DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Use of Certain Symbols in Labeling

Docket No. (FDA-2013-N-0125)

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

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I. Introduction and Summary

A. Introduction

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule imposes no new burdens, the agency proposes to certify that the final rule would not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one

year." The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Summary

The proposed rule would provide medical device manufacturers with the option to use standardized international symbols (recognized by the FDA) to communicate information to end users. This option would allow manufacturers to substitute labels containing only written statements (text-only labels) with a label containing only symbols (symbol-only labels), granted that the symbols communicate the same information as the substituted written statements.

Medical device manufacturers would adopt the proposed rule only if they expect a positive net benefit (estimated benefits minus estimated costs). Hence, the final rule is expected to provide a non-negative net benefit to each adopting manufacturer. Choosing to adopt the rule would potentially reduce the costs associated with designing and re-designing the labels on medical devices that are currently sold in the U.S. and the European Union (EU). The estimated annual benefits range from $8.1 million to $26.1 million at a 3 percent discount rate, and $7.9 million to $25.6 million at a 7 percent discount rate. Adopting the rule would incur one-time administrative costs, which we estimate to range from $2.4 million to $9.5 million. Annualized over 20 years, the estimated net benefits associated with adopting the proposed rule range from $7.8 million

to $25.5 million at a 3 percent discount rate, and $7.6 million to $24.6 million at a 7 percent discount rate. The costs and benefit accrue to the same entities, however, so any firm making the change to symbols would on net reduce costs.

II. Preliminary Regulatory Impact Analysis

A. Background

Medical devices are sold world wide. To participate in most international markets, medical device manufacturers must communicate certain information to end users, such as the manufacturer's identity, the device's intended use, and directions for use. Most countries require this information to appear in its national language. However, some countries, such as the members of EU, also allow this information to appear as standardized international symbols, such as those documented in ISO 15223 and EN 980:2008.

Using standardized international symbols (henceforth referred to as symbols for short) may substantially benefit both medical device manufactures and end users. Medical device manufacturers that export to the EU can use symbols to reduce the costs associated with designing and re-designing labels for both the U.S. and EU. For instance, some medical device labels can communicate the same information using only written statements or standardized international symbols. In this case, manufacturers who export medical devices can use the same symbol-only label, per uniquely labeled medical device, in every nation recognizing these symbols. This practice is cheaper than using

text-only labels, which would require manufacturers to create a separate label in each country with a different national language.

Using symbols could also benefit end users. Symbols use less physical space than the text for which they substitute. Manufacturers could use the extra space to make their label more understandable. For instance, they could include more detailed instructions, increase the size of the remaining text, or space out the written statements to reduce clutter.

B. Benefits

Adopting the rule would potentially reduce the costs associated with designing and re-designing the labels on medical devices that are currently sold in the U.S. and EU. The principal beneficiaries are exporters: U.S. manufacturers who export medical devices to the EU. The rule would allow exporters to use the same symbol-only label in the U.S. and EU, thus saving them the resources associated with designing and re-designing a separate label to use in the U.S. The rationale is as follows. FDA assumes that each uniquely labeled medical device contains one label that can communicate the same information using only symbols or written statements. FDA further assumes that exporters currently use text-only labeling in the U.S. market, and symbol-only labeling in the EU. Exporters probably use symbol-only labels in the EU because it is cheaper to design a single symbol-only label versus creating a separate text-only label per EU nation. The same rationale suggests that exporters would probably opt to use a single symbol-only label in the U.S. and EU, rather than continue to create and revise a separate

label for both markets. As a result, exporters would avoid the costs associated with designing and re-designing a unique U.S. label on those medical devices sold in both the U.S. and EU.

The proposed rule would provide exporters with the option to use a single symbol-only label in the U.S. and EU. This option allows exporters to avoid the costs associated with creating a separate label to use in the U.S., particularly, for new medical device products. Estimating these costs requires data that projects the number of new medical devices manufacturers are expected to sell in the future. Because these data are unavailable, we cannot quantify this particular benefit.

Medical device manufacturers regularly revise and re-design their labels in response to changes in markets, regulations, and technology. The proposed rule would allow exporters to avoid the costs associated with re-designing separate U.S. and EU labels each time they make a change. Total labeling re-design costs are roughly equal to re-design costs multiplied by the number of labels [(the average cost associated with re-designing medical device labels) x (the number of unique medical device labels used in the U.S. and EU)]. Data on the latter is unavailable. To calculate this value, we assume that each uniquely labeled medical device contains one label that can communicate the same information using either written statements or symbols.

