Ref. 3

Task Order No. 8
Contract No. 223-94-8031

Cost Impacts of the Over-the-Counter Pharmaceutical Labeling Rule

Final Report
March 5, 1999

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EXECUTIVE SUMMARY

On February 27, 1997, the agency published the proposed rule to establish standardized format and content requirements for the labeling of over-the-counter (OTC) drug products. Industry comments on the proposed rule revealed an extreme divergence between the agency and industry cost assessments. The industry estimate of compliance costs was a minimum of 10 times greater than the agency estimate of $14 million. The industry further estimated that 33 percent of branded and 95 percent of private label products would need altered packaging configurations. In order to help the agency address and respond to industry comments, the agency contracted with ERG to collect supplementary data and to assist the agency in reviewing its analysis of currently marketed OTC products and labeling. ERG thus was commissioned to survey retail establishments to determine the percentage of OTC drug products that could not accommodate the agency's requirements, to estimate the incremental costs of package reconfiguration, and to make an assessment of the cost of label redesign.

In the winter of 1998, ERG conducted a survey and recorded data on all OTC products, nearly 2,700 shelf keeping units (SKUs), found in three retail establishments in the Boston area. ERG collected and analyzed data sufficient to distribute SKUs according to several compliance categories--those with labeling that would accommodate the new format, need larger labeling, or need to reconfigure packaging. The results are presented by type of packaging for four combinations of minimum font size (4.5 and 6 point) and print type (condensed and uncondensed). ERG found that for a minimum of 6 point condensed font with 0.5 leading between the lines of text, 93.5 percent of the SKUs could accommodate the new labeling without changes to the packaging configuration. Manufacturers will accomplish this using the existing labeling space or by using a larger label on the existing container. Manufacturers of the remaining 6.5 percent of SKUs will need to modify their packaging configuration by increasing container or carton size, or adding peelback or accordion labels. If smaller minimum fonts are allowed, a lower percentage of SKUs will need to have existing labeling and packaging configurations modified.

ERG employed a pharmaceutical labeling cost model to forecast the industry responses to alternative formats and calculate the compliance costs of regulatory alternatives. The total annualized costs of compliance are $33.5 million per year if industry is given one year to meet revised labeling, again

assuming a minimum of 6 point condensed font with 0.5 leading. This total is comprised of costs to revise the labeling content ($16.3 million or 48.7 percent), costs to revise the packaging configuration ($5.6 million or 16.7 percent), and incremental label, carton, and container material costs ($11.6 million or 34.6 percent). If a 2-year or 3-year implementation period is provided, the total annualized compliance costs fall to $20.7 million and $18.3 million per year, respectively. Under the 2-year implementation period, FDA is also considering a small volume product extension that would give manufacturers of these products an extra year to comply. The small product extension would reduce the total annualized compliance costs by 3.9 percent to $19.9 million per year from those for the 2-year implementation period.

SECTION ONE

INTRODUCTION AND STUDY METHODOLOGY

On February 27, 1997, the agency published the proposed rule to establish a standardized format for the labeling of over-the-counter (OTC) drug products. The agency estimated that the costs of the proposed rule with a 2-year implementation period were $14.2 million. This estimate included costs for label redesign and allowed one additional year to comply for individual OTC products with sales of less than $25,000. Industry comments submitted in response to the agency's economic analysis of the proposed rule asserted that the average cost to redesign labeling was too low, the methodology to calculate the economic impact was inappropriate and the agency incorrectly assumed that package and labeling sizes would not need to be increased. The NDMA, an industry trade organization, submitted an economic analysis which concluded that the cost for label redesign alone would be a minimum of $140 million, assuming a two year implementation period. NDMA further estimated that 33 percent of branded and 95 percent of private label products would need altered package configurations at a cost over $1 billion.

In order to help the agency address and respond to the industry estimates, the agency contracted with ERG to collect supplementary data and to assist the agency in reviewing its analysis of currently marketed OTC products and labeling. ERG thus was commissioned to survey retail establishments to determine the percent of OTC drug products that could not accommodate the agency's requirements, to estimate the incremental costs of package reconfiguration, and to make an assessment of the cost of label redesign.

The final rule establishes a standardized order and format for OTC labeling. The standardized format includes uniform headings, graphical features, and minimum standards for type size and spacing. The rule also amends specific wording of terms and warnings.

1.1 OVERVIEW OF COST ESTIMATION METHODOLOGY

ERG examined the costs that pharmaceutical companies will incur to revise the OTC labeling. The major elements of this study are:

- Performance of a survey of OTC products to estimate the share of existing pharmaceutical products that cannot accommodate revised labeling on existing labels or packages.
- Data collection on average costs for label redesign.
- Data collection on average costs to modify packaging configurations to accommodate new labeling.

ERG began its investigation by reviewing data gathered from an earlier study in which ERG and FDA personnel visited four pharmaceutical companies to discuss the logistics and costs of revising the labeling of pharmaceutical products. To supplement this information, ERG also solicited data from five industry consultants specializing in pharmaceutical industry regulatory affairs and labeling and packaging practices. The OTC product survey and data collected from consultants provided additional information on the likely frequency of packaging configuration changes and the costs of modifying labeling and changing packaging configurations. The combined data were then used in a pharmaceutical industry labeling cost model.

The discussion below describes relevant aspects of the OTC product survey and the pharmaceutical labeling cost model. Section Two presents the industry compliance cost estimates derived using the model and Appendix A provides additional detail on the model's structure and data inputs. Section Two also presents the small business analysis.

1.2 DATA GATHERED THROUGH THE OTC PRODUCT SURVEY

Information on several essential parameters of OTC labeling could not be reliably estimated without a direct examination of OTC products. ERG conducted a survey of OTC SKUs found in selected marketing outlets. ERG performed the OTC product survey during the winter of 1998. The principal

elements of the survey methodology are described below, with additional details on the survey protocol described in Appendix B. The principal question to be addressed in the survey was: To what extent will manufacturers need to revise their packaging configurations in order to accommodate the requirements of the OTC labeling rule?

1.2.1 Survey Protocol

For its survey of OTC SKUs, ERG staff visited three retail outlets: a large nationwide drug store, a family owned pharmacy, and a convenience (mini-market) store. The three different types of outlets were selected in order to create as diverse a group of SKUs as possible within project constraints. The convenience store was selected because, presumably, its stock included numerous small-size OTC products (i.e., the smallest containers and cartons). The family owned pharmacy, representing a small, independent outlet, and the large store, representing a nationwide chain, were selected because their stock included numerous OTC products of many sizes.

ERG staff examined and compiled information on 2,689 SKUs in its OTC product survey, or 2.7 percent of the estimated total number of SKUs. Included in the sample are several hundred SKUs of private label products (largely store brand products) covering almost all major product categories. Although many private label SKUs in other stores were not examined, the large majority of these other private label products are likely to be similar to those sampled. ERG judged, therefore, that its survey of OTC products provides a reliable representation of the universe of OTC SKUs.

Labeling Area and Font Measurement Assumptions

During its store visits, ERG staff examined each OTC SKU to determine whether labeling prepared according to FDA's OTC labeling rule would fit on existing labeling, on an expanded label on the existing container, or whether the manufacturer would need to change the packaging configuration (i.e., increase carton or container size, change the carton type by adding a fifth panel, or add accordion or peelback labels). While surveying products in the drug store, ERG staff first recorded the product name

and container type for each SKU (i.e., carton, bottle, etc.). Next, ERG measured the labeling font. If the existing labeling was printed in 6 point font or larger, ERG assumed that the revised labeling could fit on the existing container or carton. This assumption was based on ERG's work prior to the survey during which ERG examined labeling on a selection of approximately 50 OTC products. ERG compared these products' current labeling to labeling formatted according to the OTC labeling rule. With this comparison, ERG determined that all labeling now printed with 6 point font or larger could accommodate the new requirements. ERG also noted that 6 point font product labeling generally had multiple presentations of marketing information and logos and, in many cases, some unused labeling areas. Given the ample labeling space available, ERG therefore concluded that its assumption about 6+ point font labeling was justified. ERG performed additional analysis of the labeling for all SKUs with less than 6 point font.[1] ERG's protocol for the OTC product survey measurements is presented in Appendix B.

Fonts may be condensed or uncondensed. In condensed fonts, the horizontal width of the characters is reduced by approximately 20 percent while the vertical height of the characters is unchanged. Again using its collection of OTC products, ERG concluded that most SKUs printed with 6 point font or larger are uncondensed, but that most SKUs printed with smaller fonts are condensed. Due to the likely measurement error in assessing whether fonts are condensed or uncondensed while in the retail outlets, ERG did not attempt a SKU-by-SKU evaluation of whether fonts were condensed but rather assumed that labeling printed with 6 point fonts was uncondensed and that the smaller fonts were condensed. This assumption influences the estimates of the increase in labeling area needed to comply with the OTC labeling rule.

FDA is also requiring that manufacturers present a specific title prominently on labeling. This labeling element will also increase required labeling text area. ERG considered this element in pre-survey labeling observations but judged that its impact was too small to warrant separate measurement of heading fonts.

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[1] ERG noted that some labeling uses fonts smaller than 6 point, but include extra "leading" or space between lines of text. In its OTC product survey, ERG staff measured the combined effect of font and leading to determine whether the space being used was equivalent to that needed for a 6 point font (with no extra leading). Thus, a small percentage of the SKUs recorded as having 6 point fonts actually had smaller fonts but included sufficient leading to cover equivalent area.

Labeling also varies in the amount of "leading,"or space between lines of text. Based on pre-survey observations, products with 6 point font or larger fonts generally have sufficient labeling space including white space or the ability to delete marketing information. Therefore, ERG assumed that this labeling could easily accommodate a minimum of 0.5 point leading if not already present. Because of limitations on the time that could reasonably be spent in the drug store, ERG staff did not estimate the leading on labeling printed with 6 point font or larger sizes.

The assumptions about condensed fonts, heading fonts, and leading might cause an underestimate of compliance costs for manufacturers of some SKUs. For example, in assuming that current 6 point font labeling can accommodate the new specifications, ERG is judging that these manufacturers can absorb a modest increase in labeling space without needing to change their packaging configurations. ERG's reviews of packaging with 6 point font labeling indicate that virtually all packaging could accommodate even fairly substantial increases in FDA-required labeling if space devoted to marketing information were reduced. While respecting the area needed for the Principal Display Panel (PDP), most products with 6 point font use substantial portions of the information panel and other labeling surfaces for marketing information. ERG also notes that several other space rearrangements are often possible, such as reducing the area used to present expiration and lot number information. These reductions in areas taken for marketing and other information are assumed to be possible for the 6 point font products but are explicitly measured on a SKU-by-SKU basis for all other products, as explained below.

During the OTC product survey, if a SKU's labeling font was less than 6 point, ERG measured the dimensions of the carton or container (as appropriate, height, width, depth, circumference, height of fifth panel) and estimated the proportions of the existing labeling taken up by FDA-required information, company marketing and other information, and white space. ERG also measured available space for increasing label size.[2]

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[2] In measuring available space on the container for increasing label size, ERG considered only obviously available areas, such as the potential for extending a bottle label around the entire circumference. ERG did not consider possibilities for using the neck or bottom of bottles, or making other unconventional labeling presentations.

