

August 2015

# 2014 FDA Labeling Cost Model

Contract No. HHSF-223-2011-10005B, Task Order 20

## Final Report

Prepared for

**Matthew Parrett**  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
5100 Paint Branch Parkway  
College Park, MD 20740

Prepared by

**Mary K. Muth**  
**Samantha Bradley**  
**Jenna Brophy**  
**Kristen Capogrossi**  
**Michaela C. Coglaiti**  
**Shawn A. Karns**  
RTI International  
3040 E. Cornwallis Road  
Research Triangle Park, NC 27709

RTI Project Number 0212926.020



# **2014 FDA Labeling Cost Model**

**Contract No. HHSF-223-2011-10005B, Task Order 20**

## **Final Report**

**August 2015**

Prepared for

**Matthew Parrett**  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
5100 Paint Branch Parkway  
College Park, MD 20740

Prepared by

**Mary K. Muth**  
**Samantha Bradley**  
**Jenna Brophy**  
**Kristen Capogrossi**  
**Michaela C. Coglaiti**  
**Shawn A. Karns**  
RTI International  
3040 E. Cornwallis Road  
Research Triangle Park, NC 27709

# Contents

---

Section	Page
<b>1 Introduction</b>	<b>1-1</b>
1.1 Background on the Labeling Cost Model.....	1-2
1.2 Objective .....	1-3
1.3 Organization of this Report .....	1-3
<b>2 Overview of Packaging Types, Label Types, and Printing Methods</b>	<b>2-1</b>
2.1 Printing Methods .....	2-1
2.1.1 Flexography .....	2-1
2.1.2 Offset Lithography .....	2-2
2.1.3 Rotogravure .....	2-3
2.2 Printing Methods Used by Packaging Type.....	2-4
2.2.1 Preprinted Labels .....	2-5
2.2.2 Directly Printed Packaging .....	2-5
2.2.3 Package Inserts .....	2-7
2.2.4 Package-Label Types and Printing Methods Relevant for the Labeling Cost Model.....	2-7
2.3 Label Contents Across Product Types .....	2-9
2.3.1 Food and Dietary Supplements Label Contents .....	2-10
2.3.2 Cosmetics Label Contents .....	2-12
2.3.3 Over-the-Counter Medicine Label Contents.....	2-13
2.3.4 Pet Food Label Contents .....	2-14
2.3.5 Retail Medical Device Label Contents .....	2-16
2.3.6 Tobacco Label Contents.....	2-18

<b>3</b>	<b>Overview of Labeling Changes Conducted by Manufacturers</b>	<b>3-1</b>
3.1	Overview of the Label Change Process.....	3-2
3.2	Estimating the Frequency of Baseline Labeling Changes .....	3-5
3.2.1	Reasons for and Frequency of Nonregulatory Labeling Changes .....	3-5
3.2.2	Derivation of Default Percentages of Nonregulatory Labeling Changes.....	3-7
<b>4</b>	<b>Model Structure, Data, Assumptions, and Calculations</b>	<b>4-1</b>
4.1	Overview of the Model Inputs and Outputs.....	4-1
4.1.1	Model Inputs .....	4-1
4.1.2	Model Outputs .....	4-4
4.2	Product Categories and Data.....	4-5
4.2.1	Private-Label UPC Counts .....	4-5
4.2.2	Product Categories, Subcategories, and Adjustments to the UPC Counts and Unit Sales .....	4-6
4.3	Formulas for Calculating the Costs of Labeling Changes.....	4-27
4.3.1	Costs of Changing Product Labels .....	4-27
4.3.2	Adjustments for Short Compliance Periods .....	4-34
4.3.3	Adjustments for Inflation .....	4-35
4.4	Cost Calculation Data Included in the Model .....	4-36
4.4.1	Per-UPC Cost Calculation Data.....	4-36
4.4.2	Per-Formulation Cost Calculation Data.....	4-41
4.4.3	Per-Sales Unit Cost Calculation Data .....	4-44
4.4.4	Accounting for Uncertainty in the Cost Estimates .....	4-65
4.5	Assumptions and Limitations of the Methodology .....	4-65
<b>5</b>	<b>Instructions for Using the Labeling Cost Model</b>	<b>5-1</b>
5.1	An Operational Overview of the Model .....	5-1
5.2	Selecting Model Inputs and Running the Model .....	5-3
5.2.1	Selection of Affected Products .....	5-4
5.2.2	Percentage of Affected Products Modification (Optional) .....	5-9
5.2.3	Type of Labeling Change Selection .....	5-11

5.2.4	Analytical and Market Testing Costs Selection .....	5-14
5.2.5	Wage Rates Selection.....	5-16
5.2.6	Compliance Period Selection .....	5-17
5.2.7	Inflation Factor Modification (optional).....	5-19
5.2.8	Running the Model Using Input Values.....	5-20
5.3	Viewing the Model Outputs .....	5-21

<b>References</b>	<b>R-1</b>
-------------------	------------

## **Appendixes**

A:	Industry Interview Materials .....	A-1
B:	Detailed Information on Nielsen Product Modules Included in Each Model Subcategory .....	B-1

# Figures

Number	Page
2-1. Example of Parts of Food Labels that May Change as a Result of a Regulation: Canned Corn .....	2-10
2-2. Example of Parts of Dietary Supplement Labels that May Change as a Result of a Regulation: Calcium Supplements.....	2-11
2-3. Example of Parts of Cosmetic Labels that May Change as a Result of a Regulation: Toothpaste without Fluoride .....	2-12
2-4. Example of Parts of Over-the-Counter Medicine Labels that May Change as a Result of a Regulation: Toothpaste with Fluoride.....	2-14
2-5. Example of Parts of Pet Food Labels that May Change as a Result of a Regulation: Canned Dog Food .....	2-16
2-6. Example of Parts of Retail Medical Device Labels that May Change as a Result of a Regulation: Pregnancy Test....	2-18
2-7. Example of Parts of Tobacco Labels that May Change as a Result of a Regulation: Cigarettes .....	2-19
3-1. Process of Changing Labeling Information on Consumer Products.....	3-3
5-1. Main Menu Selection Screen .....	5-4
5-2. Affected Products by Type Selection Screen—Drop-Down Menu for Product Type .....	5-6
5-3. Affected Products by Type Selection Screen—Selecting Entire List of Product Subcategories .....	5-6
5-4. Affected Products by NAICS Selection Screen—Selecting 3-Digit NAICS from a Drop-Down Menu .....	5-8
5-5. Affected Products by NAICS Selection Screen—Selecting and Adding 6-Digit NAICS and Product Subcategories .....	5-8

5-6.	Percentage of Affected Products Screen—Entering a Percentage to Apply to All Subcategories Previously Selected .....	5-10
5-7.	Percentage of Affected Products Screen—Entering a Percentage for Each Subcategory .....	5-11
5-8.	Type of Labeling Change—Selecting Type of Labeling Change and Whether Package Inserts Are Affected .....	5-12
5-9.	Type of Labeling Change—Extensive Labeling Change and Percentage of Products with Peel-Back Labels .....	5-13
5-10.	Selecting Analytical Tests.....	5-15
5-11.	Selecting Market Tests .....	5-16
5-12.	Viewing and Editing Hourly Wage Rates .....	5-17
5-13.	Compliance Period Selection Screen—Select Amount of Time Manufacturers Will Have to Comply with the Labeling Regulation.....	5-18
5-14.	Compliance Period Selection Screen—Modify the Percentages of Changes That Cannot Be Coordinated with a Scheduled Change.....	5-19
5-15.	Inflation Factor Modification .....	5-20
5-16.	Saved Scenarios Screen .....	5-21
5-17a.	Model Output—Input Selections Summary (Upper Portion).....	5-23
5-17b.	Model Output—Input Selections Summary (Lower Portion).....	5-24