FDA assumes that the number of uniquely labeled medical devices (ULMD) sold in the U.S. and EU is approximately equal to the total estimated number of uniquely

labeled medical devices that U.S. companies produce multiplied by the percentage sold in the U.S. and EU. Table 1 presents these data. We assume that the percentage of uniquely labeled medical devices sold in the U.S. and EU is roughly equal to the ratio of EU sales to total U.S. sales (= value of total medical device sales in the EU in 2009 / value of total U.S. medical device sales in 2009). Censtats reports that the total value of U.S. medical device sales in the EU equaled $16.4 million in 2010 (Ref. E1), while the 2009 Annual Survey of Manufacturers reports that the total value of medical device sales equaled $112.6 million in 2010 dollars (Ref. E2). Censtats and the 2009 Annual Survey of Manufacturers classify industries using the North American Industry Classification System (NAICS). To estimate the above values, we used the NAICS codes associated with those medical device industries participating in international trade: 334510, 334517, 339112, 339113, 339114 and 339115.

TABLE 1—ESTIMATED NUMBER OF UNIQUE LABELS FOR MEDICAL DEVICES SOLD IN THE US AND EU

Company Size	**Number of Establishments**
Large	741
Medium	1,237
Small	3,770

Company Type	**Average Number of Unique Labels for Medical Devices Sold in the US and EU**
Large	99.13
Medium	25.74
Small Exporter to EU	9.4

Total U.S. Medical Device Sales in 2009	112,644,239
Average Total Value of Medical Devices Sales in EU	16,442,219
Value Total Sales in EU to Total Medical Device Sales in 2009	0.146
Estimated Number Unique Labels used in US and EU	20,542

Notes—Rounding may produce slight variations to the above estimates. The 2009 Annual Survey of Manufacturers reports the number of establishments and the total value of medical device sales in 2009. To calculate this number, we used NAICS codes 334510, 334517, 339112, 339113, 339114, 339115. Average EU sales were calculated using data from years 2008-2010.

FDA assumes that the total estimated number of uniquely labeled medical devices produced by U.S. companies approximately equals the number of U.S. medical device manufacturers multiplied by the average number of uniquely labeled medical devices they produce. However, larger establishments probably produce more uniquely labeled medical devices than smaller establishments, on average. Hence, to compute the total estimated number produced, we performed the following steps: first, we separated companies by size; second, we estimated the number of companies within each size category; third, we estimated the average number of uniquely labeled medical devices produced within each company size category; fourth, we took the product of these estimates within each size category; and finally, we summed the products. To capture this variation, we separately study establishments that are very small, small, and medium large in size. We use these size descriptions to correspond to the size categories reported in the 2009 Annual Survey of Manufacturers, which classifies establishments by the following employment categories 1 to 19, 20 to 99, and 100 or more workers. The Small Business Administration classifies most device manufacturing firms as small if they have fewer than 500 employees. Because the 2009 Annual Survey of Manufacturers does not have an estimate of the numbers with more than 500 employees, we put all firms with 100 or more employees in the medium large category.

To estimate the average number of uniquely labeled medical devices by establishment size, we randomly sampled approximately 110 very small manufacturers, 40 small manufacturers and 30 medium large size manufacturers. The Technical Appendix discusses the data source and its construction in detail. The results indicate that

very small, small, and medium large establishments sell approximately 9, 26, and 99 uniquely labeled medical devices, on average, respectively. Given these data, we estimate that U.S. medical device companies use approximately 20,542 labels in the U.S. and EU (Table 1).

We estimate the average cost of re-designing a medical device label using a model developed by a contractor, RTI International (Ref. E3). The model does not cover every medical device industry studied above. However, it does examine a relatively similar industry: retail medical device manufacturers (NAICS codes 322121, 325412, 325413, 325620, 326299, 335211, 339112, 339113, 339114, and 339994). We capture the average cost to re-design a medical device label using the costs associated with re-designing retail medical devices. The model proxies the latter cost using the average re-design costs per universal product. We recognize that re-designing costs are not the same across these two industries; however, these are the best data available to study this topic.

Changing labels commonly requires the following resources: labor, materials, inventory, market testing, analytical testing, and recordkeeping. The costs associated with using these resources vary with compliance time. More compliance time reduces costs as it enables manufacturers to coordinate more labeling activities. Because companies want to minimize costs, we assume that every adopting company would start using symbols once it is possible to maximize coordinating resources. Once companies start using symbols, we assume every proceeding revision occurs at the average re-design rate. The RTI model indicates that the average re-design rate among medical device manufacturers

is approximately once every 3.25 years, and that the re-design in question—converting written statements to symbols—is a minor change that only requires some labor and recordkeeping resources (Ref. E3). Medical devices enter the market at various times, and thus not all device labels are revised at the same time. Because revisions occur approximately every 3.25 years, on average, we assume that roughly one third of the current stock of medical devices is revised every year. This assumption suggests that approximately 6,321 (= 20,542/3.25) labels are revised every year.