Determining Whether Revised Labeling Will Fit

In subsequent in-house analysis, ERG used three approaches in deciding whether revised labeling will fit on existing packaging:

- Comparison of existing labeling to FDA-prepared "templates" incorporating new requirements.
- Comparison of existing labeling to ERG-prepared "templates" incorporating new requirements.
- Calculation of the expansion in labeling area needed to incorporate new requirements.

For the first approach, FDA provided "templates" of revised OTC labeling for approximately 16 product categories. These templates suggest arrangements of labeling information for specific products and provide an overall estimate of the area needed for FDA-required labeling information. By comparing the templates to existing products and packaging, ERG was able to determine whether the revised labeling for that SKU and similarly labeled SKUs could be accommodated.

For the second approach, where FDA template information was not available, ERG prepared its own templates to approximate revised labeling area requirements. The ERG templates were based on the labeling found in the OTC Physician's Desk Reference (PDR) and the OTC rule labeling font specifications. First, ERG calculated the expansion in labeling area needed to account for possible increases in the font size used as discussed further below and in Table 1-2. Next, ERG noted that the OTC labeling rule formatting requirements, such as bulleting of information and special headings, might increase the area needed for the PDR-derived templates beyond the increase due simply to using a larger font size. Therefore, in addition to increasing the labeling found in the PDR based on font size, ERG increased the labeling area by an additional 15 percent. ERG's templates were used for approximately 40 SKUs.

Table 1-1 presents the minimum labeling area needed using the FDA and ERG templates for numerous OTC product categories. Some variation occurs between the FDA and ERG templates because sometimes more white space was included on the FDA templates. ERG did not attempt to predict the use of white space in its templates. As the table shows, most products will need over 50 cm^2 labeling area, and

Table 1-1

Labeling Area Needed for Selected OTC Product Categories

Product Category	Brands Addressed by FDA In Formal Templates	Labeling area needed (in sq. cm)	Brands Addressed by ERG In Informal Templates	Labeling area needed (in sq. cm)
Analgesic	CVS Ibuprofen	114	Tylenol Extra Strength	76
			Tylenol Cold	81
			Advil	104
			Bayer Aspirin	76
Antihistamine/Cough & Cold	CVS Allergy	67	Benadryl Allergy	67
			Vicks 44 Cough	67
			Vicks 44M	94
			Dimetapp DM Elixir	99
			Alka Seltzer Plus	108
			Comtrex Deep Chest Cold	99
			Halls Plus Maximum Strength Cough Drops	48
			Sucrets Sore Throat Lozenges	53
Appetite suppressant			Acutrim	78
Antacid and antiflatulent combination	Children's Mylanta	57	Children's Mylanta	60
Antiflatulent			Phazyme Gas Relief	30
			Maalox Antigas	31
Antidiarrheal			Kaopectate	44
Antiemetics	Pepto Bismol	116	Pepto Bismol	81
			Emetrol	58
Antacid	Pepto Bismol	116	Tagamet HB 200	69
			Tums EX	44
			Pepto Bismol	81
Laxative	Dulcolax	67	Citrucel	97
Fecal softener			ExLax	64
Laxative and antacid combination			Phillips Milk of Magnesia	81
Motion sickness			Dramamine	69
Nasal Spray	Afrin 12 hour spray	67	Afrin 12 hour spray	64
			Neosynephrine	62
Eyedrops	Opcon-A	42	Visine LR	53
Ear drops			Murine ear drops	60
Sedatives			Nytol	53

Table 1-1

Labeling Area Needed for Selected OTC Product Categories

Product Category	Brands Addressed by FDA In Formal Templates	Labeling area needed (in sq. cm)	Brands Addressed by ERG In Informal Templates	Labeling area needed (in sq. cm)
Topical analgesics	Neosporin (anti-infective)	54	Neosporin (anti-infective)	46
			Aspercreme (muscle relaxant)	48
			Benadryl (anti-itch)	53
			Caladryl (anti-itch)	48
			Preparation H (hemorrhoids)	74
			Desenex (antifungal for feet)	92
Dandruff shampoo	Head and Shoulders	50	Selsun Blue	41
Diaper rash			Goldbond Medicated Baby Powder	46
Canker and cold sores			Orajel Mouth Aid	60
Sunscreen	CVS Sunscreen	115	Shade Sunblock SPF 45	67
Feminine hygiene			Mycelex-7	67
Toothpaste	Crest	48	Crest for Sensitive Teeth	43
Lip products	Blistex	66		
Antiperspirants	CVS Antiperspirant	27		
Acne products	Clearasil	61		
Lice products	CVS Lice shampoo	145		

Source: Information provided by FDA or estimated by ERG, as indicated.

many will need 80 or 90 cm^2. ERG endeavored to use the templates as broadly as possible, applying the template estimates to as many related SKUs as possible. Because of the constant variation among SKU characteristics, however, ERG was able to apply the template estimates to only a limited number of SKUs beyond the specific products for which they were prepared.

For all SKUs not addressed by template information, ERG used a third approach, based on the existing labeling language, the package dimensions, and the OTC labeling rule font requirements, to calculate the expansion in labeling area needed. With the dimensions of each SKU, ERG calculated the available surface area for labeling. ERG then estimated the labeling area needed for FDA-required information for each of the four font sizes under consideration (6 point uncondensed, 6 point condensed, 4.5 point uncondensed, and 4.5 point condensed). The new formatting (e.g., bulleting of information and special headings) was not taken into account because the package labeling displays generally incorporate sufficient white space to allow for reformatting without any further expansion in labeling area used. These measurements were then compared to the available surface area on the package, less the space allotted for the PDP. ERG allowed the following percentages of available labeling area for the PDP and other marketing purposes: rectangular cartons-30 percent; fifth panel cartons-30 percent; bottles-40 percent; two-panel labels-50 percent; all others-40 or 50 percent (depending upon the specific presentation).[3]

To calculate the expansion of package labeling areas needed to meet OTC labeling rule requirements, ERG compared the size of sample paragraphs prepared in each font size found on labeling (4 point, 4.5 point, etc.) to the same paragraph prepared according to the OTC labeling rule. The ratio of the latter paragraph to the former established the expansion in labeling area needed to convert from smaller to larger fonts. These expansion factors were then applied to the estimates of the existing labeling area taken up by FDA-required information on the packages. Table 1-2 presents the expansion factors used to calculate surface area needed for fonts now printed in less than 6 point font uncondensed. As the table indicates, labeling currently printed in condensed 5.5 font was estimated to increase in surface area by 48 percent if it were to be printed in 6 point uncondensed with 0.5 point leading.

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[3] Bottle labels that go around the entire circumference were allotted 40 percent for marketing and other company information. For bottles that were designed to present two-panel labels, however, the SKU was allotted 50 percent for presentation of marketing and other company information.

Table 1-2

Projected Increase in Area Needed For Labeling Printed With Fonts Smaller Than OTC Labeling Rule Requirements

	Percentage Increase in Labeling Area to Accommodate 6 Point Font with 0.5 Leading		Percentage Increase in Labeling Area to Accommodate 4.5 Point Font with 0.5 Leading	
Initial Font Size (Points)	**Uncondensed**	**Condensed**	**Uncondensed**	**Condensed**
4 condensed	166%	121%	56%	31%
4.5 condensed	116%	80%	31%	NA
5 condensed	76%	49%	NA	NA
5.5 condensed	48%	26%	NA	NA

(a) All current labeling in smaller than 6 point font is assumed to be condensed with zero leading based on observations of a selection of OTC products made by ERG.

Source: Estimates are approximate and are based on ERG's measurements of sample paragraphs.

ERG also noted, however, that when the expansion factors were applied to existing labeling they suggested that some SKUs would need unusually large surface areas (e.g., 120 cm^2 or more) under the OTC labeling rule. Such results are misleading, however, because the FDA and ERG templates showed that very few products would need more than 120 cm^2 of labeling area.[4] To correct this flaw in the calculation methodology, ERG placed a maximum cap on the labeling area so that no products would need more than 120 cm^2 of labeling area. The flaw occurred because the drug store measurements of labeling area taken during the survey could not adequately account for the white space allowed in existing labeling and tended to overstate the labeling areas.

1.2.2 OTC Product Survey Results

Table 1-3 presents the results of ERG's product survey for alternative font sizes and print types. Overall, ERG found that 51.9 percent of SKUs are sold in conventional (i.e., rectangular) cartons, and 12.6 percent in fifth panel cartons (i.e., cartons with a fifth panel that rises above the carton and often provides a slot for hanging the product in drug store displays). An estimated 26.7 percent of SKUs are sold in bottles and 4.5 percent in "other" packaging. Blister packs (1.8 percent), aerosols (1.5 percent), and tubes (1.0 percent), are used for a small percentage of SKUs.

For the alternative of a minimum of 6 point font, condensed, ERG estimated that revised labeling will fit within the area now apportioned for regulatory information for 76.1 percent of the SKUs surveyed, will fit on the existing labeling area with an expanded share for the regulatory information area for 15.8 percent of SKUs, will fit on an expanded label that can be accommodated on the existing container for 1.7 percent, will not fit on 4.6 percent, and is indeterminate for 1.9 percent of SKUs. [ERG did not attempt a final judgment when the available labeling area (excluding the designated percentage for the PDP and FDA-required information besides that addressed in the OTC labeling rule) was within 5 square centimeters of the needed area.]

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[4] Among the templates prepared, FDA predicted a template larger than 120 cm^2 only for lice eradication products. For this product, the FDA estimate of 145 cm^2 was used in the analysis.

Table 1-3

Distribution of OTC Product Packaging by Type

Type of Packaging	Carton	Cartou w/ 5th panel	Bottle	Tube	Aerosol	Blister pack	Other	Total
	Percentage of SKUs							
Percentage of all SKUs in drug store survey	51.9%	12.6%	26.7%	1.0%	1.5%	1.8%	4.5%	100.0%
Percentage of SKUs that do not presently display inactive ingredients	2.5%	0.9%	1.8%	0.4%	0.0%	0.3%	0.8%	6.7%
	Assuming 6 point font, only uncondensed type allowed (a) (c)							
Revised labeling can fit using existing area apportioned for regulatory information	75.5%	88.5%	67.9%	84.6%	90.0%	85.4%	70.0%	75.4%
Revised labeling can fit if area apportioned for regulatory information is increased	19.7%	11.5%	6.8%	0.0%	2.5%	4.2%	0.0%	13.6%
Will fit on larger label on existing container	N/A	N/A	5.8%	N/A	0.0%	N/A	N/A	1.6%
Revised labeling will not fit	1.7%	0.0%	16.4%	15.4%	7.5%	0.0%	30.0%	6.8%
Indeterminate	3.2%	0.0%	3.1%	0.0%	0.0%	10.4%	0.0%	2.6%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
	Assuming 6 point font, condensed type allowed (a) (b) (c)							
Revised labeling can fit using existing area apportioned for regulatory information	76.5%	88.8%	68.6%	84.6%	90.0%	85.4%	70.0%	76.1%
Revised labeling can fit if area apportioned for regulatory information is increased	22.4%	11.2%	8.8%	0.0%	7.5%	14.6%	0.0%	15.8%
Will fit on larger label on existing container	N/A	N/A	6.3%	N/A	0.0%	N/A	N/A	1.7%
Revised labeling will not fit	0.6%	0.0%	10.4%	11.5%	2.5%	0.0%	30.0%	4.6%
Indeterminate	0.5%	0.0%	6.0%	3.9%	0.0%	0.0%	0.0%	1.9%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Table 1-3 (cont.)