# Tables

Number	Page
1-1. 3-Digit NAICS Codes Corresponding to the Products Included in the FDA Labeling Cost Model .....	1-2
2-1. Package-Label Type on Which Labeling Information Is Printed by FDA Product Type .....	2-8
3-1. Assumed Percentages of Changes to Branded ( $\rho^B$ ) and Private-Label ( $\rho^{PL}$ ) UPCs that Cannot be Coordinated with a Planned Change .....	3-10
4-1. Types of Labeling Changes that May Be Required by Regulation .....	4-3
4-2. Assumed Percentages of Active Private-Label UPCs Based on Proportion of Inactive Branded UPCs Included in the Nielsen ScanTrack Data .....	4-6
4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 .....	4-7
4-4. Adjustments to UPCs, Formulas, and Sales Units to Account for Nonrepresentation in the Nielsen ScanTrack Data .....	4-25
4-5. Estimated Labor Hours and Materials Costs Associated with Uncoordinated Labeling Changes, 2014 .....	4-37
4-6. Estimated Labor Hours Associated with Coordinated Labeling Changes, 2014 .....	4-38
4-7. Hourly Wage Rates for Activities Conducted in Changing Product Labels, 2014 .....	4-39
4-8. Estimated Percentages of UPCs Printed Using Each Printing Method by Package Label Type, 2014 (%) .....	4-40
4-9. Estimated Analytical Testing Costs in the Labeling Cost Model, 2014 (\$/Formula) .....	4-42
4-10. Estimated Market Testing Costs in the Labeling Cost Model, 2014 (\$/Formula) .....	4-43
4-11. Estimated Sticker Costs, Sticker Application Time, Peel-Back Label Costs, and Package Insert Costs on a Per-Sales Unit Basis, 2014 .....	4-45
4-12. Assumed Remaining Percentages of Package-Label Inventory Based on Compliance Period .....	4-45
4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) .....	4-47



# 1

## Introduction

This report documents the 2014 update of the FDA Labeling Cost Model. The scanner data for foods, pet foods, and dietary supplements and the cost data for all products were updated in the model.

The U.S. Food and Drug Administration (FDA) has periodically contracted with RTI International to provide a model to estimate the costs of various product labeling changes required by regulation. Prior to this update, the most recent version of the model was delivered to FDA in 2010.

The 2014 FDA Labeling Cost Model is programmed in Microsoft Excel 2010 with a Visual Basic interface that steps the user through the selection of the model inputs. The model outputs are provided in an Excel spreadsheet, allowing users to easily tailor the results for each specific use. The product types included in the model are as follows:<sup>1</sup>

- cosmetics (2008 data)
- dietary supplements (2012 data)
- foods (2012 data)
- over-the-counter (OTC) medications (2008 data)
- pet foods (2012 data)
- retail medical devices (2008 data)
- tobacco products and accessories (2008 data)

The associated 3-digit North American Industry Classification System (NAICS) codes that correspond to these product types are provided in Table 1-1.

In the remainder of this section, we provide the background and objectives for the task order and an overview of the contents of the report.

---

<sup>1</sup> The date range for the 2012 Nielsen ScanTrack data provided by FDA was September 4, 2011, through September 1, 2012.

**Table 1-1. 3-Digit NAICS Codes Corresponding to the Products Included in the FDA Labeling Cost Model**

3-Digit NAICS Code	Description
111	Crop Production
311	Food Manufacturing
312	Beverage and Tobacco Product Manufacturing
322	Paper Manufacturing
325	Chemical Manufacturing
326	Plastics and Rubber Manufacturing
335	Electrical Equipment, Appliance, and Component Manufacturing
339	Miscellaneous Manufacturing

## 1.1 BACKGROUND ON THE LABELING COST MODEL

Many of the risk-reduction strategies undertaken by FDA require labeling changes for affected products as either a direct risk-reduction strategy or as an indirect effect of a risk-reduction strategy that requires a corresponding labeling change.

FDA promulgates many consumer labeling regulations that require estimating the cost of label changes. For example, labeling has been part of FDA's recent risk-reduction strategies for potential health concerns associated with indoor tanning devices, adverse reactions to drug products, and international supply chains for pet foods. Furthermore, in March 2014, FDA issued proposed regulations to revise the Nutrition Facts label on all foods under its jurisdiction and to revise the serving sizes of foods that can be reasonably consumed at one eating occasion on a substantial number of products.

The FDA economists must estimate the costs of many different types of labeling changes that give consumers information about potential risks, including changes in listed ingredients, warnings, handling directions, health and structure function claims, lists of allergens, ingredient names, and adverse event reporting information. FDA used previous versions of the FDA Labeling Cost Model to estimate the costs associated with labeling changes required for foods and dietary supplements. These estimates were then used in conducting the economic impact analysis of proposed FDA regulations intended to reduce the risk associated with using or consuming specific products. RTI developed the original version of the model in the early

1990s and subsequently updated and expanded the model in the early 2000s and again in 2010.

---

## **1.2 OBJECTIVE**

The objective of this task order was to update a model that estimates labeling costs for a broad range of FDA-regulated consumer products using current data. The user specifies the

- categories of products affected,
- nature of the labeling change,
- the compliance period, and
- additional inputs as specified.

Based on the user specifications, additional collected data, and FDA-provided data (including Nielsen ScanTrack scanner data), the model generates an estimate of costs Per Universal Product Code (UPC) for the labeling change, total costs per product type, and an aggregate cost across all affected products. The user can view the derivation of the estimates as part of the model's full output. The model quantifies uncertainty or variability with high and low estimates constructed in a way that facilitates interpretation as bounds on 90% probability ranges. The completed model thus enables FDA to estimate the costs of label-based risk and nutritional information regulations as needed depending on the specific parameters of the regulation. Because it is anticipated that labeling regulations would affect numerous products at the same time, the model estimates assume that manufacturers are implementing changes simultaneously across multiple products.

---

## **1.3 ORGANIZATION OF THIS REPORT**

This report is organized to provide background information useful to model users, explanations of the data and calculations within the model, and instructions on how to operate the model. The sections of the report are as follows:

- Section 2 provides an overview of packaging types, label types, and printing methods.
- Section 3 provides an overview of labeling changes as initiated by manufacturers.

- Section 4 outlines the labeling cost model structure, including data, assumptions, and calculations.
- Section 5 provides instructions on operating the model.

In addition, Appendix A provides the project description and interview guide used to obtain updated information on the costs of labeling changes from industry, and Appendix B provides the detailed Nielsen product modules that are included in each model subcategory.

# 2

## Overview of Packaging Types, Label Types, and Printing Methods

*Note that the text in this section has only minor changes compared with the labeling cost model report delivered in 2011.*

In this section, we describe the three main printing methods, the materials on which labeling information is typically printed, the distribution of printing methods by packaging type, and the contents of retail product labels. This information provides the background for describing the process of changing labeling information in Section 3 and the structure of the cost model in Section 4.

---

### 2.1 PRINTING METHODS

Below we describe each of the three main printing methods (flexography, offset, rotogravure) used on retail product packaging. In addition to these, digital printing is beginning to be used for small runs of package labels. Each printing method has advantages and disadvantages for certain types of printing based on run lengths, cost, printing substrate, and image quality. To allow for variability in the printing methods used for each type of packaging or labeling material, the model calculates weighted averages of costs based on the distribution of the use of these methods.

#### 2.1.1 Flexography

The flexography printing method is generally the least costly printing method.

Flexography is a relief printing process where the image area is raised above the nonimage area (Bruno, 1995). The plates are made from soft rubber-like sheets, which are then wrapped around a cylinder (Hawley, 2000). Flexographic plates are less expensive than both offset and rotogravure plates (Mykytiuk, 1999). The flexibility of the plates allows them to print on a

variety of substrates, but it can also cause shifting during printing, which lowers the quality of the image. Flexography is used on substrates to which the one-dimensional blanket used in the offset printing process cannot conform (Hawley, 2000). These substrates include pressure-sensitive nonpaper labels and flexible packages (Bruno, 1995). However, flexography is also increasingly being used for printing paperboard cartons (Demetrician, 1996).

In the flexography process, a graphic image is burned onto a thin rubber-like sheet by placing the film, which is created from the proofs generated in the prepress process, on top of the rubber sheet and exposing it to a light source. The rubber sheet is washed in a machine with brushes that wipe away the nonimage areas. Because the image areas had been hardened by the light source, they remain. The sheet is then dried with heat. Creating plates for designs with process color is more complicated than with line colors because process color requires small cells to be burned into the rubber rather than solid areas. Therefore, the brushes need to wipe away small areas between the cells, which is more difficult than brushing away a large solid area as with designs using line colors.