Table 2 reports the average initial re-design costs per label, and the average proceeding re-design costs per label. On average, the initial costs associated with labor range from $176 to $490, while recordkeeping costs range from $38 to $63. The average proceeding re-design costs associated with using labor range from $1,297 to $4,295, while recordkeeping costs range from $52 to $91.

TABLE 2—ESTIMATED LABELING RE-DESIGNING COSTS

Cost Factor (Coordinated)	Low	Midpoint	High
Labor	175.83	339.09	489.80
Recordkeeping	37.68	50.24	62.80

Cost Factor (Coordinated & Uncoordinated)	Low	Midpoint	High
Labor	1297.11	2476.54	4295.16
Recordkeeping	51.69	78.27	90.83

Total Per Label Costs	Low	Midpoint	High
Initial Coordinated Labeling Re-designs	213.50	389.33	552.60
Future Labeling Re-designs	1,348.80	2,554.81	4,385.99

Table 3 reports the estimated total quantified benefits. Using a 20 year time horizon, the total present discounted value of benefits range from $119.9 million to $388.9 million at a 3 percent discount rate, and from $83.6 million to $271.1 million at a

7 percent discount rate. Annualized over 20 years, total benefits range from $8.1 million to $26.1 million at a 3 percent discount rate, and from $7.9 million to $25.6 million at a 7 percent discount rate.

TABLE 3—ESTIMATED LABELING RE-DESIGNING COSTS

Total Labeling Re-design Costs Avoided

Labeling Re-design Savings	Low	Midpoint	High
3 Percent	119,874,637	226,966,338	388,935,669
7 Percent	83,615,316	158,289,726	271,061,124

Annualized Labeling Re-design Costs Avoided

Labeling Re-design Savings	Low	Midpoint	High
3 Percent	8,057,459	15,255,703	26,142,586
7 Percent	7,892,694	14,941,430	25,586,253

C. Costs

Firms will only adopt symbols if they expect to save labeling costs or experience other benefits, on net. However, companies would incur some potential costs in order to use symbols, such as one-time administrative and outreach costs. Furthermore, some studies indicate that end users may be more likely to misinterpret symbols than written statements. These studies suggest that using symbols may cause more end users to use medical devices incorrectly, resulting in potentially more medical errors and thus more adverse events, all else the same (Ref. E4).

1. Administrative Costs

Adopting the proposed rule would require one-time administrative costs. We use the labeling cost model to estimate this cost. Table 4 reports the average administrative costs associated with adopting the proposed rule. The model estimates the average

administrative costs per Universal Product Code to range from $176 to $490. Total one-time administration costs range from $3.6 million to $10.1 million.

TABLE 4—ADMINISTRATIVE COSTS

Administrative Costs	Low	Midpoint	High
Administrative Costs per UPC	175.83	339.09	489.8
Estimated Total Medical Device UPC	20,542	20,542	20,542
Total One-Time Administrative Costs	3,611,822	6,965,657	10,061,505

2. Outreach

We estimate incremental outreach costs to be approximately zero. Providing an outreach program is optional, and most manufacturers would likely choose to not provide one. However, some manufacturers could conduct an educational program to minimize potential litigation costs. The most likely program would change the medical device's instruction manual to include written statements that explain what each symbols means. This program incurs two costs: the costs associated with physically changing the instruction manual and market testing costs. Manufacturers may conduct market tests, such as focus groups, to make their written statements more clear and visible. As argued above, we assume that manufacturers would likely start using symbols once it is possible to coordinate resources: e.g. when they are in the process of re-designing their label. At this time, the labeling cost model indicates that manufacturers can coordinate market tests (focus groups) and make minor changes to their instruction manuals at no additional cost. To the extent that some outreach occurs, however, we assume it would be included in our estimated administrative costs.

3. Adverse Events

The available empirical evidence suggests that end users would be more likely to misinterpret symbols than written statements, resulting in more medical errors that translate to adverse events. For instance, Liu et al. (Ref. E4) estimated the percentage of German nurses and doctors that could comprehend the symbols recognized in the EU. Their results indicate that most nurses and doctors misunderstood the symbols intended to communicate instructions aimed at preventing adverse events. For example, roughly 75 percent of nurses and doctors misunderstood the symbol intended to convey "do not re-use".