Distribution of OTC Product Packaging by Type

Type of Packaging	Percentage of SKUs							
	Carton	Carton w/ 5th panel	Bottle	Tube	Aerosol	Blister pack	Other	Total
Assuming 4.5 point font, only uncondensed type allowed (a) (b) (c)								
Revised labeling can fit using existing area apportioned for regulatory information	92.6%	99.4%	84.4%	88.5%	92.5%	100.0%	70.0%	90.3%
Revised labeling can fit if area apportioned for regulatory information is increased	7.1%	0.6%	4.9%	3.9%	5.0%	0.0%	5.0%	5.4%
Will fit on larger label on existing container	N/A	N/A	3.1%	N/A	2.5%	N/A	N/A	0.9%
Revised labeling will not fit	0.4%	0.0%	5.4%	7.7%	0.0%	0.0%	13.3%	2.3%
Indeterminate	0.0%	0.0%	2.2%	0.0%	0.0%	0.0%	11.7%	1.1%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Assuming 4.5 point font, condensed type allowed (a) (b) (c)								
Revised labeling can fit using existing area apportioned for regulatory information	95.1%	99.4%	85.5%	88.5%	92.5%	100.0%	73.3%	92.1%
Revised labeling can fit if area apportioned for regulatory information is increased	4.5%	0.6%	6.5%	3.9%	5.0%	0.0%	14.2%	4.9%
Will fit on larger label on existing container	N/A	N/A	2.2%	N/A	2.5%	N/A	N/A	0.6%
Revised labeling will not fit	0.4%	0.0%	2.2%	3.9%	0.0%	0.0%	11.7%	1.3%
Indeterminate	0.0%	0.0%	3.5%	3.9%	0.0%	0.0%	0.8%	1.0%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Source: Based on data compiled during drug store survey.

(a) With 0.5 point leading between lines of text.
(b) As smaller minimum font sizes are considered, the percentage of SKUs that fit increase but the percentage of SKUs in other categories might increase or decrease, depending upon how the SKUs are distributed by size.
(c) Percentages might not sum to 100 percent due to rounding.

"Other" packaging (including chapped lip products, lip balm, bags), bottles, and tubes show the largest share of labeling that will not fit at 30.0, 10.4, and 11.5 percent respectively. Much lower percentages of labeling on cartons and fifth panel cartons (0.6 and 0.0 percent, respectively) will not fit. The carton categories are presently printed in relatively large fonts and have more surface area relative to product volume for presenting labeling information. Labeling on bottles and tubes, in comparison, are more likely to be printed in small fonts and to have little available surface area.

The percentage of SKUs that do not fit is related to the font size specified. With a minimum 6 point, uncondensed font allowed, 6.8 percent of SKUs do not fit, and 2.6 percent are indeterminate. The percentage of SKUs that do not fit decreases for alternatives that allow smaller fonts (i.e., 4.5 point font, condensed or uncondensed). Nearly all SKUs can accommodate revised labeling if FDA allows 4.5 font, condensed.

Many of the products that cannot accommodate revised labeling (assuming a 6 point condensed font minimum) currently have small font labeling, i.e., 4 and 4.5 point, on small dimension containers. As was shown in Table 1-2, an increase in font size to 6 point for these SKUs will generate a doubling or more in labeling area needed.

ERG staff also recorded the presence of inactive ingredients on the surveyed labeling. Under the FDA Modernization Act (FDAMA) OTC manufacturers must list inactive ingredients on their labeling. Table 1-3 shows that inactive ingredients are listed on 93.3 percent of SKUs and missing from the remaining 6.7 percent. Private label products are somewhat more likely not to include inactive ingredients than name brand products. ERG estimated the additional space needed to list inactive ingredients. Assuming that an additional 5 cm^2 is needed to list inactive ingredients, ERG found that only 3 SKUs will no longer be able to accommodate the OTC labeling rule requirements assuming a 6 point minimum, condensed font scenario. These SKUs were included in the percentage that do not fit.

1.3 PHARMACEUTICAL LABELING REVISION PROCESSES

Most pharmaceutical companies prepare a large amount of new or revised labeling and have routine procedures for this activity. With the extensive standardization of the labeling preparation process, ERG was able to develop forecasts of the costs that companies will incur to respond to the OTC labeling rule. The principal components of the labeling preparation processes are:

- Regulatory affairs staff identify the need for revised labeling. This staff typically coordinates the labeling review and revision process with other departments (including marketing, medical, and legal departments) and prepares the new labeling language.

- Graphic artists and labeling layout specialists prepare revised labeling. This might be done by in-house or external staff. Once completed, the revised labeling is normally sent to outside vendors for final printing.

- The manufacturing side of the company receives and reviews the final revised labeling. The manufacturing operation incurs costs to:

    - Replace and discard inventory of old labeling
    - Incorporate the new labeling into the material control and inventory systems
    - Modify labeling and packaging equipment as necessary to accommodate new labeling

If a company's current labeling cannot accommodate the additional requirements of the OTC labeling rule, that company has a variety of options available to it. Some pharmaceutical manufacturers, particularly those that now produce labeling in relatively small font sizes, will have to increase the size of their labeling and perhaps their packaging configurations (assuming FDA allows a minimum 6 point font, condensed, for OTC labeling). Overall, the range of compliance options includes:

I. Modify language on existing labeling/packaging configuration, with no change or a decrease in labeling area needed (no use of white space)

II. Modify language on existing labeling/packaging configuration, with an increase in labeling area needed

-Change container label
-Increase labeling area by using available white space on existing label
-Increase size of label
-Place revised, enlarged label on existing containers

-Change labeling configuration on existing containers by using peelback or two-ply accordion labels
-Change size of containers to accommodate larger label
-Package new containers on existing packaging line
-Package new containers on retooled packaging line
-Package new containers on new packaging line

-Change carton labeling
-Increase labeling area by using available white space on existing label
-Add carton (if none previously used)
-Package new cartons on existing packaging line
-Package new cartons on retooled packaging line
-Add a fifth panel (i.e., add a panel that extends beyond a rectangular carton and is often used to hang the product on store displays)
-Package new cartons on existing packaging line
-Package new cartons on retooled packaging line
-Enlarge the carton
-Package new cartons on existing packaging line
-Package new cartons on retooled packaging line
-Add peelback or two-ply accordion labels to existing cartons

The pharmaceutical labeling model, as described in the next section, addresses and incorporates the compliance costs, as appropriate, for all options.

1.4 THE LABELING COST MODEL

ERG used a pharmaceutical labeling cost model to calculate the compliance costs for the OTC labeling rule. The model generates compliance costs using relevant assumptions of the number of shelf-keeping units (SKUs) affected and a variety of other assumptions and unit cost inputs.

ERG assumed that manufacturers of any SKU whose label redesign cycle is less than the implementation period will not incur any regulatory cost. For example, if a company that routinely revises its product labeling once a year is given at least that long to revise FDA-mandated information, ERG judged that the regulatory revision can be made at essentially no cost. If labeling is being revised in any case, pharmaceutical companies can incorporate new regulatory requirements at the same time they are making other changes. Based on this assumption, ERG did not estimate costs for those SKUs expected to be redesigned within the implementation period.

Based on FDA estimates, ERG set the labeling model default values assuming that 20 percent of all SKUs affected have a 2-year label redesign cycle, 40 percent have a 3-year label redesign cycle, and the remaining 40 percent have a 6-year label redesign cycle. The SKUs are distributed evenly among the months of the cycle. In other words, if 240 SKUs with a 2-year label redesign cycle are affected, 10 would be redesigned each month of the cycle.

The labeling revision costs per SKU are calculated using the formula:

$$TC_i = (1\text{-}VS)*[\,(RA)_i + (ART) + (MC)_i + (IIL)_i\,] + (IL)_i + (PK)_i$$

where:

i = Size of company

TC = Total costs per SKU

VS = Share of labeling redesign costs that are attributed to activities voluntarily undertaken by pharmaceutical companies to meet non-regulatory labeling objectives

RA = Costs incurred by the regulatory affairs department in modifying labeling content

ART = Artwork costs (cost for graphic art work and supplies)

MC = Costs of preparing for new printing runs and incorporating the new labeling into manufacturing operations

IIL = Irreducible inventory loss that occurs for all labeling changes due to company needs for a margin of error in labeling inventories

IL = Excess labeling inventory losses that result from the need to change labeling on a shorter cycle than originally envisioned by a company, due to regulatory implementation deadlines

PK = Cost of an increase in label size, addition of peelback or accordion labels, or a change in packaging configuration

ERG's estimates of the unit costs incurred at each stage of the labeling revision process by small, medium, and large branded companies and private label companies are incorporated into the labeling model. These unit cost estimates are discussed in Appendix A along with the explanations of each cost term of the model.

1.4.1 Interpretation and Use of the Voluntary Share Value in the Model

The labeling cost model incorporates a "voluntary share" factor that reduces regulatory costs to the extent that they might be absorbed in the normal course of voluntary industry labeling revisions. The voluntary share is applied to SKUs that are not expected to redesign labeling within the implementation period. That is, the voluntary share factor is applied to SKUs for which some label redesign costs are incurred.

In order to quantify the voluntary share concept, ERG assumed that a pharmaceutical manufacturer's demand for labeling revisions (independent of regulatory mandates) is a steadily increasing function of the time that has elapsed since the last labeling revision. Thus, the demand for new labeling changes builds steadily over time as manufacturers refine marketing techniques and strategies or improve products. At some point, the demand for labeling revisions is sufficient to cause manufacturers to undertake labeling revisions voluntarily (i.e., the investment in a labeling revision satisfies the company's required rate of return on the investment).

ERG defined the voluntary share as the ratio of the implementation period to the label redesign cycle. If a company normally revises its labeling every 3 years, and if it must revise labeling at the end of the first year of its redesign cycle, then the voluntary component is 1/3 of the total labeling revision cost. This is similar to arguing that within the first year of its labeling cycle, this company accrues 1/3 of the beneficial reasons for voluntarily label redesign. Then when it redesigns labeling at the end of the first year, 1/3 of the label redesign cost reflects voluntary activities. ERG calculated a weighted average of the voluntary share component using the distribution of SKUs across the label redesign cycles of 2, 3, and 6 years.

In the model, the voluntary share factor is applied to (and, therefore, reduces) the costs of regulatory affairs, artwork, printing/manufacturing costs, and the irreducible minimum inventory loss. The voluntary share factor does not reduce costs attributable to an inventory loss associated with a shortening of the label redesign cycle or packaging changes. Packaging configuration changes are rarely undertaken voluntarily. Therefore ERG considered packaging reconfiguration costs to be entirely regulatory costs.