Color separation is different for flexography than any other type of print. If the same color is going to be used in a design as both line color and process color, then they need to have separate plates, even though it is the same color. This is done to achieve better color saturation of line colors without bleeding. Sometimes a combination plate can be created for a color that is going to be used for both line and process, but the area of the images must be very small.

Flexography normally prints six to eight colors on a label or package. After printing, the printed substrate may be laminated with up to five layers of materials. The packages or labels are then slit and rolled or are made into preformed packages for delivery to the manufacturer.

### **2.1.2 Offset Lithography**

The offset printing method is typically used on cartons, aluminum cans, and paper labels.

Offset lithography, which is commonly referred to as offset, is a planographic process in which the image and nonimage areas exist on the same plane. Offset plates are easier to produce and less costly than rotogravure (Bruno, 1995). Offset plates are mostly created using a photographic process from film, but

the use of digital-to-plate methods is on the rise (Hawley, 2000).

In making offset plates, a water-receptive solution is coated on the nonimage area of the plate, and an ink-receptive solution is coated onto the image area of the plate (Bruno, 1995). These coatings are applied to ensure that when the plate is dipped into the ink, only the image areas will pick up the ink and the ink will be repelled from the water-receptive nonimage areas. During the printing process, the plate is first dipped into the ink and then the image is transferred to a rubber blanket wrapped around a cylinder. The blanket, in turn, transfers the image to the substrate. The rubber cylinder allows the image to be printed on a wide range of substrates (Speirs, 1998). However, the one-dimensional blanket does not conform to unusual substrates as well as a two-dimensional flexographic plate (Hawley, 2000).

Another type of offset called dry (or waterless) offset is used for direct printing of two-piece aluminum cans. In the dry offset process, instead of coating the image and nonimage areas of the plate with special solutions, silicone rubber is placed in the nonprinting areas. The silicone rubber material is not ink receptive so only the area not coated with the rubber material picks up the ink.

Offset is commonly used for printing paper materials, such as paperboard cartons and paper labels. Although the offset process is not able to print on many of the new packaging films, it is still the most common printing method today (Hawley, 2000). It is the most common printing method for glue-applied labels, paperboard cartons, metal cans, and paper labels (Bruno, 1995; Brody, 2000).

### 2.1.3 Rotogravure

The rotogravure printing method is used for long print runs and is the most costly printing method in the United States.

Rotogravure is an intaglio printing process in which the image area is below the nonimage area (Bruno, 1995) and is the least commonly used printing method. Rotogravure printing can be done using traditional printing methods or by direct digital-to-plate. In a traditional rotogravure process, proofs of the images for each printing plate are generated for use in the engraving process. In a digital-to-plate rotogravure process, the images are transmitted digitally for use in the engraving process.

From the proofs or a digital file, an engraving machine cuts cells into a copper cylinder using either electromechanical (diamond) engraving or chemical etching. Chemical etching, or conventional rotogravure, creates cells with equal areas but varying depths, while diamond engraving creates cells with varying areas as well as depths. The cylinder is then coated with chrome for durability. Rotogravure plates are the longest lasting of all of the printing methods and are capable of printing runs that go for millions of impressions (Bruno, 1995).

During the printing process, rotogravure cylinders are dipped in ink and a doctor blade scrapes off the excess ink. Rotogravure has unyielding plates that come in direct contact with the label or package (Hawley, 2000). Rotogravure is the most expensive of the printing processes because of the costly copper cylinders, the required solvent recovery systems, the time required for engraving the cylinders, and a longer downtime during changeover from one printing run to the next. Because of the expensive cost and unyielding plates, rotogravure is ideally suited for long runs using inexpensive paper, but it is also used for approximately 10% of the flexible packaging market (Mykytiuk, 1999). Many manufacturers prefer rotogravure because it can reproduce high-quality graphics.

---

## 2.2 PRINTING METHODS USED BY PACKAGING TYPE

Labeling information can be printed directly on packaging or on labels and on both inner and outer packaging.

Labeling information can be displayed on a retail package in two ways—it can be printed directly onto the package or it can be printed on a label, which is then applied to the package. Furthermore, some retail products use inner and outer packaging to enclose one product. Most of the time, the inner packaging does not contain labeling information, particularly if it is not packaged for individual sale. However, sometimes the inner packaging does have labeling information that must also be changed when a new labeling regulation occurs.

Packaging converters and product manufacturers determine which printing method to use based on whether the labeling information is directly printed on the packaging or is preprinted on a label and on which material is used for the packaging or label. Certain packaging and print materials are better suited for specific printing methods. In this section, we explain the



different types of product packaging and labeling and the commonly used printing methods for each below.

### **2.2.1 Preprinted Labels**

Packages that are not printed directly have a preprinted label applied instead. Typical packages that have preprinted labels include glass bottles and jars, plastic bottles and jars, and steel metal cans (Shulman and Elred, 2007). Using preprinted labels lowers inventory costs and has advantages for products with shorter production runs (NPES, 2000). Of all preprinted labels printed on paper, 51% are printed with offset, 20% with flexography, and 7% with rotogravure (Shulman and Elred, 2007). A variety of substrates and application methods are used for printed labels. These include glue-applied labels, pressure-sensitive labels, heat-sealed and in-mold labels, heat-transfer labels, and sleeve labels. Approximately 75% of all preprinted labels are paper, and 25% are plastic, foil, or laminates of plastic/foil/paper in various combinations (Reardon, 2008). We describe each of the materials on which labels are printed in more detail below.

- Paper: Paper is the most commonly used material in label production. Paper labels are most often printed on coated unbleached Kraft paper and are applied to all container types (Shulman and Elred, 2007).
- Plastic: Plastic labels used on products included in the model are generally made from PET (polyethylene terephthalate) or acetate. Clear plastic sleeves, such as those found on water bottles, are typically used to achieve a “no-label” look on plastic bottles and containers.
- Other materials: Foil and laminate combinations of paper, foil, and plastic are also commonly used in label production.

### **2.2.2 Directly Printed Packaging**

The advantages to printing labeling information directly onto the package are that the cost of paper and the two-step process of printing and applying are eliminated (Bruno, 1995). Direct printing also results in more attractive packaging, and the graphics will not be removed inadvertently during the process of manufacturing and shipping (NPES, 2000). However, direct printing may only be cost-effective with highly automated printing systems because of the high cost of packaging waste when an error occurs. Throwing away an entire package is

much more costly than throwing away a preprinted label (Bruno, 1995).

- Manufacturers choose packaging substrates based on the optimal combination of print performance, product protection, design features and requirements, sustainability, and overall value (Malenke, 2010). Three basic types of packages that are directly printed are cartons, flexible packages, and metal cans. Other directly printed packages include rigid plastic containers, gable-top cartons, and aseptic boxes. All cartons and flexible packages are directly printed, but metal cans and rigid plastic containers are either directly printed or have a label applied. Below we describe each of the major types of packaging materials on which information is directly printed. Paper-based packaging: Paper-based packaging materials are generally used because of their print quality, tear strength, and stiffness (Malenke, 2010). Paper-based packaging is used across all retail products as the primary or secondary packaging material.
- Flexible packaging: Seventy-one percent of materials used in flexible packaging production are plastic resin, plastic film, and plastic sheets. Other materials include paper (6%), foil (4%), and coatings/adhesives (3%) (Flexible Packaging Association, 2009). Products packaged with flexible packaging include fresh produce, pharmaceuticals, medical devices, pet foods, and snacks (Shulman and Elred, 2007).
- Metal cans: Metal, either pure aluminum or aluminum accompanied by magnesium and manganese, is used in over two-thirds of all carbonated beverage units and 7% of all fruit and vegetable juice units. Metal cans are popular among manufacturers because of their versatility, corrosion resistance, light weight, and malleability (Theodore, 2005).
- Rigid plastic packaging: Rigid plastic is typically used in beverage containers and snack container manufacturing. In 2007, 61% of total gallons packaged were packaged using plastic (Theodore, 2005).
- Other directly printed materials used in packaging include
  - aseptic cartons, such as those used for milk, soup, and juice containers, which are made from laminates of paperboard, foil, and polyethylene plastic;

- gable-top cartons that are used to package juice, milk, soup, and some snacks and are made from polyethylene-coated paperboard or laminated foil;
- foam cartons, which are generally used in packaging delicate items, such as eggs, and are made from polystyrene; and
- blister packaging, which is popular for OTC medicines in unit-dose packaging.