Estimating the potential costs associated with misinterpreting symbols requires the following data: the rate with which end users misinterpret symbols, the extent to which misinterpreting symbols translates to an adverse event, the average severity of adverse events associated with misinterpreting symbols, and the end user's willingness-to-pay to avoid such an adverse event. These data are unavailable, however, and thus this cost cannot be quantified. Nevertheless, the expected costs are probably quite small. Most severe adverse events occur with the medical devices used by medical professionals. For instance, misusing pedicle screw systems is more risky than misusing band aids. Medical professionals probably consult a medical device's instructions prior to using it. This usual preparation should prevent the adverse events associated with misinterpretation of symbols. FDA requests comments on this potential cost.

4. Total Estimated Costs

One-time administrative costs are the only expected costs associated with adopting the proposed rule.[1] Table 5 reports the total estimated costs. Annualized over 20 years, total estimated costs range from $0.24 million to $0.68 million at a 3 percent discount rate, and from $0.34 million to $0.95 million at a 7 percent discount rate.

TABLE 5—TOTAL ESTIMATED COSTS

Cost Factor	Low	Midpoint	High
Total One-Time Administrative Costs	3,611,822	6,965,657	10,061,505
Annualized Cost			
3 Percent	242,771	468,202	676,291
7 Percent	340,930	657,509	949,735

D. Summary of Costs and Benefits

Table 6 presents the estimated quantified annualized costs, benefits and resulting net benefits associated with adopting the proposed rule. Annualized over 20 years, net benefits range from $7.8 million to $25.5 million at a 3 percent discount rate, and from $7.6 million to $24.6 million at a 7 percent discount rate.

TABLE 6—ESTIMATED ANNUALIZED NET BENEFITS

Description	Low	Midpoint	High
Annualized Benefits			
3 Percent	8,057,459	15,255,703	26,142,586
7 Percent	7,892,694	14,941,430	25,586,253
Annualized Costs			
3 Percent	242,771	468,202	676,291
7 Percent	340,930	657,509	949,735
Annualized Net Benefits			
3 Percent	7,814,687	14,787,501	25,466,295
7 Percent	7,551,764	14,283,922	24,636,518

[1] FDA intends to create a symbols-glossary webpage explaining each symbol, and to make this page available on the FDA web site. The costs associated with constructing this webpage would approximately equal the average wages associated with each employee group contributing to the page's construction (e.g., administrators and webmasters) multiplied by each groups' respective hours worked. Discussions with FDA indicate that constructing and maintaining the website is a modest undertaking (i.e., it may take one or two hours) and thus including its costs into the analysis would not noticeable change the total estimated costs.

E. Uncertainty Analysis and Sensitivity Analysis

The proposed rule would provide medical device manufacturers with the option to use standardized international symbols to communicate information to end users. This option allows manufacturers to substitute labels containing text-only labels with symbol-only labels.

1. Label Revision Rates

The total estimated net benefits associated with using symbols are highly sensitive to labeling costs, which are contingent upon the rate at which medical device manufacturers revise their labels; the higher the rate, the greater are the cost savings from reducing the number of labels per product. The RTI model indicates that the mean revision rate is roughly once every 3 years. However, this revision rate may overstate the rule's total estimated benefits because the rate applies to the retail medical device industry, who we expect revises their labels more regularly than the non-retail medical device industry.

One alternative to using the mean revision rate is the mode: the most frequent revision rate. According to the labeling cost model, the most common revision rate is once every 5 years (Ref. E3). During the 5^{th} year, retail medical device companies revise approximately 50 percent of their labels. This rate is substantially greater than every other revision rate (e.g., during the second most common revision rate year, medical device companies only revise approximately 20 of their labels). If revisions occur every 5 years,

on average, roughly one fifth of the current stock of medical devices would be revised every year. As a result, we expect medical device companies to now revise approximately 4,108 (= 20,542/5) labels every year.

Table 7 presents the total estimated benefits associated with an average revision rate of 5 years. The results indicate that extending the revision rate approximately two more years corresponds to a 90 percent reduction in total expected benefits. The reduction is attributed to medical device companies using the extra time to coordinate more productive resources, resulting in substantially lower resource costs. As a result, total estimated benefits now range from $13.0 million to $33.8 million at a 3 percent discount rate, and from $9.3 million to $24.0 million at a 7 percent discount rate. Annualized over 20 years total estimated benefits range from $0.88 million to $2.3 million.