Because of the possibility of differing viewpoints on the VS factor and in order to examine its influence on costs, ERG also considers another approach in which label redesign is assumed to occur in highly erratic cycles. The estimates derived using this approach are not considered to represent actual costs but rather an upper bound for label redesign costs based on the extreme assumption that there is no voluntary share. Instead of viewing the label redesign process as reflecting a steadily increasing demand for a label redesign, this method suggests that various exogenous influences (such as a competitor's label redesign) compel sudden label redesign responses, and that there is no gradual accumulation of beneficial labeling refinements to incorporate. Thus no portion of the label redesign costs for SKUs labeled after the end of the implementation period is judged to be voluntary and the voluntary share is zero (in the model formula, VS=0).

SECTION TWO

ESTIMATES OF COMPLIANCE COSTS

A Pharmaceutical Labeling Model was used to estimate the industry costs of compliance with FDA OTC labeling rule. This section describes the specific assumptions used in the model (Section 2.1), the regulatory scenarios addressed (Section 2.2), the compliance cost estimates (Section 2.3), and the small business impacts (Section 2.4).

2.1 ASSUMPTIONS FOR THE OTC LABELING MODEL

The OTC labeling rule applies to the labeling viewed by consumers on OTC drug products. FDA estimated that the total number of SKUs is 98,639. The three principal components of the regulatory compliance costs are 1) the costs for redesigning OTC labeling, 2) the costs for modifying packaging and labeling configurations to accommodate larger labeling, and 3) the incremental annual materials costs for using larger labels, cartons, or containers. Manufacturers of an OTC drug product that is marketed pursuant to a final monograph, an approved new drug application, or an abbreviated new application at the time of publication of the OTC labeling rule (an estimated 39,310 SKUs) will be subject to these costs, where applicable, within the implementation period. The remaining 59,329 SKUs, will be allowed up to 6 years to revise labeling. Because the format changes may be incorporated with routine labeling revisions, no redesign costs are assigned to these remaining SKUs. However, ERG assumed that manufacturers of these remaining SKUs would incur the costs of packaging reconfiguration, where applicable, on average at 4 years from the publication date of this final regulation. Thus, these compliance costs were discounted to the present.

Based on the ERG retail store survey results presented in Section 1, manufacturers will have to increase the labeling or reconfigure the packaging for only a small percent of the 98,639 SKUs. To change their labeling and/or packaging configurations, manufacturers might switch to larger cartons or containers, or add peelback or accordion labels. If manufacturers change to new packaging, their compliance costs will vary with the extent of those changes.

For the purposes of forecasting the compliance options used by manufacturers and estimating compliance costs, ERG applied the following series of inputs and assumptions to the OTC model.

- Where cartons are used, manufacturers are not required to make inner container labels conform to outer labeling. It is recognized that many manufacturers will modify both outer and inner labeling to ensure consistency and avoid consumer confusion; nevertheless, for this analysis, ERG did not estimate the costs to modify inside labeling.

- Based on the store survey, ERG estimated that container labels will be affected for 34 percent of SKUs and carton labeling will be affected for 66 percent of SKUs.

- FDA has estimated that 30 percent of OTC drugs are branded products and that the remaining 70 percent are private label products. ERG used this estimate in the model and assumed that of the branded products, 50 percent are manufactured by small companies, 17 percent are manufactured by medium companies, and 33 percent are manufactured by large companies, as based on the 1992 Census of Manufactures. The private label category includes all company size categories, but is heavily dominated by large firms such as Perrigo.

- Of the SKUs presently covered by final monographs, many will be redesigned voluntarily within the FDA implementation period. Out of the total SKUs subject to label redesigns, under a 1-year regulatory implementation period, 27,517 SKUs will actually incur costs. The remainder (11,793) will have been redesigned voluntarily within the implementation period. For a 2-year implementation period, 15,724 will incur label redesign costs. For a 3-year implementation period, 7,862 will incur label redesign costs. Nevertheless, even the manufacturers that incorporate the FDA-required labeling changes within a voluntary redesign cycle might still incur regulatory costs if they must also change their packaging configuration because the reconfiguration costs are always judged to be regulatory costs.

- ERG estimated the average increase in labeling text area needed for products now labeled with fonts smaller than FDA's labeling specification. For example, if FDA allows a 6 point minimum uncondensed font, ERG estimated the average percentage increase in labeling text area for labeling with smaller fonts. The average increase in text area was derived by judging the average font size of labeling needing revision based on the OTC product survey and then estimating the increase in labeling text using the projections presented in Table 1-2. Thus, if FDA allows 6 point minimum uncondensed or condensed fonts, ERG judged that the average font needing revision would be 5 point condensed font and that the average labeling area increase for such labeling would be 76 percent for a 6 point uncondensed font and 49 percent for a 6 point condensed font. Similarly, if FDA allows 4.5 point minimum uncondensed font, ERG judged the average font needing revisions to be 4.5 point font condensed and that the average labeling area increase for such labeling would be 31 percent. If FDA allows 4.5 point minimum, condensed font, the average font was estimated to be 4 point condensed font with an average labeling area increase of 31 percent.

- Regarding containers that cannot accommodate revised labeling with existing packaging, ERG estimated that manufacturers will increase container size to accommodate the larger label for approximately 37 percent of these SKUs. For another 5 percent of these SKUs, manufacturers will add a carton. For the remaining 58 percent, manufacturers will switch to a nonstandard label that can hold more information, such as a peelback or accordion label.

- Regarding cartons that cannot accommodate revised labeling with existing packaging, ERG estimated that manufacturers will increase carton size or add a fifth panel to the carton for 95 percent of their SKUs. For the remaining 5 percent of SKUs, manufacturers will switch to a non-standard peelback or accordion label.

- ERG did not estimate the probability that manufacturers might either obtain special exemptions or remove SKUs from the market in response to the regulation.

2.2 REGULATORY SCENARIOS USED IN MODELING OF COMPLIANCE COSTS

ERG examined the following regulatory scenarios:

- A regulatory implementation period of 12, 24, or 36 months.

- Minimum of 6 point and 4.5 point font size, condensed or uncondensed, all with 0.5 point leading.

- A 1-year extension on compliance for small volume products (i.e., those with sales less than $25,000) when the overall regulatory implementation period is 2 years. This scenario is developed by combining results from the 2-year lead time scenario with the results for small businesses assuming a 3-year lead time.

2.3 ESTIMATES OF COMPLIANCE COSTS

Tables 2-1 and 2-2 present the total compliance cost estimates for the regulatory scenarios. The total industry compliance outlays (Table 2-1), consisting of label redesigns and packaging reconfiguration outlays, are estimated at $89.6 million for a 1-year implementation period, $51.9 million

Compliance Outlays
for the OTC Labeling Rule (a)
($millions)

Regulatory Scenario (b)	Label Redesigns		Packaging Configurations		Total One-Time Industry Outlays	Annual Incremental Label, Carton, and Container Materials Costs		Total Annual Incremental Costs
	Final SKUs	Nonfinal SKUs	Final SKUs	Nonfinal SKUs		Final SKUs	Nonfinal SKUs	
6 point font, only uncondensed type allowed								
1-yr leadtime	$50.25	NA	$21.99	$25.32	$97.57	$8.50	$9.79	$18.28
2-yr leadtime	$13.80	NA	$20.62	$25.32	$59.74	$8.50	$9.79	$18.28
With small product exemption for 2-year leadtime	$11.23	NA	$20.62	$25.32	$57.18	$8.50	$9.79	$18.28
3-yr leadtime	$5.91	NA	$20.62	$25.32	$51.86	$8.50	$9.79	$18.28
6 point font, condensed type allowed								
1-yr leadtime	$50.25	NA	$18.28	$21.04	$89.57	$5.34	$6.15	$11.48
2-yr leadtime	$13.80	NA	$17.08	$21.04	$51.93	$5.34	$6.15	$11.48
With small product exemption for 2-year leadtime	$11.23	NA	$17.08	$21.04	$49.36	$5.34	$6.15	$11.48
3-yr leadtime	$5.91	NA	$17.08	$21.04	$44.04	$5.34	$6.15	$11.48
4.5 point font, only uncondensed type allowed								
1-yr leadtime	$50.25	NA	$10.07	$11.60	$71.91	$2.37	$2.73	$5.10
2-yr leadtime	$13.80	NA	$9.41	$11.60	$34.80	$2.37	$2.73	$5.10
With small product exemption for 2-year leadtime	$11.23	NA	$9.41	$11.60	$32.24	$2.37	$2.73	$5.10
3-yr leadtime	$5.91	NA	$9.41	$11.60	$26.92	$2.37	$2.73	$5.10
4.5 point font, condensed type allowed								
1-yr leadtime	$50.25	NA	$6.73	$7.75	$64.73	$1.56	$1.79	$3.35
2-yr leadtime	$13.80	NA	$6.29	$7.75	$27.84	$1.56	$1.79	$3.35
With small product exemption for 2-year leadtime	$11.23	NA	$6.29	$7.75	$25.27	$1.56	$1.79	$3.35
3-yr leadtime	$5.91	NA	$6.29	$7.75	$19.95	$1.56	$1.79	$3.35

(a) Outlays for nonfinal SKUs are assumed to begin in year 5 and are discounted to year 1 using a 7% discount rate.
(b) For all scenarios, 0.5 point leading is assumed to be required.

Tabl

Annualized Industry Compliance Costs for the OTC Labeling Rule (a) ($millions)

Regulatory Scenario (b)	Label Redesigns		Packaging Configurations		Incremental Label, Carton, and Container Materials Costs		Total Annualized Costs
	Final SKUs	Nonfinal SKUs	Final SKUs	Nonfinal SKUs	Final SKUs	Nonfinal SKUs	
6 point font, only uncondensed type allowed							
1-yr leadtime	$16.29	NA	$3.13	$3.61	$8.50	$9.98	$41.51
2-yr leadtime	$3.68	NA	$2.94	$3.61	$8.50	$9.98	$28.71
With small product exemption for 2-year leadtime	$2.89	NA	$2.94	$3.61	$8.50	$9.98	$27.91
3-yr leadtime	$1.24	NA	$2.94	$3.61	$8.50	$9.98	$26.26
6 point font, condensed type allowed							
1-yr leadtime	$16.29	NA	$2.60	$3.00	$5.34	$6.27	$33.49
2-yr leadtime	$3.68	NA	$2.43	$3.00	$5.34	$6.27	$20.72
With small product exemption for 2-year leadtime	$2.89	NA	$2.43	$3.00	$5.34	$6.27	$19.92
3-yr leadtime	$1.24	NA	$2.43	$3.00	$5.34	$6.27	$18.28
4.5 point font, only uncondensed type allowed							
1-yr leadtime	$16.29	NA	$1.43	$1.65	$2.37	$2.79	$24.53
2-yr leadtime	$3.68	NA	$1.34	$1.65	$2.37	$2.79	$11.83
With small product exemption for 2-year leadtime	$2.89	NA	$1.34	$1.65	$2.37	$2.79	$11.04
3-yr leadtime	$1.24	NA	$1.34	$1.65	$2.37	$2.79	$9.39
4.5 point font, condensed type allowed							
1-yr leadtime	$16.29	NA	$0.96	$1.10	$1.56	$1.83	$21.73
2-yr leadtime	$3.68	NA	$0.90	$1.10	$1.56	$1.83	$9.06
With small product exemption for 2-year leadtime	$2.89	NA	$0.90	$1.10	$1.56	$1.83	$8.27
3-yr leadtime	$1.24	NA	$0.90	$1.10	$1.56	$1.83	$6.62

(a) The present value of the cost streams from Table 2-1 is annualized starting from year 1. A 7% interest rate is used. For nonfinal SKUs, no costs are incurred until year 5, which is reflected in the present value of the cost stream.