### **2.2.3 Package Inserts**

Package inserts, which include supplemental product information, are commonly used in cosmetics, dietary supplements, OTC medicines, retail medical devices, and pet foods and are typically printed on paper. Personal care products and dietary supplements containing package inserts have information related to application instructions, safety precautions, and manufacturer contact information. OTC medications routinely have package inserts containing information related to the medical condition the medication is intended to treat, product safety, and dosage recommendations. Retail medical devices have information related to product use, safety precautions, and risks associated with improper use (e.g., toxic shock syndrome with improper use of tampons). Pet products, such as flea products, include package inserts containing application information, safety precautions, and manufacturer contact information.

### **2.2.4 Package-Label Types and Printing Methods Relevant for the Labeling Cost Model**

In the labeling cost model, product subcategories were assigned with package-label types according to the package-label type used by the top-selling product in that subcategory. The original Nielsen ScanTrack data included a field for package type, but this field was not sufficiently populated to identify the package-label type for each product subcategory in the labeling cost model. Thus, we assigned the most common package-label type for each product subcategory based on the top-selling products in each product subcategory in 2008. Table 2-1 shows a summary of the package-label types identified for each FDA product type included in the model.

**Table 2-1. Package-Label Type on Which Labeling Information Is Printed by FDA Product Type**

Material	Cosmetics	Dietary Supplements	Foods	OTCs	Pet Food	Retail Medical Devices	Tobacco
Aluminum can	●		●				
Aseptic carton			●				
Foam carton			●				
Foil-backed paper			●				
Foil-backed paper— pouch			●				
Foil—bag			●				
Foil—top			●				
Gable-top carton			●				
Paper—bag			●		●		
Paper—label	●	●	●	●	●	●	●
Paper—pouch			●				
Paperboard—carton	●	●	●	●	●	●	●
Paperboard—cigarette carton							●
Paperboard—molded			●				
Paperboard—sheet	●			●		●	
Paperboard—sleeve	●		●				
Plastic bag—clear			●			●	
Plastic bag—opaque			●			●	
Plastic bag—resealable		●	●	●	●		
Plastic—carton				●			
Plastic—label	●		●	●	●		
Plastic—molded	●		●				
Plastic—sheet	●	●	●	●	●	●	
Plastic—tube				●		●	
Steel can	●		●	●		●	
Tin steel can			●				
Package inserts	●	●	●	●	●	●	

### ***Printing Methods Used by Package-Label Type***

For most of the package-label types listed in Table 2-1, different printing methods are used across different product types and manufacturers. For some package-label types, such as aluminum cans and foam cartons, a single printing method is used (e.g., lithography for aluminum cans and flexography for foam cartons). For others, two or all of the printing methods are used for some products. To account for the variation in methods used, the labeling cost model calculates weighted averages of costs based on the distribution of printing methods used. We obtained initial estimates of the distributions using Shulman and Elred's *Trends in Package Printing*, published in 2007. For packaging types not directly discussed in the publication, we used percentages from similar package-label types instead. The percentages were originally reviewed and adjusted in 2010 by Packaging Technology Integrated Solutions (PTIS) based on their labeling and packaging knowledge.<sup>1</sup> PTIS provided updates to these percentages in 2014. Further details regarding the distribution of printing methods by package-label types are provided in Section 4.4.1 and Table 4-7.

---

## **2.3 LABEL CONTENTS ACROSS PRODUCT TYPES**

The part of the label that is affected determines the number of plates (colors) that must be changed and thus the complexity of making a change. In the labeling cost model, a minor change is one in which only one color is affected and the label does not need to be redesigned. Examples of this type of change include changing an ingredient list or adding a toll-free number.<sup>2</sup> A major change requires multiple color changes and label redesign. An example of a major change is adding a facts panel or modifying the front of a package. An extensive change is a major format change requiring a change to the product packaging to accommodate labeling information. An example of an extensive change is adding a peel-back label or otherwise increasing the package surface area.

---

<sup>1</sup> PTIS, a division of HAVI Global Solutions Direct, LLC, is a consulting firm with expertise in retail product packaging and printing, including how manufacturers choose packaging types and printing methods.

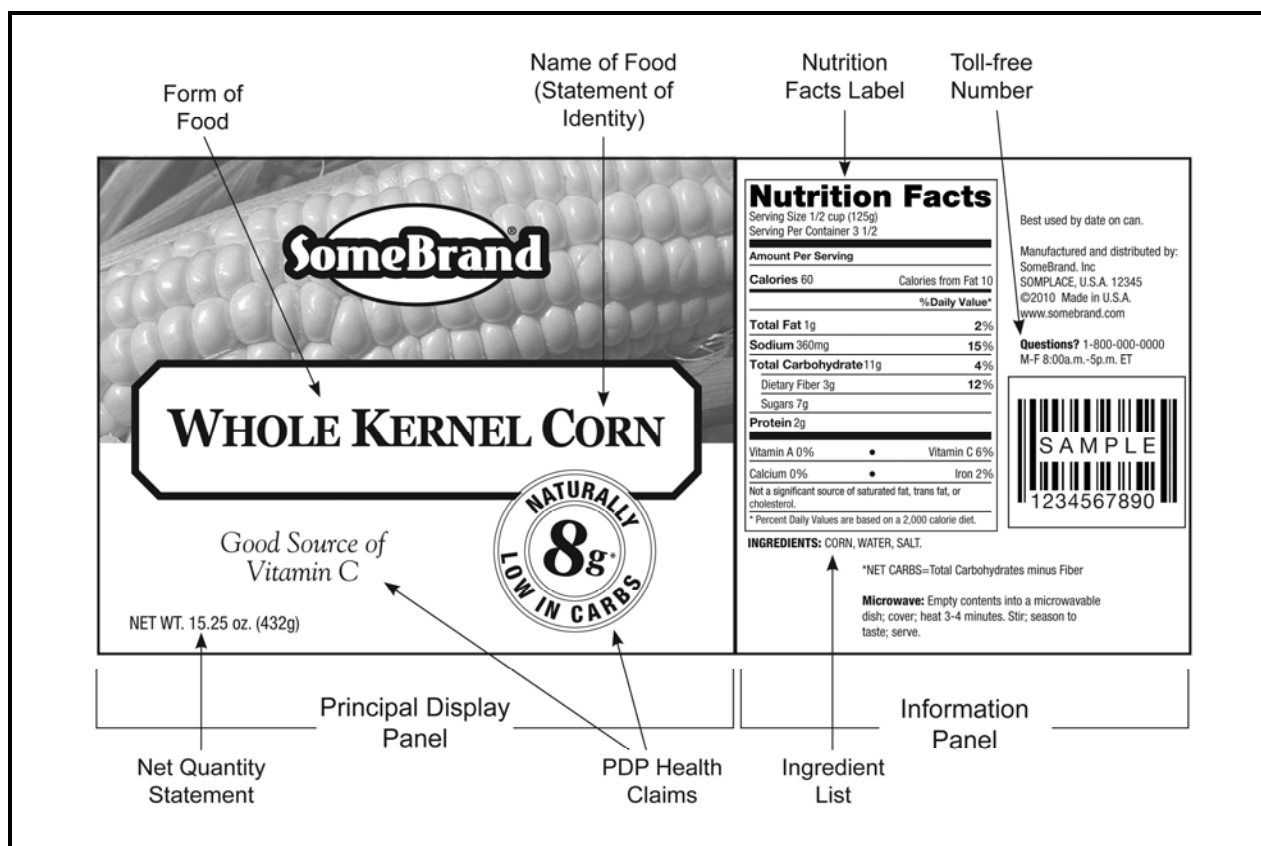
<sup>2</sup> Many manufacturers list ingredients using black ink; however, some manufacturers that we spoke with use colored inks, in which case, a change in ingredients would be considered a major change.