TABLE 7—ESTIMATED LABELING RE-DESIGNING COSTS

Revision Rate = 5 years

Labeling Re-design Savings	Low	Midpoint	High
Total Labeling Re-design Costs Avoided			
3 Percent	13,048,408	23,794,552	33,773,070
7 Percent	9,291,565	16,943,724	24,049,268
Annualized Labeling Re-design Costs Avoided			
3 Percent	877,058	1,599,368	2,270,081
7 Percent	877,058	1,599,368	2,270,081

Revision Rate = 1.5 years

Labeling Re-design Savings	Low	Midpoint	High
Total Labeling Re-design Costs Avoided			
3 Percent	308,982,353	586,218,883	1,013,816,638
7 Percent	220,021,441	417,437,183	721,922,773
Annualized Labeling Re-design Costs Avoided			
3 Percent	20,768,468	39,403,117	68,144,403
7 Percent	20,768,468	39,403,117	68,144,403

Table 8 presents the total estimated net benefits associated with an average revision rate of 5 years. Extending the revision rate does not change the total costs associated with using symbols, and thus increasing the revision rate time period only changes the total estimated net benefits via changing total estimated benefits. Annualized over 20 years, net benefits range from $0.63 million to $1.59 million at a 3 percent discount rate, and from $0.54 million to $1.32 million at a 7 percent discount rate.

TABLE 8—ESTIMATED ANNUALIZED NET BENEFITS
Revision Rate = 5 years

Description	Low	Midpoint	High
Annualized Benefits			
3 Percent	877,058	1,599,368	2,270,081
7 Percent	877,058	1,599,368	2,270,081
Annualized Costs			
3 Percent	242,771	468,202	676,291
7 Percent	340,930	657,509	949,735
Annualized Net Benefits			
3 Percent	634,287	1,131,166	1,593,790
7 Percent	536,128	941,859	1,320,346

Revision Rate = 1.5 years

Description	Low	Midpoint	High
Annualized Benefits			
3 Percent	20,768,468	39,403,117	68,144,403
7 Percent	20,768,468	39,403,117	68,144,403
Annualized Costs			
3 Percent	8,149,652	12,025,913	16,749,051
7 Percent	11,444,788	16,888,331	23,521,168
Annualized Net Benefits			
3 Percent	12,618,815	27,377,204	51,395,351
7 Percent	9,323,680	22,514,786	44,623,235

Changing economic conditions (e.g., an increase in competition or changes in regulation) could encourage companies to revise their labels more rapidly than originally planned. According to the labeling cost model, the quickest revision rate occurs once every 1.5 years, which is when approximately 10 percent of retail medical device companies revise their labels. If revisions occur once every 1.5 years, on average, then

we assume that roughly two-thirds of the current stock of medical device labels would be revised every year. As a result, we expect medical device companies to now revise approximately 13,695 (= 20,542/1.5) labels every year.

Table 7 presents the total estimated benefits associated with an average revision rate of 1.5 years. The results indicate that reducing the revision rate approximately two years corresponds to a 300 percent increase in total expected benefits. The increase corresponds to the substantial amount of uncoordinated resources that companies can avoid via switching to using symbols. As a result, total estimated benefits now range from $309.0 million to $1,013.8 million at a 3 percent discount rate, and from $220.0 million to $721.9 million at a 7 percent discount rate. Annualized over 20 years total estimated benefits range from $20.77 million to $68.14 million.

The labeling cost model indicates that more frequent revisions reduce a company's ability to coordinate productive resources, which would increase the one-time administration and outreach costs associated with switching to use symbols. Table 9 presents the one-time administrative costs associated with using symbols at the reduced revision rate. The average administrative costs per UPC range from $1,467.7 to $4,889, resulting in total one-time administration costs ranging from $23.8 million to $79.7 million. Outreach costs are mostly associated with marketing test costs: the costs associated with conducting focus groups and similar consumer tests. In the analysis above, outreach costs were estimated to approximately equal zero because we assumed that companies would switch to using symbols once it is possible to coordinate all

resources. However, now we assume that companies are switching to use symbols as rapidly as possible. In this case, companies cannot coordinate as many resources, and thus incur higher marketing test costs. The average marketing test costs per UPC range from $3,064 to $12,172 , resulting in total one-time marketing test costs ranging from $97.4 million to $169.5 million. Total one-time costs range from $121.2 million to $249.2 million. Annualized over 20 years, total estimated costs range from $12.6 million to $51.4 million at a 3 percent discount rate, and from $9.3 million to $44.6 million at a 7 percent discount rate.