(b) For all scenarios, 0.5 point leading is assumed to be required.

for a 2-year implementation period, and $44.0 million for a 3-year regulatory implementation period, assuming FDA requires a minimum of 6 point condensed font on OTC product labeling. In addition, annual incremental costs for larger labels, cartons, and containers are estimated at $11.5 million per year. Annualizing the capital costs to put all figures on annual terms (Table 2-2), the annualized total compliance costs are $33.5 million per year for a 1-year implementation, $20.7 million for a 2-year implementation period, and $18.3 million for a 3-year implementation plan.

With the 2-year implementation period, FDA is also considering an additional 1-year extension (to a total of 3 years) for small volume OTC products. With the small product extension, the total industry compliance outlays for the 2-year case fall by approximately 4.9 percent, and the final annualized cost total falls by approximately 3.9 percent. The cost incurred by small entities was estimated using the assumption that small volume products represent 75, 10, 5, and 40 percent, respectively, of SKUs produced by small, medium, and large branded companies and private label companies. This distribution of small volume products was based on data from Nielsen that 40 percent of SKUs have sales less than $25,000 per year (as cited in the proposed rule for OTC labeling requirements published in the February 29, 1997 Federal Register) and the assumption that mostly small companies produce small volume products.

If FDA allows an uncondensed instead of condensed 6 point font, the costs of packaging configuration changes and incremental label, carton, and container costs will be higher. The total annualized costs would then vary from $41.5 million for a 1-year implementation scenario to $26.3 million for a 3-year implementation period, which represent increases of 24 and 44 percent respectively.

FDA could also allow smaller fonts on OTC labeling. If FDA allows 4.5 point uncondensed fonts, the costs of packaging configuration changes and incremental label, carton, and container costs decline by 27 percent with a 1 year implementation period and by 49 percent if a 3 year implementation period is granted.

ERG also estimated compliance costs assuming that the voluntary share is zero, i.e., the alternate upper bound assumption described in Section One. Using this assumption, the estimates of labeling redesign costs are higher. Tables 2-3 and 2-4 present the cost estimates using the alternative version of the

Table 2-3

Compliance Outlays
for the OTC Labeling Rule (a)
($millions)

Alternative Upper Bound Version

Regulatory Scenario (b)	Label Redesigns: Final SKUs	Label Redesigns: Nonfinal SKUs	Packaging Configurations: Final SKUs	Packaging Configurations: Nonfinal SKUs	Total One-Time Industry Outlays	Annual Incremental Label, Carton, and Container Materials Costs: Final SKUs	Annual Incremental Label, Carton, and Container Materials Costs: Nonfinal SKUs	Total Annual Incremental Costs
6 point font, only uncondensed type allowed								
1-yr leadtime	$81.29	NA	$21.99	$25.32	$128.61	$8.50	$9.79	$18.28
2-yr leadtime	$35.48	NA	$20.62	$25.32	$81.42	$8.50	$9.79	$18.28
With small product exemption for 2-year leadtime	$29.70	NA	$20.62	$25.32	$75.65	$8.50	$9.79	$18.28
3-yr leadtime	$17.74	NA	$20.62	$25.32	$63.68	$8.50	$9.79	$18.28
6 point font, condensed type allowed								
1-yr leadtime	$81.29	NA	$18.28	$21.04	$120.61	$5.34	$6.15	$11.48
2-yr leadtime	$35.48	NA	$17.08	$21.04	$73.61	$5.34	$6.15	$11.48
With small product exemption for 2-year leadtime	$29.70	NA	$17.08	$21.04	$67.83	$5.34	$6.15	$11.48
3-yr leadtime	$17.74	NA	$17.08	$21.04	$55.87	$5.34	$6.15	$11.48
4.5 point font, only uncondensed type allowed								
1-yr leadtime	$81.29	NA	$10.07	$11.60	$102.96	$2.37	$2.73	$5.10
2-yr leadtime	$35.48	NA	$9.41	$11.60	$56.49	$2.37	$2.73	$5.10
With small product exemption for 2-year leadtime	$29.70	NA	$9.41	$11.60	$50.71	$2.37	$2.73	$5.10
3-yr leadtime	$17.74	NA	$9.41	$11.60	$38.75	$2.37	$2.73	$5.10
4.5 point font, condensed type allowed								
1-yr leadtime	$81.29	NA	$6.73	$7.75	$95.77	$1.56	$1.79	$3.35
2-yr leadtime	$35.48	NA	$6.29	$7.75	$49.52	$1.56	$1.79	$3.35
With small product exemption for 2-year leadtime	$29.70	NA	$6.29	$7.75	$43.75	$1.56	$1.79	$3.35
3-yr leadtime	$17.74	NA	$6.29	$7.75	$31.78	$1.56	$1.79	$3.35

(a) First-year costs for nonfinal SKUs are assumed to begin in year 5 and are discounted to year 1 using a 7% discount rate.
(b) For all scenarios, 0.5 point leading is assumed to be required.

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Annualized Industry Compliance Costs
for the OTC Labeling Rule (a)
($millions)

Alternative Upper Bound Version

Regulatory Scenario (b)	Label Redesigns		Packaging Configurations		Incremental Label, Carton, and Container Materials Costs		Total Annualized Costs
	Final SKUs	Nonfinal SKUs	Final SKUs	Nonfinal SKUs	Final SKUs	Nonfinal SKUs	
6 point font, only uncondensed type allowed							
1-yr leadtime	$26.35	NA	$3.13	$3.61	$8.50	$9.98	$51.57
2-yr leadtime	$9.47	NA	$2.94	$3.61	$8.50	$9.98	$34.49
With small product exemption for 2-year leadtime	$7.60	NA	$2.94	$3.61	$8.50	$9.98	$32.62
3-yr leadtime	$3.72	NA	$2.94	$3.61	$8.50	$9.98	$28.75
6 point font, condensed type allowed							
1-yr leadtime	$26.35	NA	$2.60	$3.00	$5.34	$6.27	$43.55
2-yr leadtime	$9.47	NA	$2.43	$3.00	$5.34	$6.27	$26.51
With small product exemption for 2-year leadtime	$7.60	NA	$2.43	$3.00	$5.34	$6.27	$24.64
3-yr leadtime	$3.72	NA	$2.43	$3.00	$5.34	$6.27	$20.76
4.5 point font, only uncondensed type allowed							
1-yr leadtime	$26.35	NA	$1.43	$1.65	$2.37	$2.79	$34.59
2-yr leadtime	$9.47	NA	$1.34	$1.65	$2.37	$2.79	$17.62
With small product exemption for 2-year leadtime	$7.60	NA	$1.34	$1.65	$2.37	$2.79	$15.75
3-yr leadtime	$3.72	NA	$1.34	$1.65	$2.37	$2.79	$11.87
4.5 point font, condensed type allowed							
1-yr leadtime	$26.35	NA	$0.96	$1.10	$1.56	$1.83	$31.79
2-yr leadtime	$9.47	NA	$0.90	$1.10	$1.56	$1.83	$14.85
With small product exemption for 2-year leadtime	$7.60	NA	$0.90	$1.10	$1.56	$1.83	$12.98
3-yr leadtime	$3.72	NA	$0.90	$1.10	$1.56	$1.83	$9.10

(a) The present value of the cost streams from Table 2-3 is annualized starting from year 1. A 7% interest rate is used. For nonfinal SKUs, no costs are incurred until year 5, which is reflected in the present value of the cost stream.

(b) For all scenarios, 0.5 point leading is assumed to be required.

voluntary share calculation. The alternative assumption produces a significant increase in the costs of label redesigns. For the case of a 1-year leadtime and a minimum of 6 point font, condensed, compliance outlays for labeling redesign costs (Table 2-3) increase from $50.3 million to $81.3 million. For the 2-year and 3-year implementation scenarios, the labeling redesign costs increase by more than a factor of 2. The voluntary share factor has no affect on the other cost terms so these are unchanged. The percentage increase in total annualized compliance costs (Table 2-4) for the 1-year, 2-year, and 3-year scenarios assuming a minimum of 6-point font, condensed, are 30.0 percent, 27.9 percent, and 13.6 percent, respectively.

2.4 SMALL BUSINESS IMPACTS

This section addresses the potential impact of the OTC labeling rule on small businesses, which for this regulation are primarily small pharmaceutical manufacturers. ERG estimates the affected number of small businesses and then calculates regulatory impacts as a share of industry revenues.

2.4.1 Estimated Number of Affected Firms

The Regulatory Flexibility Act (RFA) requires agencies to determine whether a new rule may have a significant effect on a substantial number of small entities. According to the Small Business Administration (SBA), a pharmaceutical manufacturing firm that employs 750 employees or less is considered a small business (SBA, 1996).

The OTC labeling rule also affects numerous supermarket and drug store chains that employ private label companies to produce store brands (e.g., "Safeway" brands) of OTC products. Supermarkets are classified in SIC 5411 and drug stores are classified in SIC 5911. The small business classification maximums for these SICs are $20 million and $5 million in revenues per year, respectively. ERG judged that all supermarket and drug store chains that produce private label products generate much larger revenues than these limitations and, therefore, are classified as large businesses. These SICs are therefore excluded from further consideration.

ERG estimated the number of small entities in SIC 2834 affected by the final rule using SBA's database of small businesses, as compiled from U.S. Bureau of the Census data. Table 2-5 shows the distribution of pharmaceutical companies (classified in Standard Industrial Classification 2834) by employment size from that source. The estimate of 592 firms reported in SIC 2834 encompasses both prescription and OTC companies and, therefore, overstates the number of companies affected. Pharmaceutical companies can make both OTC and prescription products or specialize in only one area. As an alternative source, FDA reported that their review of data provided by a private database company (IMS) showed approximately 400 manufacturers of OTC products. Given that the SBA/Census estimate of 592 firms is certain to include a substantial number of manufacturers of only prescription products, the IMS estimate of 400 firms appears more reasonably accurate.

To estimate the employment and revenue of OTC manufacturers, ERG relied on the SBA/Census data. These data are presented in Table 2-6. Based on the SBA/Census data, approximately 11 percent of the 400 OTC manufacturers are estimated to be large firms, leaving a total of 357 small OTC manufacturers.

Table 2-6 also shows receipts by employment size class. (Note that the SBA/Census database does not define an employment size class that precisely identifies firms with 750 employees or less. ERG defined this group using the assumptions described in the table.) These data show that the average small business employs approximately 53 workers and generates approximately $20.8 million in revenues.

2.4.2 Compliance Costs as a Share of Small Pharmaceutical Manufacturer Revenues

In order to measure the impact of the final rule on small businesses, ERG calculated the ratio of industry compliance costs to industry revenues. Because many of the affected businesses produce prescription as well as OTC products, the impact of the OTC final rule is diluted to some extent when viewing aggregated industry data. Nevertheless, no other revenue information by employment size class covering only OTC products is available.