Below, we describe the contents of principal display panels (PDP) and information panels (IPs) for products under each FDA category, noting differences in the contents across each category.

### 2.3.1 Food and Dietary Supplements Label Contents

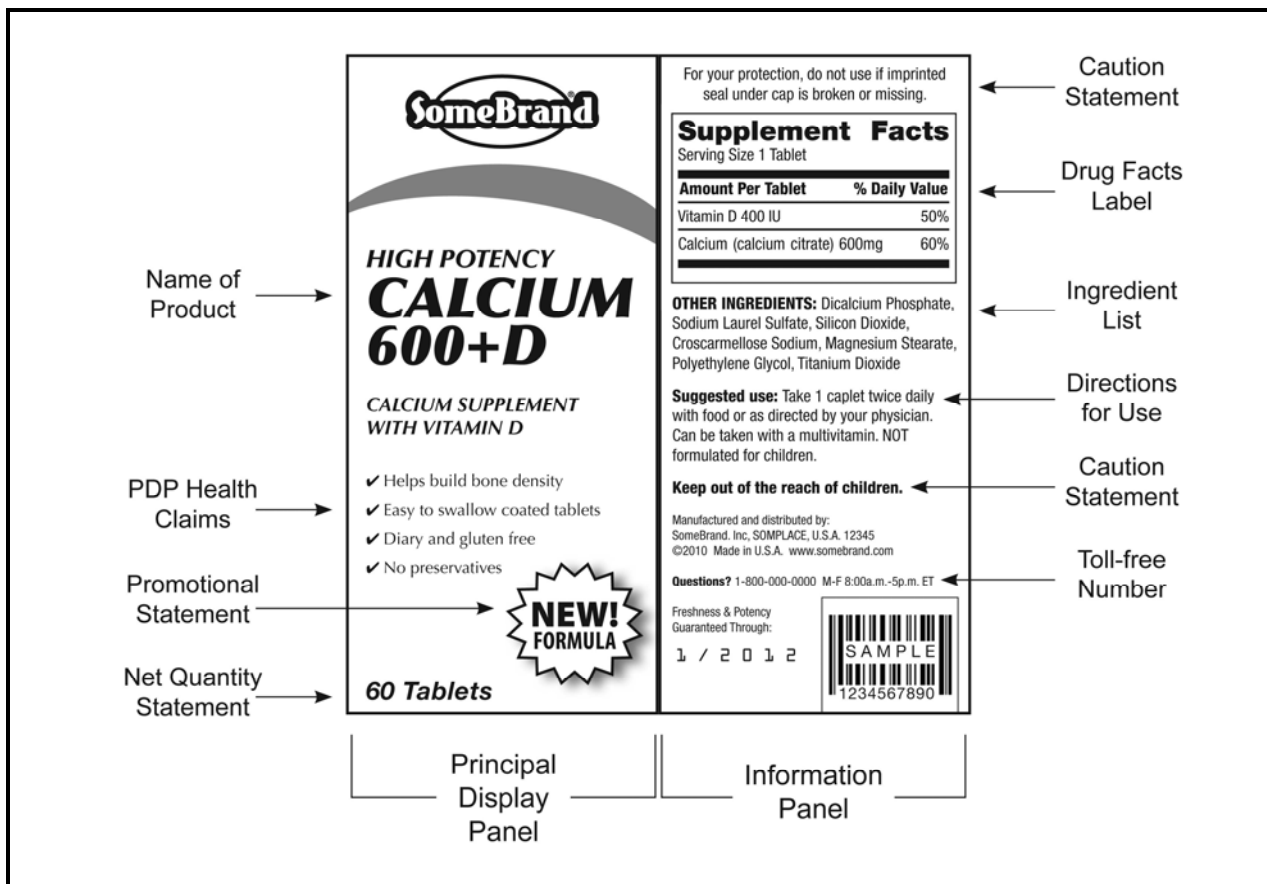
The two sections of the labeling information on a food or dietary supplement package are the PDP and the IP. As indicated in an example of a food product label in Figure 2-1, the PDP is the portion of the package label that faces the consumer when the package sits on a store shelf. The IP is the panel located immediately to the right of the PDP or on the back of the package. Each panel must contain specific information about the product.

**Figure 2-1. Example of Parts of Food Labels that May Change as a Result of a Regulation: Canned Corn**



In the example product in Figure 2-1, a labeling regulation may affect the following parts of the PDP: the name of the food (the statement of identity or fanciful name), the form of the food or dietary supplement, the net quantity statement, or a nutrient content or health claim. Other parts of the PDP such as the brand name or vignette (picture) are unlikely to be affected by a labeling regulation. On the IP, a labeling regulation may affect, for example, the Nutrition Facts label or the ingredient list. In the case of dietary supplements, a labeling regulation may affect the Supplement Facts panel, shown in Figure 2-2. If the product had or was required to have a caution statement or health claim on the PDP or IP, it might also be affected by a labeling regulation. Other parts of the IP such as the manufacturer information or the UPC are unlikely to be affected by a labeling regulation.

**Figure 2-2. Example of Parts of Dietary Supplement Labels that May Change as a Result of a Regulation: Calcium Supplements**

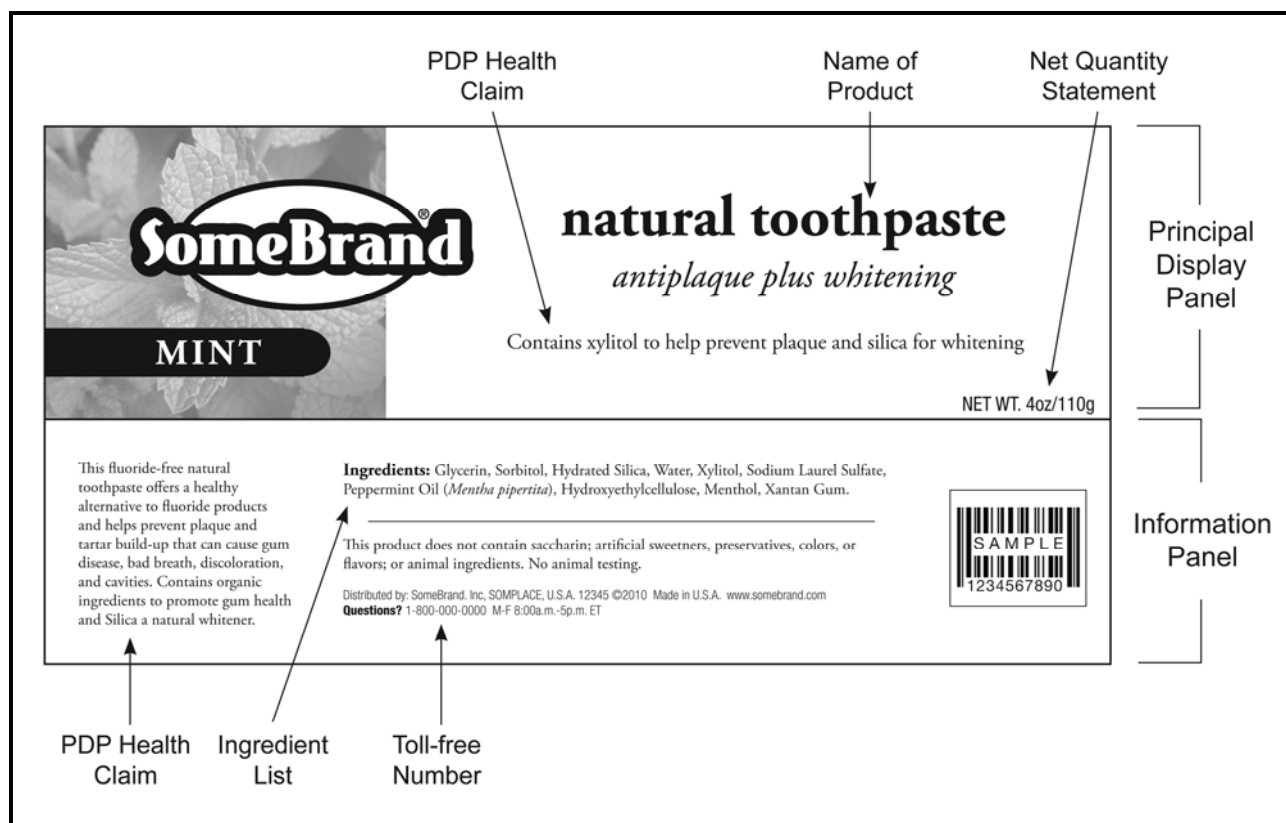


### 2.3.2 Cosmetics Label Contents

Note that toothpaste without fluoride, as shown in Figure 2-3, is classified as a cosmetic, while toothpaste with fluoride is classified as an OTC medication, as shown in Figure 2-4. Thus, very similar products can fall in two different FDA product types based on whether a specific active ingredient is included.