TABLE 9—ESTIMATED RE-LABELING COSTS

Cost Factor	Low	Midpoint	High
Total One-time Marketing Costs	97,416,943	133,447,816	169,478,690
Total One-Time Administrative Costs	23,829,300	45,467,400	79,704,900
Total One-Time Costs	121,246,243	178,915,216	249,183,590
Annualized Focus Group Marking Costs			
3 Percent	8,149,652	12,025,913	16,749,051
7 Percent	11,444,788	16,888,331	23,521,168

Table 8 reports the total estimated net benefits associated with an average revision time of 1.5 years. Annualized over 20 years, total estimated net benefits range from $12.6 million to $51.4 million at a 3 percent discount rate, and from $9.3 million to $44.6 million at a 7 percent discount rate.

2. Medical Device Growth Rates

The above analysis assumes that there is no growth in medical device exports. However, changes in markets, regulations and technology could cause the export rate to increase or decrease. An increase in the rate with which companies export uniquely labeled medical devices would result in an increase in the total estimated net benefits associated with using symbols, and vice versa. For instance, an increase in the export

growth rate would result in an increase in the number of unique medical device labels requiring revisions. The option to use symbols would allow exporters to avoid the costs associated with revising the increasing number of separate U.S. only labels, which would result in an increase in total estimated net benefits. Estimating the export growth rate requires data that projects the number of uniquely labeled medical devices that manufacturers are expected to sell in the future. Because these data are unavailable, we cannot quantify the extent to which changes in the growth rate would change the total estimated net benefits associated with using symbols.

III. Regulatory Flexibility Analysis

FDA has examined the economic implications of the final rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. This analysis serves as the Initial Regulatory Flexibility Analysis as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

The Small Business Administration (SBA) considers medical device manufacturers (NAICS codes 334510, 334517, 339112, 339113, 339114 and 339115) to be small when they employ under 500 workers (Ref. E5). The 2007 Economic Census provides the most currently available employment statistics (Ref. E6). The resource

indicates that most medical device establishments are small: approximately 98 percent. However, this resource omits certain companies that are affected by the proposed rule, such as medical device relabelers, repackers and distributors. Some of these entities may be exporters. Hence, our estimate may understate the actual number of small establishments and their respective cost savings.

B. Economic Effect on Small Entities

Table 10 reports the proposed rule's estimated impact on small entities. We approximate the estimated impact using percent costs per UPC: the ratio between unit labeling costs and revenues among small entities. To proxy unit revenues, we use the total value of shipments corresponding to the average medical device manufacturer within various size categories. Table 10 presents these values across three size categories, establishments that employ 0-19, 20-99 and 100-499 employees. The average value of shipments across these size categories—going from the smallest staff size to largest—is $1 million, $9.3 million and $63.6 million, respectively. We estimate that the average percent costs per UPC are less than 0.01 percent. Hence, the agency concludes that this rule would not have a significant adverse impact on any small entities.

TABLE 10—ESTIMATED IMPACT OF THE FINAL RULE ON SMALL BUSINESS ENTITIES

Establishments			Value of Shipments (1000's)		Percent Cost per UPC of Average Value of Shipment		
Employees	Count	Percent	Total	Average	Low	Middle	High
0-19	3,784	67%	$ 2,665,118	$1,031	0.00	0.00	0.00
20-99	1,250	22%	$11,357,488	$9,271	0.00	0.00	0.00
100-499	628	11%	$39,941,838	$63,602	0.00	0.00	0.00

Notes—2007 Economic Census omits the value of shipments associated with 1,199 establishments employing 0-19 employees, and 25 establishments employing 20-99 employees. The value of shipments estimates correspond to the establishments that report value shipments data. Hence, the average value of shipments estimate of establishments employing 0-19 employees only corresponds to the 2,585 establishments that report value of shipments data.
Source: Electromedical and electrotherapeutic apparatus manufacturing, Irradiation apparatus manufacturing, Surgical and medical instrument manufacturing, Surgical appliance and supplies manufacturing, Dental equipment and supplies

manufacturing, and Ophthalmic goods manufacturing (NAICS 334510, 334517, 339112, 339113, 339114, 339115), 2007 Economic Census (Ref. E6)

The impact analysis indicates that companies can reap moderate cost-savings via switching to using symbols. On average, companies who switch to using symbols can expect to receive an average annual cost savings ranging from $1,000 to $4,000 per UPC. As a result, it is possible that providing medical device manufacturers with the option to use symbols may encourage companies, including small companies, to either start exporting products or export more products.