TABLE 2-5

Distribution of Pharmaceutical Manufacturing Firms (SIC 2834) by Employment Size

	Industry Total (a)	Employment Size							
		0	1-4	5-9	10-19	20-99	100-499	500-750 (b)	750+
Firms	592	27	129	63	72	146	75	17	64
Establishments	707	27	129	63	72	149	85	28	154
Employment	128,537	0	293	431	1,027	6,184	14,776	5,324	100,502
Avg. employ. per firm	217	0	2	7	14	42	197	323	1,583
Receipts ($000)	$62,696,704	$47,750	$60,862	$90,280	$246,099	$2,139,421	$5,970,830	$2,413,567	$51,727,895
Receipts per firm ($000)	$105,907	$1,769	$472	$1,433	$3,418	$14,654	$79,611	$146,277	$814,613

(a) Totals may not add due to rounding

(b) SBA does not report data for the 500-750 size range. These estimates were derived by assuming that this group includes 50 percent of the firms and establishments and 33 percent of the employment and revenues of firms in the 500-2,500 size range (the 500-2,500 size range is presented in the source but is not shown in table).

Source: Small Business Administration, 1994.

Table 2-6

Estimated Number and Size Distribution of OTC Manufacturers, by Employment Size (a)

	OTC Manufacturing Total	Employment Size 0	1-4	5-9	10-19	20-99	100-499	500-750 (b)	OTC Small Business Total
Firms	400	18	87	43	49	99	51	11	357
Establishments	478	18	87	43	49	101	57	19	374
Employment	86,849	0	198	291	694	4,178	9,984	3,597	18,942
Average employment per firm	217	0	2	7	14	42	197	323	53
Percentage of total small business employment	NA	0.0%	1.0%	1.5%	3.7%	22.1%	52.7%	19.0%	100.0%
Receipts ($000)	$42,362,638	$32,264	$41,123	$61,000	$166,283	$1,445,555	$4,034,345	$1,630,788	$7,411,357
Receipts per firm ($000)	$105,907	$1,769	$472	$1,433	$3,418	$14,654	$79,611	$146,277	$20,755
Total SKUs affected	98,639	0	688	1,011	2,410	14,513	34,676	12,494	65,792
As percentage of all SKUs	100.0%	0.0%	0.7%	1.0%	2.4%	14.7%	35.2%	12.7%	66.7%
Total annualized compliance costs ($millions)									
1-yr leadtime	$33.5	$0.0	$0.2	$0.3	$0.8	$4.9	$11.8	$4.2	$22.3
2-yr leadtime	$20.7	$0.0	$0.1	$0.2	$0.5	$3.0	$7.3	$2.6	$13.8
With small product exemption for 2-year leadtime	$19.9	$0.0	$0.1	$0.2	$0.5	$2.9	$7.0	$2.5	$13.3
3-yr leadtime	$18.3	$0.0	$0.1	$0.2	$0.4	$2.7	$6.4	$2.3	$12.2
Total annualized compliance costs as percentage of annual revenues									
1-yr leadtime	0.08%	0.00%	0.57%	0.56%	0.49%	0.34%	0.29%	0.26%	0.30%
2-yr leadtime	0.05%	0.00%	0.35%	0.35%	0.30%	0.21%	0.18%	0.16%	0.19%
With small product exemption for 2-year leadtime	0.05%	0.00%	0.34%	0.33%	0.29%	0.20%	0.17%	0.15%	0.18%
3-yr leadtime	0.04%	0.00%	0.31%	0.31%	0.27%	0.19%	0.16%	0.14%	0.16%

(a) Estimates based on SBA/Census database of firm statistics with total number of OTC manufacturing firms restricted to 400. Data are for 1994.

(b) SBA does not report data for the 500-750 size range. These estimates were derived by assuming that this group includes 50 percent of the firms and establishments and 33 percent of the employment and revenues of firms in the 500-2,500 size range.

In order to calculate small manufacturer impacts, ERG first distributed the OTC SKUs affected between large and small firms and then across the small business employment size categories. Large firms (producing private label or branded products) are estimated to produce approximately 1/3 of all SKUs, with the remainder (or 65,792 out of 98,639) being produced by small businesses. Next, it was assumed that the small business SKUs are distributed across the employment size classes in the same manner as employment. Thus, firms employing 100-499 workers represent 52.7 percent of small business employment in the industry and are assumed to produce the same percentage of small business SKUs.

The distribution of SKUs determines the distribution of compliance costs by employment size category. Table 2-6 presents the distribution of compliance costs for each of the four cases estimated. For the 1-year leadtime case, total annualized small business compliance costs are estimated at $22.3 million per year. These compliance costs would represent 0.3 percent of revenues for all small OTC manufacturers. For the 3-year leadtime, annualized compliance costs are estimated at $12.2 million per year, which represents 0.2 percent of small OTC manufacturer revenues. The small volume product exemption is estimated to lower the small business compliance costs by $0.5 million per year.

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Small Business Administration. 1996. Table of Size Standards. March 1.

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APPENDIX

APPENDIX A

COMPONENTS OF THE OTC LABELING MODEL

Each section of the OTC labeling model is described below with the exception of the Voluntary Share (VS) component, which was described in the text of Section Two. The discussion covers:

A.1 Regulatory Affairs
A.2 Artwork Costs
A.3 Manufacturing and Printing Costs
A.4 Inventory Costs
  A.4.1 Irreducible Inventory Costs
  A.4.2 Excess Inventory Losses
A.5 Increases in Label Size and Changes in Packaging and Labeling Configuration
A.6 Incremental Labeling, Container, and Carton Costs
A.7 Annualized Costs

Table A-1 summarizes the assumptions made for each component. The table estimates and assumptions are discussed further in the sections below.

A.1 Regulatory Affairs

This component of the base model addresses the labor costs needed to analyze new or revised regulatory requirements, prepare labeling revisions, and obtain signoffs on the labeling revisions from all relevant departments (not including manufacturing areas, such as materials control and quality control). Labor costs are those costs generated by regulatory affairs professionals and labeling department personnel (if separate), including editors and proofreaders. This category also covers professionals from other departments (including those responsible for legal affairs, medical issues, and marketing) that review and sign off on labeling revisions.

Table A-1

Assumptions Applied to Model Components

Element	Components involved	Company Size: Small	Medium	Large	Private label
Regulatory Affairs (RA)	Labor hours per sku	16	24	32	16
	Regulatory affairs labor wage rate ($ per hour)	$33.66	$33.66	$33.66	$33.66
Artwork (ART)	Artwork costs per sku	$500	$500	$500	$500
Manufacturing (MC)	Hours per sku to incorporate new labeling into process	4	8	20	4
	Production worker wage rate ($ per hour)	$18.06	$18.06	$18.06	$18.06
Irreducible Minimum Inventory Loss (IIL)	Container label inventory loss	$250	$1,000	$1,500	$250
	Carton inventory loss (based on leadtime)	$833	$3,333	$5,000	$833
Inventory Loss (IL)	Container label inventory loss	$250	$1,000	$1,500	$250
	Carton inventory loss (based on leadtime)	$833	$3,333	$5,000	$833
Packaging Changes (PK)	*For all packaging changes*				
	Additional hours of regulatory affairs input per sku	8	12	20	8
	Regulatory affairs labor wage rate ($ per hour)	$33.66	$33.66	$33.66	$33.66
	Additional artwork cost per sku	$500	$500	$500	$500
	Container size changes				
	Labor hours to adjust line for a container size change*	0.9	1.4	2	0.9
	Production worker wage rate ($ per hour)	$18.06	$18.06	$18.06	$18.06
	Probability of adjusting line	74%	74%	74%	74%
	Hours to retool line for a container size change*	9	14	20	9
	Production worker wage rate ($ per hour)	$18.06	$18.06	$18.06	$18.06
	Capital cost of parts needed to retool*	$2,700	$3,600	$4,500	$2,700
	Engineering costs (50% of capital costs)*	$1,350	$1,800	$2,250	$1,350
	Probability of retooling	25%	25%	25%	25%
	Capital cost of replacing a packaging line *	$250,000	$500,000	$2,000,000	$250,000
	Engineering costs (50% of capital costs)*	$125,000	$250,000	$1,000,000	$125,000
	Labor hours to train*	32	40	48	32
	Production worker wage rate ($ per hour)	$18.06	$18.06	$18.06	$18.06
	Validation of packaging line*	$12,500	$25,000	$100,000	$12,500
	Probability of new packaging line	1%	1%	1%	1%
	Stability testing costs per sku	$15,000	$15,000	$15,000	$15,000
	Probability larger container size available in production	5%	30%	60%	20%
	Stability test costs when existing container is used	$7,500	$7,500	$7,500	$7,500
	Container inventory loss (based on leadtime)	$2,500	$10,000	$15,000	$2,500
	Carton changes				
	Hours of labor time to adjust cartoner*	0.25	0.50	0.75	0.25
	Production worker wage rate ($ per hour)	$18.06	$18.06	$18.06	$18.06
	Probability of carton change	85%	85%	85%	85%
	Hours of labor time to retool cartoner*	2	4	6	2
	Production worker wage rate ($ per hour)	$18.06	$18.06	$18.06	$18.06
	Capital cost of parts needed to retool*	$27,000	$36,000	$45,000	$27,000
	Engineering costs (50% of capital costs)*	$13,500	$18,000	$22,500	$13,500
	Probability of retooling cartoner	15%	15%	15%	15%
	5% of total cost of carton changes for tabs to hold container	$38.03	$50.74	$63.45	$0.61