For cosmetics labels, the PDP must include an identity statement (i.e., name of product) and net quantity of contents, as shown in the example in Figure 2-3. The PDP may also include a voluntary claim highlighting a beneficial ingredient as long as it does not claim to prevent or cure a disease or otherwise affect any function of the body. The PDP must consist of the entire front side of a rectangular package or, depending on how the product is packaged, be at least 40% of the total container surface. The IP must include the name of the manufacturer, place of business (e.g., city and state), toll-free number, distributor statement, material facts (e.g., directions for safe use), warning and caution statements, and an ingredient list. The IP may also expand on any claim made on the PDP as long as any explanation does not claim to prevent or cure a disease or otherwise affect any function of the body (FDA, 2006).

**Figure 2-3. Example of Parts of Cosmetic Labels that May Change as a Result of a Regulation: Toothpaste without Fluoride**



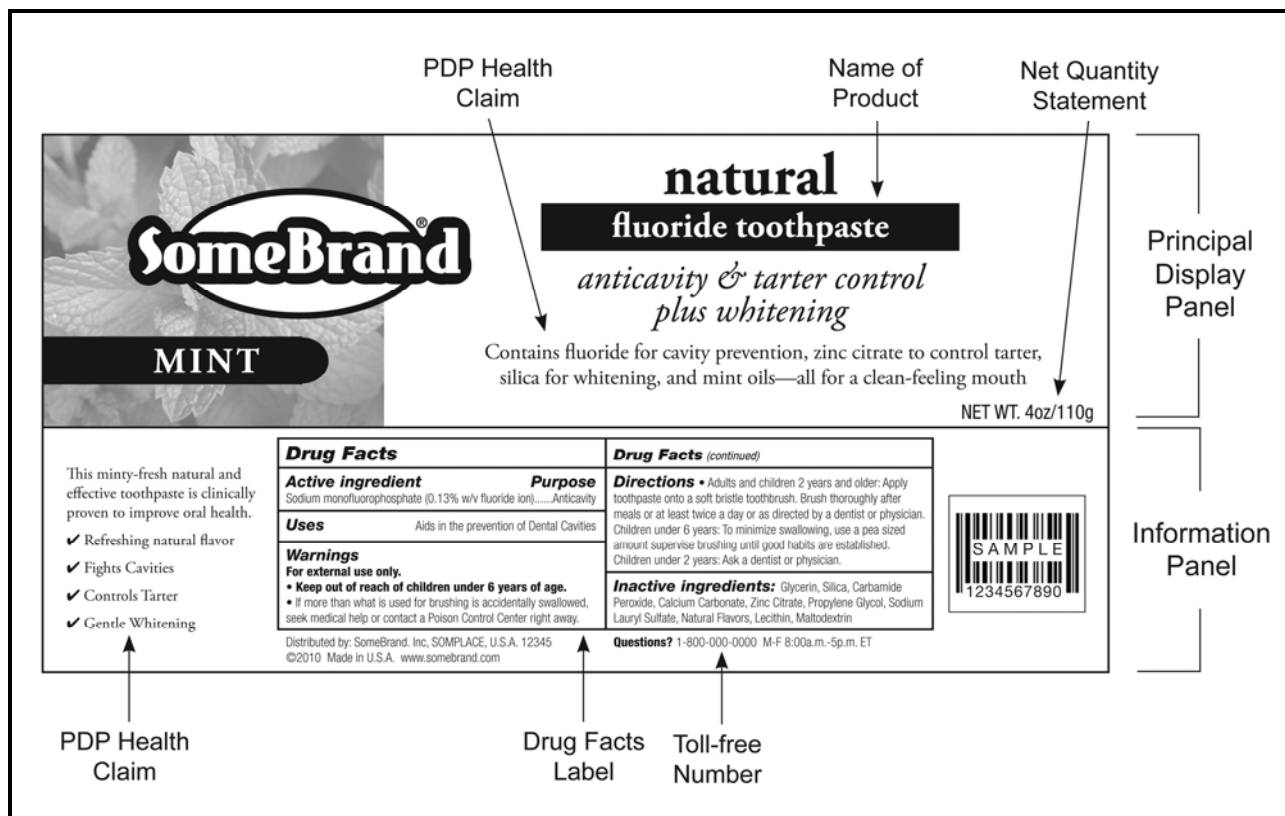


In the example cosmetic product in Figure 2-3, a labeling regulation may affect the following parts of the PDP: the name of the cosmetic, the health claim or marketing claim, or the net quantity statement. Other parts of the PDP such as the brand name or vignette are unlikely to be affected by a labeling regulation. On the IP, a labeling regulation may affect, for example, the ingredient list, health claim, or marketing claim. Because of size constraints, some cosmetics have peel-back labels, which consist of information typically found on the IP. If the product had or was required to have a caution statement or health claim on the PDP or IP, it might also be affected by a labeling regulation. Other parts of the IP such as the manufacturer information or the UPC are unlikely to be affected by a labeling regulation.

### **2.3.3 Over-the-Counter Medicine Label Contents**

OTC medicines are medicines that are available without a prescription. This includes products that can also be categorized as drug cosmetics, which are cosmetic products that contain drug ingredients requiring a drug facts panel on the IP (e.g., sunscreen products). For all OTCs, the PDP must include an identity statement (e.g., name of product, statement of intended purpose) and net quantity of contents, as shown in the example in Figure 2-4. Unlike nondrug cosmetics, OTCs and drug cosmetics can make a health claim on a label as long as there is scientific evidence or other empirical research supporting the claim. The PDP must consist of the entire front side of a rectangular package or, depending on how the product is packaged, be at least 40% of the total container surface. The IP must include the drug facts panel, name of the manufacturer, place of business (e.g., city and state), and toll-free number. The drug facts panel must include a list of active and inactive ingredients, intended uses, warnings and precautions, and dosing and dose frequency instructions. In addition to the drug facts panel, the IP may expand on any health claim made on the PDP, including the scientific basis for the respective claim. Similar to cosmetics, some OTCs have peel-back labels to include information typically found on the IP if space is limited.

**Figure 2-4. Example of Parts of Over-the-Counter Medicine Labels that May Change as a Result of a Regulation: Toothpaste with Fluoride**



In the example OTC medicine in Figure 2-4, a labeling regulation may affect the following parts of the PDP: the name of the drug, the health claim or marketing claim, or the net quantity statement. Other parts of the PDP such as the brand name or vignette are unlikely to be affected by a labeling regulation. On the IP, a labeling regulation may affect, for example, the drug facts label or health claim. Other parts of the IP such as the manufacturer information or the UPC are unlikely to be affected by a labeling regulation.

### 2.3.4 Pet Food Label Contents

Regulatory labeling of pet food and pet products is broadly defined at the federal level; however, many states have enacted stricter regulations regarding labeling and claims on pet foods and specialty pet products. In an effort to consolidate regulations into a uniform set of standards, AAFCO—a consortium of animal food and animal products trade associations—issued a publication outlining “model” regulations

to guide states' legislative and regulatory entities. Although the model regulations are not inclusive of all states' regulations on animal foods and animal products, they do offer a starting point for manufacturers to plan for regulatory labeling of the products. It is the responsibility of each manufacturer to research the regulations of each state in which the manufacturer plans to market animal products.