IV. References

E.1. U.S. Census Bureau U.S. International Trade Statistics, "Value of Exports, General Imports, and Imports for Consumption by (NAICS - 334510, 334517, 339112, 339113, 339114 and 339115)," http://censtats.census.gov/cgi-bin/naic3_6/naicMonth.pl, accessed Nov 2011.

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V. Appendices

A. Technical Appendix: Average Number of Uniquely Labeled Medical Devices by Establishment Size.

FDA assumes that the total number of uniquely labeled medical devices (ULMD) that U.S. companies use is approximately equal to the number of U.S. companies multiplied by the average number of devices they produce. However, larger establishments probably produce more uniquely labeled medical devices than smaller establishments, on average. Hence, to compute the total estimated number of uniquely

labeled medical devices produced, we performed the following steps: first, we separated companies via size; second, we estimated the number of companies within each size category; third, we estimated the average number of uniquely labeled medical devices that companies produced within each size category; fourth, we took the product of these estimates within each size category; and finally, we summed the products.[2] We group manufacturers by size using the Census categorizations (Ref. E2). The Census groups companies together using their employee size; very small in size institutions employ 1-19 workers, small institutions employ 20-99 employees, and medium to relatively large in size institutions employ 100 or more workers.

To estimate the average number of uniquely labeled medical devices produced by different sized U.S. companies, FDA randomly sampled approximately 180 medical device manufacturers and collected the following data: the company's name, employee size, and the number of uniquely labeled medical devices available for purchase. Employee sizes are reported in manta.com and dnb.com. The number of uniquely labeled medical devices available for purchase was estimated via counting the total uniquely labeled medical devices in each company's product catalog, which includes any medical devices or medical device accessories registered with FDA. To illustrate the way we counted medical devices, we use an example. For instance, we considered pedicle screw

[2] This estimation method may overstate the proposed rule's expected benefits. FDA currently permits companies to use symbol-only labels on medical devices intended for health professional use. This caveat suggests that my approach may overstate the number of uniquely labeled medical devices that could be converted to symbol-only labels. However, medical devices intended for health professional use make up a modest portion of all uniquely labeled medical devices, suggesting that my method would modestly overstate the proposed rule's benefits.

systems and syringes as two separate uniquely labeled medical devices, while we considered syringes of varying colors and sizes as only one.

Table 11 presents the sample data. The table indicates that the random sample contains approximately 110 very small companies, 40 small companies and 30 medium large companies. On average, very small companies produce approximately 9.4 uniquely labeled medical devices, small companies produce 25.7 uniquely labeled medical devices, and medium large companies produce 99.1 uniquely labeled medical devices.

TABLE 11—ESTIMATED AVERAGE NUMBER OF UNIQUELY LABELED MEDICAL DEVICES

Medium to Large Companies: 100 + Employees

Company Name	**Uniquely Labled Medical Devices**
3M	120
Airlife	190
Animas Corp	2
ArthroCare ENT	10
Aseptico	63
Atrion Medical Products, Inc	2
Bard Davol	75
Bio-Detek Inc	37
Burton Medical	24
Chad Therapeutics	5
Covidien	337
Cutera	15
Dale Medical Products Inc	12
Dexcom	1
Invacare	160
Jelco	19
Johnson & Johnson	850
King Systems Inc	60
Level 1	35
Lumitex	2
Medex	121
Mesa Laboratories, Inc.	15
Nonin	50
Physio Control	136
Portex	297
Propper Manufacturing CO Inc	30
Therma Solutions	1
Verathon	6
WelchAllyn	207
Xltek	92
Avg Exports	99.1

TABLE 11—ESTIMATED AVERAGE NUMBER OF UNIQUELY LABELED MEDICAL DEVICES

Small Companies: 20 - 99 Employees

Company Name	**Uniquely Labled Medical Devices**
Aci Medical	5
Acteon Satelec, Inc	7
Belmont Instrument Corporation	12
Brasch Group	6
Cadwell Laboratories	8
Celo Nova	1
Consensus Orthopedics	3
Convaid	31
Criticare Systems Inc	17
Dentronix Inc	113
Dupaco Inc	4
Essential Dental Systems, Inc	8
Gebaurer	5
Goldman Products, Inc	150
Key Surgical Inc	15
Konigsberg Instruments Inc	20
Lead Lok	8
Marpac	11
Mediflex Surgical Products	202
MHC Medical Products	8
Mimedx Group	4
Morrison Medical	85
Odyssey Medical	40
OmniLife Science	7
Orasure	5
Osseon Therapeutics Inc	4
Parcus Medical LLC	50
parksmed	24
Passy-Muir Inc	8
QRS Diagnostic	8
Ranfac Corp	26
River Rain Medical	2
Sciton	11
Scottcare Corporation	7
Cuda Surgical	17
Sunoptic Technologies LLC	4
Surgiform	27
ThermoTek Inc	12
Vita Needle Company	9
Westmed	80
X-Spine	10
Z Medica	7
Average Exports	25.7