Table A-1

Assumptions Applied to Model Components

Element	Components involved	Company Size: Small	Medium	Large	Private label
Packaging Changes (PK)	*Use of non-standard labels (peelback, accordion)*				
	Capital cost of additional labeler*	$20,000	$22,000	$24,000	$20,000
	Engineering costs of new labeler (50% of capital costs)*	$10,000	$11,000	$12,000	$10,000
	Capital cost of adjusting labeler (parts, labor)*	$2,400	$2,600	$2,850	$2,400
	Engineering costs of adjustments (25% of capital costs)*	$600	$650	$713	$600
	Probability of new labeler and adjustments	50%	50%	50%	50%
	Probability that current labeler will be adjusted	50%	50%	50%	50%
	*Cost must be divided by 8 and 500 for branded and private label companies, respectively, to get per sku cost.				
Annual Incremental Costs per SKU	*Change in label size on existing containers and larger containers*				
	Original cost per label for pressure sensitive labels	$0.0200	$0.0100	$0.0050	$0.0150
	Original cost per label for heat generated labels	$0.0300	$0.0150	$0.0075	$0.0200
	Percentage of containers with pressure sensitive labels	75%	75%	75%	75%
	Percentage of containers with heat generated labels	25%	25%	25%	25%
	Average original cost per label (pressure sensitive, heat gen.)	$0.0225	$0.0113	$0.0056	$0.0163
	Factor multiplied with percentage increase in required label text area to determine percentage increase in cost	40%	40%	40%	40%
	Number of labels produced per sku per company size	40,000	100,000	400,000	70,000
	Change in container				
	Original cost of tube and bottle containers	$0.1050	$0.0950	$0.0900	$0.1000
	Original cost of aerosol containers	$0.3100	$0.3000	$0.2950	$0.3050
	Percentage of tube and bottle containers	95%	95%	95%	95%
	Percentage of aerosol containers	5%	5%	5%	5%
	Average original cost per container (aerosols, tubes, bottles)	$0.1153	$0.1053	$0.1003	$0.1103
	Factor multiplied with percentage increase in required label text area to determine percentage increase in cost	50%	50%	50%	50%
	Number of containers produced per sku per company size	40,000	100,000	400,000	70,000
	Independent change in carton size/addition of carton/fifth panel				
	Original cost per carton	$0.0850	$0.0750	$0.0700	$0.0800
	Factor multiplied with percentage increase in required label text area to determine percentage increase in cost	15%	15%	15%	15%
	Number of cartons produced per sku per company size	40,000	100,000	400,000	70,000
	Change to peelback or accordion label				
	Original cost per label (pressure sensitive)	$0.0200	$0.0100	$0.0050	$0.0150
	Cost of a peelback label	$0.030	$0.020	$0.015	$0.025
	Cost of an accordion label (2 ply)	$0.035	$0.025	$0.020	$0.030
	Number of labels produced per sku per company size	40,000	100,000	400,000	70,000
	Probability that peelback label will be adopted	50%	50%	50%	50%
	Probability that accordion label will be adopted	50%	50%	50%	50%

Under the base models outlined above, regulatory affairs costs vary with the size of the manufacturer and the complexity and scope of the labeling revision. ERG based its estimates of hours needed by regulatory affairs to approve a labeling revision on conversations with project consultants and pharmaceutical manufacturers. On average, companies spend 16 to 32 hours per SKU on major labeling revisions for OTC products, depending on company size. Larger companies expend more hours per SKU due to the higher number of reviews and signoffs required for a labeling revision. Private label companies were judged to spend the same number of hours per SKU as small companies because their labeling is not as complicated to review (it contains somewhat less marketing information) and these companies perform such a high volume of labeling revisions.

A.2 Artwork Costs

Manufacturers incur costs for the labor of graphic artists, the purchasing of graphic art supplies, film supplies (to produce camera-ready copies of revised labeling), new printing plates, and the printing of sample labeling. The variables that influence artwork costs include the complexity of the labeling revision, the potential for conflict with marketing or other labeling considerations, and the design complexity. Variables that influence the cost of new printing plates include the type of printing process used and the design complexity (especially the number of colors) of the original labeling. Based on data collected in discussions with pharmaceutical manufacturers, ERG assumed an average of $500 per SKU for artwork costs of containers and cartons for OTC drugs.

A.3 Manufacturing and Printing Costs

Manufacturing and/or materials management personnel order printing of new labeling, perform necessary quality-control reviews of new labeling when it arrives, incorporate the new labeling into manufacturing processes, and oversee removal of old labeling from the master batch records and from bill-of-materials records that govern manufacturing operations. The manufacturing and printing cost category is defined to consist entirely of labor costs.

Although one large manufacturer quoted a much higher cost, most manufacturers and project consultants estimated that it takes 3 to 5 hours to incorporate revised labeling into manufacturing operations and to initiate printing. ERG concluded that small and private label companies require an average of 4 hours to incorporate new labeling into manufacturing operations. Incorporating the large manufacturer data, ERG assumed that 8 and 20 hours are needed to revise manufacturing procedures for medium and large companies, respectively. (Some large manufacturers prepare new printing cylinders with each labeling revision for use in production line printing of labeling. The 20-hour estimate for large companies is intended to suffice for these circumstances as well.)

A.4 Inventory Losses

A.4.1 Irreducible Inventory Losses

The irreducible minimum inventory loss represents the extra labeling that manufacturers prepare to allow a margin of error in production and that are then discarded when labeling is revised. It is considered irreducible because manufacturers generally print enough labeling materials to ensure that sales are not constrained by a shortfall in this relatively low cost input to the production process. Based on discussions with industry consultants and information submitted to FDA by the National Drug Manufacturers Association (NDMA, 1997), ERG estimated irreducible minimum container label inventory losses at $250 for small companies, $1,000 for medium companies, $1,500 for large companies, and $250 for private label companies. Irreducible minimum carton inventory losses are estimated at 3.33 times the container label inventory losses.

A.4.2 Conventional Inventory Losses

In developing the models, ERG determined that manufacturers generally require no more than 6 months of regulatory lead time to deplete nearly their entire inventory of labeling. Many labeling inventories represent no more than 3 months of production. Furthermore, ERG determined that the average inventory remaining after 6 months is reduced further if additional lead time is granted. The lead time

beyond 6 months allows manufacturers to manage inventory better by improving coordination efforts. Also, those relatively few manufacturers that keep larger labeling inventories can deplete more of their supply if additional time is allowed. Accordingly, the inventory loss after 6 months declines at a slow rate to the irreducible minimum loss at 24 months.

For the purpose of developing the inventory loss calculation, ERG used a quadratic specification for the first 6 months of lead time granted to model the essential characteristic that the shorter the implementation lead time, the larger the inventory loss. During the first 6 months, losses will decline rapidly as implementation lead time increases. To reflect this relationship, inventory losses were modeled nonlinearly, according to the following quadratic equation:

$$IL = at^2 + bt + c$$

where:

IL = inventory loss

a, b, c = coefficients that vary with initial inventory loss and the rate at which inventory losses change with increases in the implementation period (see below)

t = implementation lead time in months

The quadratic specification assumes that losses will grow relatively larger as the implementation lead time shrinks. Indeed, when t equals zero months, container label inventory losses (including the irreducible minimum inventory losses described above) are $1,500 for small companies, $6,000 for medium companies, and $9,000 for large companies. Based on information provided by a private label manufacturer, inventory losses per SKU for private label companies are assumed to be equivalent to those incurred by small companies. At t equals 3 months, inventory losses are assumed to be ½ of initial losses. At t equals 6 months, losses are reduced to 1/3 of initial losses.

If carton losses are involved, the default values for inventory losses are 3.33 times the container label inventory losses. Carton inventory losses are based on container inventory losses as discussed below in the section on packaging configuration changes.

A.5 Increases in Label Size and Changes in Packaging and Labeling Configuration

Manufacturers who cannot fit the revised text on their existing label might be able to increase the labeling area on their existing containers. For example, the labels on some bottles does not reach entirely around the circumference. Other containers sometimes have only small label panels on the front and back and could accommodate larger label panels without changing container size. The cost of increasing label size is discussed below in the section on incremental costs.

If new information does not fit on current or expanded labeling, some manufacturers might reconfigure packaging to comply with the labeling rule. Based on the NDMA report, manufacturers may also respond to a mandate to expand labeling space by adding a carton (if not already present), expanding carton size by adding a fifth panel (i.e., adding a panel that extends up and beyond the normal carton), increasing packaging size (interpreted as container size), or switching to use of nonstandard labels (NDMA, 1997). The most common response is to add a fifth panel. ERG also considered increasing carton size as an option. Because carton equipment purchases represent major capital expenditures, manufacturers will generally go the considerable lengths to avoid purchasing new equipment. ERG assumed that manufacturers would add cartoning only if an appropriate cartoning machine is already available in their production facility. Similarly, the addition of a fifth panel is only a feasible option if the cartoning machines currently used in production are capable of producing a fifth panel.

The labeling model considers the role of contract packagers for OTC products. When manufacturers face possible changes in packaging and labeling configurations, they could shift from in-house to contract packaging or shift from one contract packager to another. These shifts might circumvent the need to make new investments in labeling or packaging equipment. Also, when packaging or labeling reconfiguration is needed, contract packagers are judged to be (1) more efficient in making a change, and (2) more likely to have available parts to accomplish the reconfiguration. ERG adjusted the cost estimates to account for a 20 percent participation by contract packagers. Their influence lowers the overall reconfiguration cost estimates discussed below.

In addition to the costs normally incurred from a labeling revision, all packaging and labeling configuration changes require additional hours of technical review. Additional artwork costs are also needed because new and larger master plates have to be generated.

Changes in container size are the most expensive and involve stability testing, container inventory loss, and adjustment of the packaging line for the new container size (definitions of terms used in this discussion are listed in Table A-2). Based on consultant estimates, ERG estimated that stability test costs average about $15,000 per test. Generally FDA requires three batches to be tested per product; however, if a product has multiple SKUs, the number of tests conducted per SKU might be reduced. ERG assumed on average that companies would only need to conduct one stability test per SKU. In some cases, manufacturers might be able to use a larger container size that is already used in production. In these cases, consultants have indicated that stability testing costs can then be reduced by 50 percent.[1] According to project consultants, the probability that a larger container is available elsewhere in production varies with company size from 5 percent to 60 percent.

Obsolete inventories of containers will have to be thrown away. Project consultants estimated that container inventory loss is approximately five times the container label inventory loss.

Manufacturers can generally adjust their packaging lines to accommodate a new container size when the dimensions of the new container are within the capacity of all the machines on the packaging line. If the new container size is larger than the adjustment capability of the packaging line, new equipment parts (feed screws or grips) can be purchased and used in retooling of the line. According to project consultants, retooling of the packaging line can take anywhere from 1 to 3 days to complete. The cost of material parts is estimated at approximately $2,700 to $4,500. Engineering costs are estimated at 50 percent of the cost of equipment parts. Adjusting a line takes only 10 percent of the time needed to retool a line.

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[1] Stability testing requirements are not eliminated because it is not likely that all new container sizes have previously been used and it is assumed that the new containers have not been previously used with the same product.

Table A-2

Definitions of Terms Used in Discussion of Packaging Changes

Term	Definition
Container	The immediate plastic, paper, or metal packaging that holds the pharmaceutical product.
Carton	The outer cardboard box that holds the pharmaceutical container.
Cartoner	The piece of equipment on the packaging line that folds the carton into a desired configuration.
Packaging line adjustments	Modification of settings on a packaging line using existing equipment to accommodate the new package size.
Packaging line retooling	Replacement of selected parts on a packaging line to accommodate the new package size.
Peelback label	Term used for a label that is partially attached and can be peeled back to be read. The label does not fully detach.
Accordion label	Term used for a label with two or more parallel folds, which open like an accordion.
Pressure-sensitive labeler	Labelers that apply pressure to attach labels with an active adhesive coating.

In rare cases, the revised change in container size is too large to allow retooling and the entire packaging line has to be replaced and validated. Replacing an entire line—including the filler, labeler, cotton placer, capper, insert placer, cartoner, and bundler—can cost from $250,000 to $2 million. One project consultant said that replacing the packaging line for a particular large-volume product cost $3 million. This cost includes a 10 to 15 percent markup for installation of the new equipment. Engineering costs are estimated at 50 percent of the cost of new equipment. Validation costs are estimated at 5 percent of the line replacement cost. Additional personnel training is also required when an entire line is replaced and will require 4 to 6 days to complete, depending on the size of the manufacturer. Based on conversation with project consultants, ERG determined that packaging line adjustments will suffice 74 percent of the

time, retooling is necessary in 25 percent of all cases, and replacement of the entire line occurs only 1 percent of the time.

