus not subject to these requirements). On the other hand, a large area of uncertainty was eliminated when FDA decided not to require direct marking of implants. Given the issues involved with a potentially broader scope of devices, as well as the paucity of data on current marking practices and, to a lesser extent, the issue of technological feasibility among the devices currently known to need marking, ERG has selected a factor of plus or minus 50 percent to calculate bounding estimates.

These factors produce the bounding estimates shown in Table 8-2. As the table shows, with uncertainty considered (and with no implementation schedule used), ERG has estimated that the low end of the cost under the selected option to U.S. industry will be $60.6 million per year, where the high end of the cost of the final rule would be $151.3 million per year, compared to the central, point-estimate costs to U.S. industry of $106.0 million per year.

8.2 Foreign Industry

ERG also performed a cost bounding estimate for foreign industry. After reviewing the uncertainty ranges in Table 8-1, ERG determined that these ranges do not sufficiently capture the uncertainty. All of the reasons for uncertainty shown in Table 8-1 apply to the foreign cost estimates, but given the lack of data on foreign manufacturing practices, and the assumptions that needed to be made, ERG has increased nearly all the uncertainty values by 5 percent to 25 percent, depending on the cost category. Of most concern regarding uncertainty are planning and administrative costs, equipment costs, software, and GUDID recordkeeping costs, which are given the largest increases in uncertainty values. These costs will be affected by how the foreign establishments will organize the response to the UDI

requirements (planning and administrative costs) and the extent to which they operate in a more or less automated environment. The uncertainty values for foreign costs are shown in Table 8-3.

Table 8-2. Annualized Costs of the Selected Option for U.S. Establishments under Bounding Assumptions to Account for Uncertainty

Cost Element	First-Year	Low	High	Annual Recurring	Low	High
Labeling and Database Requirements						
Administration and planning	$86,357,769	$64,768,327	$107,947,211	NA	NA	NA
Registration costs	$2,048,710	$1,843,839	$2,253,581	NA	NA	NA
Equipment and other investments	$47,527,879	$23,763,939	$71,291,818	$22,560,550	$11,280,275	$33,840,826
Incremental label cost	NA	NA	NA	$8,423,509	$6,317,632	$10,529,387
Label redesign cost	$47,724,259	$19,089,703	$76,358,814	NA	NA	NA
Software (with training)	$131,471,984	$65,735,992	$197,207,976	$14,660,866	$7,330,433	$21,991,298
Recordkeeping & Reporting (GUDID)	$26,540,230	$19,905,173	$33,175,288	$8,412,466	$6,309,349	$10,515,582
Total Labeling and Database Requirements	$341,670,830	$195,106,973	$488,234,687	$54,057,391	$31,237,689	$76,877,093
Direct Marking						
Total Direct Marking	$14,919,691	$7,459,846	$22,379,537	$1,141,787	$570,893	$1,712,680
Total	**$356,590,521**	**$202,566,818**	**$510,614,224**	**$55,199,178**	**$31,808,583**	**$78,589,773**
Annualized Investment Total (a)	**$50,770,468**	**$28,840,958**	**$72,699,978**			
Total Annualized Costs for Industry Selected Option	**$105,969,646**					
Total Annualized Costs for Industry Low Estimate	**$60,649,540**					
Total Annualized Costs for Industry High Estimate	**$151,289,751**					

(a) First-year costs are annualized at 7 percent over 10 years.

Source: See Table 4-47.

Using the costs shown in Section 4.6.4, ERG calculated results for the bounding table for foreign industry. As the table shows, with uncertainty considered (and with no implementation schedule used), the low end of the cost of the selected option to foreign industry is estimated to be $51.1 million per year and the high end of the cost is estimated to be $153.6 million per year, compared to the central, point-estimate costs to foreign industry of $102.3 million per year (see Table 8-4).

Combined cost ranges for U.S. and foreign industry are summed in Table 8-5. The low end of the cost of the selected option to all industry is estimated to be $111.7 million per year and the high end of the cost of is estimated to be $304.9 million per year, compared to the central, point-estimate costs to all industry of $208.3 million per year.[20]

Table 8-3. Bounding Assumptions for the Major Cost Categories (Foreign Industry)

Cost Element	Lower	Higher
Labeling and Database Requirements		
Administration and planning	50%	50%
Registration costs	25%	25%
Equipment and other investments	70%	70%
Incremental label cost	30%	30%
Label redesign cost	65%	65%
Software (with training)	75%	75%
Recordkeeping & Reporting (GUDID)	50%	50%
Direct Part Marking		
Multi-Use Devices	60%	60%

Source: See text.

[20] Does not include costs to issuing agencies.

Table 8-4. Annualized Costs of the Selected Option for Foreign Establishments under Bounding Assumptions to Account for Uncertainty

Cost Element	First-Year	Low	High	Annual Recurring	Low	High
Labeling and Database Requirements						
Administration and planning	$53,304,384	$26,652,192	$79,956,576	NA	NA	NA
Registration costs	$4,404,000	$3,303,000	$5,505,000	NA	NA	NA
Equipment and other investments	$29,836,515	$8,950,954	$50,722,075	$12,786,768	$3,836,030	$21,737,505
Incremental label cost	NA	NA	NA	$37,658,031	$28,243,523	$47,072,539
Label redesign cost	$23,677,075	$8,286,976	$39,067,174	NA	NA	NA
Software (with training)	$81,144,681	$20,286,170	$142,003,192	$11,511,761	$2,877,940	$20,145,582
Recordkeeping & Reporting (GUDID)	$19,839,834	$9,919,917	$29,759,750	$6,404,385	$3,202,193	$9,606,578
Total Labeling and Database Requirements	$212,206,488	$77,399,210	$347,013,767	$68,360,945	$38,159,687	$98,562,204
Direct Marking						
Total Direct Marking	$18,144,056	$9,072,028	$27,216,084	$1,168,703	$584,352	$1,753,055
Total	**$230,350,545**	**$86,471,238**	**$374,229,852**	**$69,529,648**	**$38,744,038**	**$100,315,258**
Annualized Investment Total (a)	**$32,796,735**	**$12,311,559**	**$53,281,912**			
Total Annualized Costs for Industry Selected Option	**$102,326,384**					
Total Annualized Costs for Industry Low Estimate	**$51,055,597**					
Total Annualized Costs for Industry High Estimate	**$153,597,170**					

(a) First-year costs are annualized at 7 percent over 10 years.

Source: See Table 4-67.

Table 8-5. Annualized Cost to All Industry, Foreign and Domestic, with Uncertainty Ranges

Total Annualized Cost of Rule Estimate Type	U.S Industry	Foreign Industry	All Industry
Point Estimate	$105,969,646	$102,326,384	$208,296,029
Low Estimate	$60,649,540	$51,055,597	$111,705,138
High Estimate	$151,289,751	$153,597,170	$304,886,921

Note: Annualized over 10 years at 7 percent discount rate.
Source: Tables 8-2 and 8-4.

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