TABLE 11—ESTIMATED AVERAGE NUMBER OF UNIQUELY LABELED MEDICAL DEVICES

Very Small Companies: 1 - 19 Employees

Company Name	Uniquely Labeled Medical Devices
3 Point Products	41
A&D Medical Corp	12
Adhezion	2
American Imex	42
AngioDynamics	20
AutomatedMedProducts	67
B & B Medical Technologies	17
Bertec	8
Bioclear	16
Biomeridian	3
Biowave Corp	5
BridgePoint Medical, Inc.	2
Brymill	22
C L Sturkey Inc	1
Cardia, Inc	5
Cardiocommand, Inc	6
Ceplast Medical Devices LLC	1
CW Medical, Inc	15
Eyenavision	3
Dermlite	10
DGH	16
Elliquence LLC	10
Eprt Technologies	3
Estill Medical Technologies, Inc	1
FutureMed America Inc	10
Glenveigh Pharmaceuticals, LLC	3
Great Laser	10
Griffin Laboratories	2
IDEV	2
InSightec, Inc.	6
Interrad Medical Inc	2
LAP of American LC	7
Laschal Surgical Instruments, Inc	8
Laschal Dental Instruments, Inc	15
LifeSciencePLUS	2
Maramed Orthopedic Systems	58
Mark Medical Manufacturing	111
Medical Alignment Systems	2
Medyssey Co., Ltd	5
Myerson L.L.C.	6

TABLE 11—ESTIMATED AVERAGE NUMBER OF UNIQUELY LABELED MEDICAL DEVICES (CONT.)

Very Small Companies: 1 - 19 Employees

Company Name	Uniquely Labeled Medical Devices
Myontronics Noromed, Inc	3
Neoforce group Inc	8
Neomedica Inc	7
Newmatic Medical	168
Ocular Systems Inc	1
Optical Integrity, Inc	2
Osstell Inc	1
Kowa Optimed Inc	11
PMT Corp	32
Premier heart	1
Saebo	3
Safe Stitch Medical Inc	5
Sagemax Bioceramics Inc	21
Separation Technologies, Inc	1
Signus Medical LLC	3
Sooil Inc	4
Stat Medical Devices	7
Sun Medica	11
Syris Scientific LLC	2
Tiba Medical Inc	1
Titan Spine LLC	5
Tracey Technologies Corp.	1
Trademark Medical	18
Translite LLC	4
Transmotion Medical Inc	10
Venni Instruments Inc	10
Ziemer USA	6
Zynex Medical	9
3 Test	3
Accell	4
Addto	3
AllStar Orthopedics & Medical Supplies, Inc	7
BCI Dental Laboratories Inc	5
Carolina Medical Electronics	2
Centex Dental Lab	4
Christy Manufacturing Company	1
Dental Arts Inc	7
Efficient Dental Technologies, LLC	5
Endocraft LLC	3
Equip for Independence	1
Eyesys Vision Inc	2
Fem Suite LLC	2
FMD	1

TABLE 11—ESTIMATED AVERAGE NUMBER OF UNIQUELY LABELED MEDICAL DEVICES (CONT.)

Very Small Companies: 1 - 19 Employees

Company Name	**Uniquely Labeled Medical Devices**
Focus Medical, LLC	3
Gereonics, Inc	1
Highland Medical Equipment	5
Identure	1
Imagederm Inc	4
Innovasis	6
Ion Vision Inc	7
KBCO Inc	5
Laser Engineerin, Inc	1
Laser Probe Inc	6
Lhasa OMS	4
Neuro Kinetics	3
Optima Products Incorp	*6*
Redfield Corporation	1
Rehabtek LLC	2
Rocco's Originals	1
Salmon Medical Innovations LLC	1
Secure Medical	1
Showcase Dental Lab	4
Sooka Inc.	2
Sterigearm	1
Sure Foot Inc	4
Suturtek	3
Thibido Technology Inc	1
Umbra Medical Devices	3
Uramix	2
US Therapy Inc	1
Varitronics Inc	7
Vista Medical	3
World Trend, Inc	1
Wright Therapy Products	2
Zewa Inc	7
Average Exports	9.4