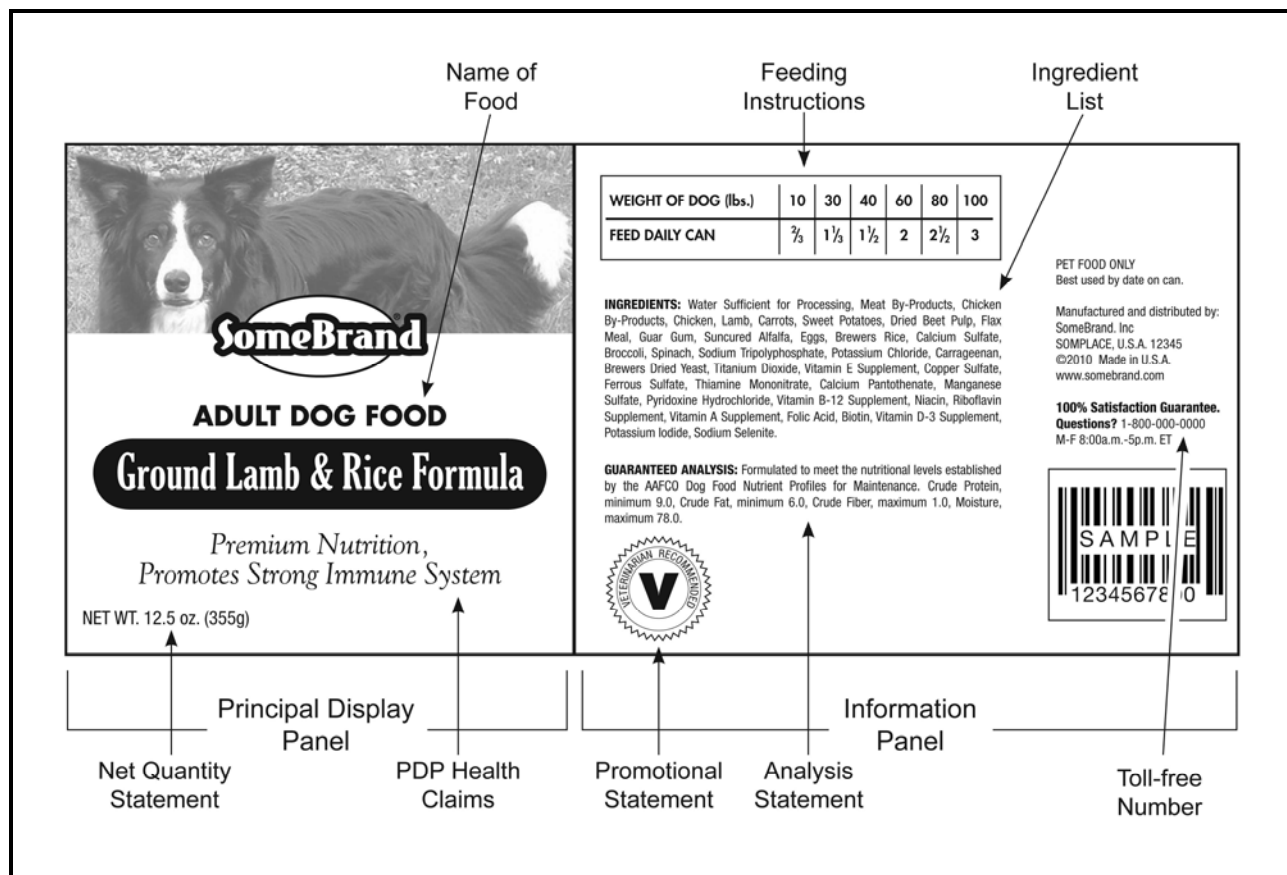
Pet products such as dry, moist, and wet pet foods; flea and tick treatments; heartworm medication; incontinence products; and pet treats are included in the labeling cost model because FDA directly regulates these products. Raw hides are not defined as pet food and are, therefore, excluded from the model. As shown in Figure 2-5, the PDP must include the name of the food and net quantity statement and can include a PDP health claim.<sup>3</sup> The IP must include feeding instructions, ingredient list, guaranteed analysis statement, the name of the manufacturer, place of business (e.g., city and state), and toll-free number.

A labeling regulation may affect the following parts of the PDP: the name of the pet product, health claims, promotional statements, or the net quantity statement. On the IP, a labeling regulation may affect, for example, feeding instructions, ingredient list, guaranteed analysis statement, or promotional statement. If the product had or was required to have a caution statement or health claim on the PDP or IP, such as tick and flea treatments, it might also be affected by a labeling regulation. Other parts of the IP such as the manufacturer information or the UPC are unlikely to be affected by a labeling regulation.

---

<sup>3</sup> The use of the word "proven" in connection with a health claim must be substantiated by scientific or other empirical evidence; otherwise, the use of the word "proven" is not permitted.

**Figure 2-5. Example of Parts of Pet Food Labels that May Change as a Result of a Regulation: Canned Dog Food**



### 2.3.5 Retail Medical Device Label Contents

Retail medical devices, also referred to as OTC devices, include any “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being

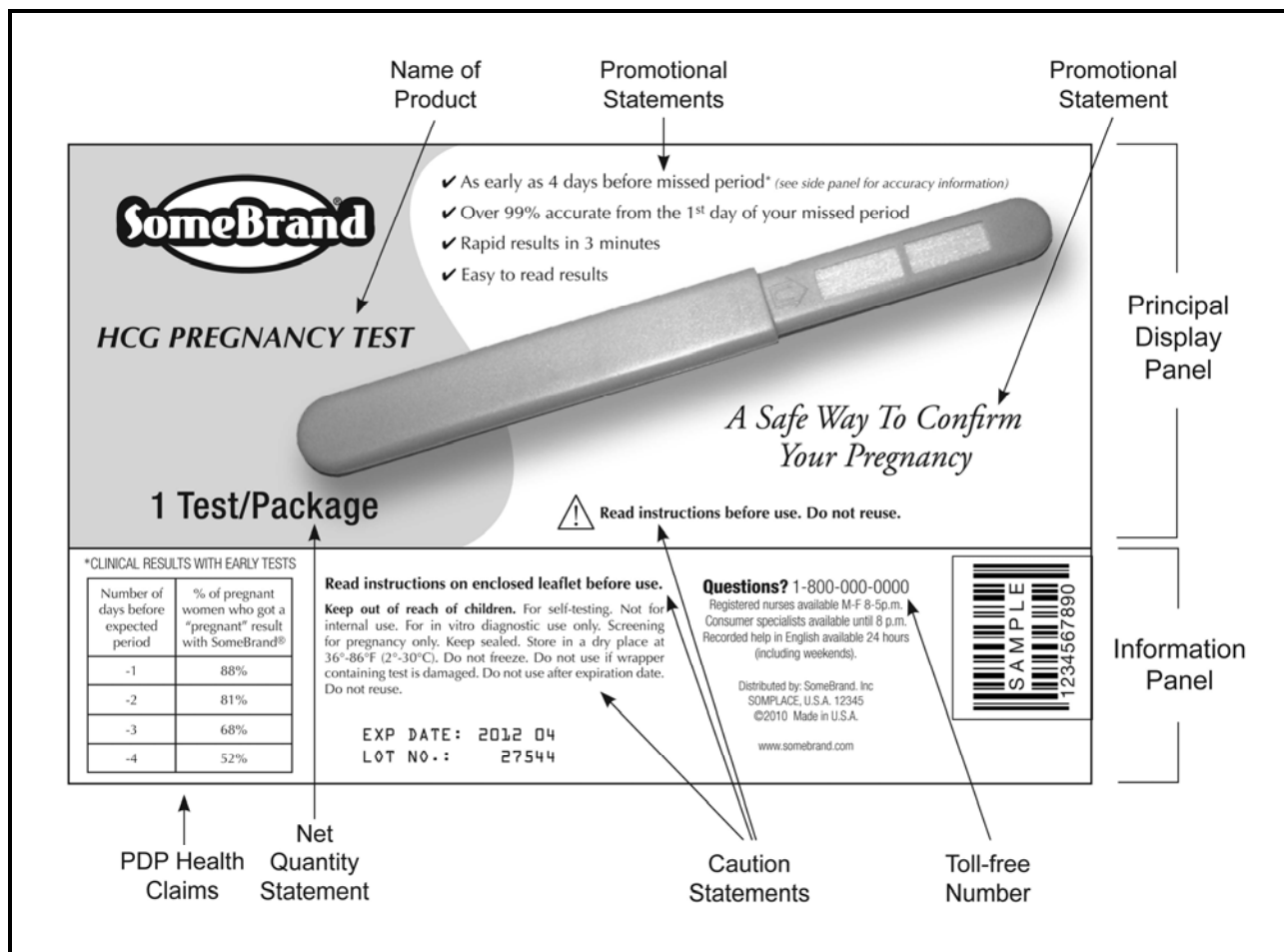
metabolized for the achievement of any of its primary intended purposes” (FDA, 2006).