Of the equipment on the packaging line, the cartoning machine is the most adaptable; carton changes can usually be accommodated by machine adjustments. According to project consultants, adjustments are expected to be sufficient for 85 percent of all carton changes, with the remaining 15 percent requiring retooling. Manufacturing personnel can generally adjust a cartoner in 15 to 45 minutes, depending on the sophistication of the equipment. Retooling a cartoner takes about 2 to 6 hours and involves changing parts valued at $27,000 to $45,000. Engineering costs are estimated at 50 percent of the cost of equipment parts.

Carton inventory loss is estimated at two-thirds of the container inventory loss estimate; however, carton inventory loss has already been included as part of the labeling revision cost and, therefore, is not included again.

Manufacturers can switch to nonstandard labels, such as peelback or accordion labels, by adjusting the pressure-sensitive labelers currently used in production. According to project consultants, the costs of such adjustments are approximately 12 percent of the equipment cost. Engineering costs are estimated at 25 percent of the equipment cost. The production process for attaching peelback or accordion labels is much slower than conventional labeling methods, however, and production typically slows. Project consultants estimate that the use of accordion labels and peelback labels will slow production by approximately 25 percent and 5 percent, respectively. To compensate for loss in production, manufacturers might purchase another labeler for the packaging line. These labelers cost about $20,000 to $24,000 plus the cost of adjustments. Engineering costs are estimated at 50 percent of the cost of the labeler. Because the use of peelback labels results in a relatively small loss in efficiency, ERG judged that a new labeler will only be purchased for the production of accordion labels.

Nonstandard labels also cost more than standard labels. Accordion labels are approximately twice as expensive as conventional labels, and peelback labels are slightly less than twice as expensive. Based on conversations with project consultants, ERG believes that accordion and peelback labels are equally popular and assigned a 50 percent probability to either one being selected.

To derive a per SKU cost for packaging changes, all costs incurred per packaging line were divided by the number of SKUs packaged on a line. Based on consultant estimates, ERG assumed that an average of 8 SKUs and 500 SKUs are packaged per line for branded and private label companies, respectively.

A.6 Incremental Label, Container, and Carton Costs

Some pharmaceutical companies will incur incremental label purchase costs because the revised label is larger. The model allows the user to specify the percentage of SKUs with larger labels (but the same packaging) and the percentage of SKUs with larger labels (and larger containers, to accommodate the increased label size). The slight increase in label size generates a corresponding increase in labeling costs. The model allows the user to estimate the increase in label text that results from a regulatory change. Based on discussions with project consultants, the label cost is assumed to increase by 40 percent of the percentage increase in label area needed.

The model also allows the user to specify the percentage of SKUs that will undergo changes in packaging configuration. The costs for cartons and containers are assumed to increase by 15 and 50 percent, respectively.

A special case occurs when a manufacturer decides to add a carton. The manufacturer then incurs the full incremental cost of the carton as a regulatory cost. This cost would only be incurred for containers that do not currently have a carton.

Peelback and accordion labels cost more than standard labels. Rather than assuming an increase in the cost of the label based on the increase in the label text area, increases in labeling costs due to changes in label type used are estimated on the basis of the average cost for a peelback or accordion label.

Based on discussions with project consultants, the model incorporates the following default values for baseline label costs and label usage rates. Baseline label costs were estimated to vary with company size from 2 cents per label for small companies to 0.6 cents per label for large companies. Baseline

container and carton costs were estimated to vary with company size from 11.5 cents per container for small companies to 10 cents per container for large companies, and from 8.5 cents per carton for small companies to 7 cents per carton for large companies. Peelback and accordion labels vary from 3 cents per peelback label for small companies to 1.5 cents per peelback label for large companies, and from 3.5 cents per accordion label (2-ply) to 2 cents per accordion label for large companies. Private label companies were assumed to pay costs that are between those for small and medium pharmaceutical companies. For OTC pharmaceuticals, small companies were estimated to use labels at the rate of 40,000 per year per SKU, medium-sized companies at a rate of 100,000 per year per SKU, large companies at a rate of 400,000 per year per SKU and private label companies at a rate of 70,000 per SKU.

A.7 Annualized Costs

The above incremental label, container, and carton costs are an annual ongoing cost. To calculate a total annualized cost, ERG annualized the cost for labeling redesigns and changes in packaging configurations, as well as the present value of the cost for all incremental labels, containers, and cartons (over an infinite horizon). ERG assumed that costs for SKUs with final monographs would be incurred in year 1. All other monographs are assumed to become final in year 4 and thus costs for SKUs with nonfinal monographs will be incurred in year 5.

For the OTC model, label redesigns are annualized using a 7 percent interest rate. The length of the annualization period is determined by the life of the labeling; therefore, if the implementation period is 2 years, the annualization factor is a weighted average of the 3-year and the 6-year annualization factor. The weights are the percentage of SKUs that have 3-year and 6-year label redesign cycles. If the implementation period is 3 years, the annualization factor is simply the 6-year annualization factor, since only SKUs with 6-year label redesign cycles are affected. The annualized cost for changes in packaging configurations was calculated by annualizing the entire PK term at 7 percent over 10 years.

APPENDIX B

PROTOCOL FOR OTC PRODUCT SURVEY

ERG personnel performing the OTC product survey shall follow these directions in measuring the characteristics of Over-the-Counter (OTC) products.

I. For all products:

Starting with the smallest SKU of each product, note the name of the product, the product category (i.e., antacids), and the size (i.e., tablets included, fluid ounces) of the SKU. Record the type of packaging used. On the survey form, the acronyms for packaging are as follows:

C= Carton
B= Bottle
T= Tube
L= Blister pack
A= Aerosol
O= Other (note on side of entry what type of other packaging, i.e., bag or wrapper)

Check whether inactive ingredients are currently listed on labeling and, using an E-scale with a leading gauge, measure the font and leading combined.

Make a judgment if the new labeling will fit on the current label. This judgment will be based partly on the font size—if the labeling is already 6-point or larger, the new labeling is very likely to fit. If a smaller SKU of the same product has already been judged to fit, then it can also be assumed that the larger version will fit. If the labeling fits, no further measurements are needed.

II. For products for which an affirmative judgment of whether revised, 6-point font labeling will fit on current packaging, cannot be made:

Measure the surface area of the package:

- For a carton, measure the height, width, and depth of the package. Also measure the height, width, and depth for any packaging similar in shape to cartons, such as rectangular rolls of cough drops. If a double-paned fifth panel is present, record height of panel to the display tab/hole.

- For a container that is oval, circular, or rectangular, measure (usually bottles, but also cylindrical rolls) the circumference of the container and the height of the label.

  When measuring the height of the label, exclude the neck of the container (if present), do not extend beyond the ridges (if present) on the body of the bottle, and subtract half a centimeter for space at the edges.

Do not record space available on labeling wrapped around the cap.

- For a container that has only two sides that can be labeled (such as blister packs, tubes, bottles with curved sides, very flat, rectangular containers, and bags), measure the height and width of one label. Subtract half a centimeter for space at the edges. If the front and back label are different in size, measure both. If the label is not rectangular but curved, estimate the additional surface area available.

Next measure the percentage of surface area taken up with FDA labeling. FDA labeling should include:

- Storage statements
- All monograph-required language and warnings
- Lot number and expiration date

Then measure the percentage of surface area taken up with "company information." This includes:

- The name of the product above directions and indications
- Duplicate indications for use
- Product name on the sides of cartons
- Any promotional material about the product or related products
- Identification of the distributor or manufacturer
- Tamper-resistant warning
- Consumer Hotline numbers
- Diagrams showing proper drug use
- Other information that, while optional, is generally protective of public health

Next, measure the percentage of surface area with white space, which is space on the label that is not currently used for labeling. White space should be well-defined area and easy to measure.

Finally, if the product in question is packaged in a container, estimate the percentage of unlabeled surface area that is available for increasing label size. As with the measurement of the surface area of the container label, do not include space outside ridges or on the neck or cap of the container. This measurement is not needed for two-sided containers unless the label can clearly be increased in size.

APPENDIX C

SMALL BUSINESS IMPACTS USING FDA COST ESTIMATES

Table C-1 presents the small business impacts using FDA's independent estimate of the annualized cost of compliance of $18.4 million for the scenario with a 6 point condensed font minimum type size requirement and a 2-year leadtime with a small product exemption. Total annualized costs to small business are estimated at $12.3 million per year and represent 0.17 percent of revenues for all small OTC manufacturers.

Table C-1

Estimated Number and Size Distribution of OTC Manufacturers, by Employment Size (a)

	OTC Manufacturing Total	Employment Size 0	1-4	5-9	10-19	20-99	100-499	500-750 (b)	OTC Small Business Total
Firms	400	18	87	43	49	99	51	11	357
Establishments	478	18	87	43	49	101	57	19	374
Employment	86,849	0	198	291	694	4,178	9,984	3,597	18,942
Average employment per firm	217	0	2	7	14	42	197	323	53
Percentage of total small business employment	NA	0.0%	1.0%	1.5%	3.7%	22.1%	52.7%	19.0%	100.0%
Receipts ($000)	$42,362,638	$32,264	$41,123	$61,000	$166,283	$1,445,555	$4,034,345	$1,630,788	$7,411,357
Receipts per firm ($000)	$105,907	$1,769	$472	$1,433	$3,418	$14,654	$79,611	$146,277	$20,755
Total SKUs affected	98,639	0	688	1,011	2,410	14,513	34,676	12,494	65,792
As percentage of all SKUs	100.0%	0.0%	0.7%	1.0%	2.4%	14.7%	35.2%	12.7%	66.7%
Total annualized compliance costs ($millions)									
1-yr leadtime	$33.5	$0.0	$0.2	$0.3	$0.8	$4.9	$11.8	$4.2	$22.3
2-yr leadtime	$20.7	$0.0	$0.1	$0.2	$0.5	$3.0	$7.3	$2.6	$13.8
With small product exemption for 2-year leadtime	$18.4	$0.0	$0.1	$0.2	$0.4	$2.7	$6.5	$2.3	$12.3
3-yr leadtime	$18.3	$0.0	$0.1	$0.2	$0.4	$2.7	$6.4	$2.3	$12.2
Total annualized compliance costs as percentage of annual revenues									
1-yr leadtime	0.08%	0.00%	0.57%	0.56%	0.49%	0.34%	0.29%	0.26%	0.30%
2-yr leadtime	0.05%	0.00%	0.35%	0.35%	0.30%	0.21%	0.18%	0.16%	0.19%
With small product exemption for 2-year leadtime	0.04%	0.00%	0.31%	0.31%	0.27%	0.19%	0.16%	0.14%	0.17%
3-yr leadtime	0.04%	0.00%	0.31%	0.31%	0.27%	0.19%	0.16%	0.14%	0.16%

(a) Estimates based on SBA/Census database of firm statistics with total number of OTC manufacturing firms restricted to 400. Data are for 1994.

(b) SBA does not report data for the 500-750 size range. These estimates were derived by assuming that this group includes 50 percent of the firms and establishments and 33 percent of the employment and revenues of firms in the 500-2,500 size range.