Classification of medical devices depends primarily on the intended use of the product and the risk posed to the user or patient. Products posing the lowest risk are considered Class I medical devices, and products presenting most risk are considered Class III medical devices. Most medical devices available on the retail market are considered Class I medical devices. Products such as feminine napkins, at-home medical test kits, bedpans, and thermometers are considered retail medical devices.

Regulatory labeling of retail medical devices mandates that the PDP include an identity statement (i.e., name of product) and net quantity of contents, as shown in the example in Figure 2-6. The PDP must consist of the entire front side of a rectangular package or, depending on how the product is packaged, be at least 40% of the total container surface. The IP must include any caution statements, the name of the manufacturer, place of business (e.g., city and state), and toll-free number.

In the example retail medical device in Figure 2-6, a labeling regulation may affect the following parts of the PDP: the name of the device, promotional statements, caution statements, or the net quantity statement. On the IP, a labeling regulation may affect, for example, instructions for use, health claim, or a promotional statement. Other parts of the IP such as the manufacturer information or the UPC are unlikely to be affected by a labeling regulation.

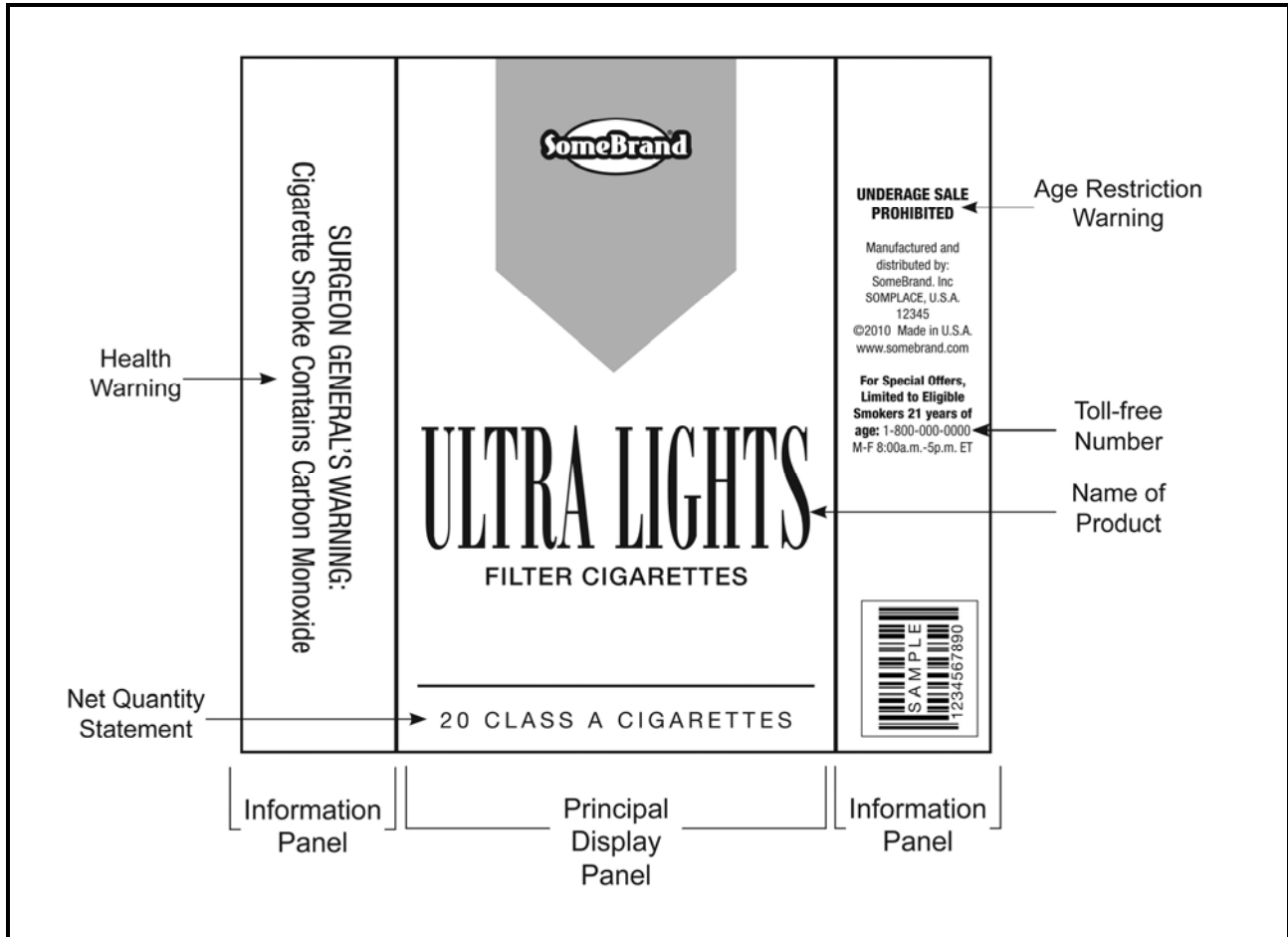
**Figure 2-6. Example of Parts of Retail Medical Device Labels that May Change as a Result of a Regulation: Pregnancy Test**



### 2.3.6 Tobacco Label Contents

Tobacco and tobacco products have only recently been under FDA's jurisdiction; therefore, regulatory labeling of tobacco products has thus far been limited to health and legal warnings. However, tobacco products have similar structures for labeling as other products under FDA's jurisdiction. The PDP must include an identity statement (i.e., name of product) and net quantity statement, as shown in the example in Figure 2-7. Tobacco products, however, must include a surgeon general's warning and age restriction warning on the IP, along with a toll-free number.

**Figure 2-7. Example of Parts of Tobacco Labels that May Change as a Result of a Regulation: Cigarettes**



In the example tobacco product in Figure 2-7, a labeling regulation may affect the following parts of the PDP: the name of the product, promotional statements, or the net quantity statement. A labeling regulation may also require more information, such as additional warning statements, on the PDP. On the IP, a labeling regulation may affect, for example, government warnings or legal warnings or require the addition of a panel detailing the product's ingredients. Other parts of the IP such as the manufacturer information or the UPC are unlikely to be affected by a labeling regulation.

# 3

## Overview of Labeling Changes Conducted by Manufacturers

*Note that the text in this section has only minor changes compared with the labeling cost model report delivered in 2012.*

The cost estimates developed in Section 4 were based on the process of changing labels described in this section. In addition, the model accounts for the likelihood that manufacturers can coordinate regulatory labeling changes with planned changes.

In this section, we provide a brief overview of the process of changing labeling information on retail consumer products. We then describe the typical frequency and reasons that manufacturers update labeling information on a routine basis. This information is used to construct estimates of the percentages of UPCs for which a required labeling change could be coordinated with a planned labeling change.

Product manufacturers often update their labeling information for marketing purposes, because of a change in packaging or for other reasons. When manufacturers update labels for nonregulatory reasons, they can often incorporate a change required by regulation at minimal additional cost. Thus, it is important to account for these nonregulatory labeling changes when estimating the costs of regulatory labeling changes to avoid overstating the costs of compliance. It is likely that a regulation affecting labeling will cause affected firms to incur some level of costs, regardless of how well coordinated the regulatory labeling change is with nonregulatory labeling changes. Therefore, even if the change can be coordinated, the model accounts for the incremental costs associated with the regulation, such as staff time for reviewing the regulatory requirements, determining options for complying with the regulatory requirements, and coordinating the required change with a scheduled change.<sup>1</sup>

---

<sup>1</sup> The costs are described in more detail in Section 4.



### 3.1 OVERVIEW OF THE LABEL CHANGE PROCESS

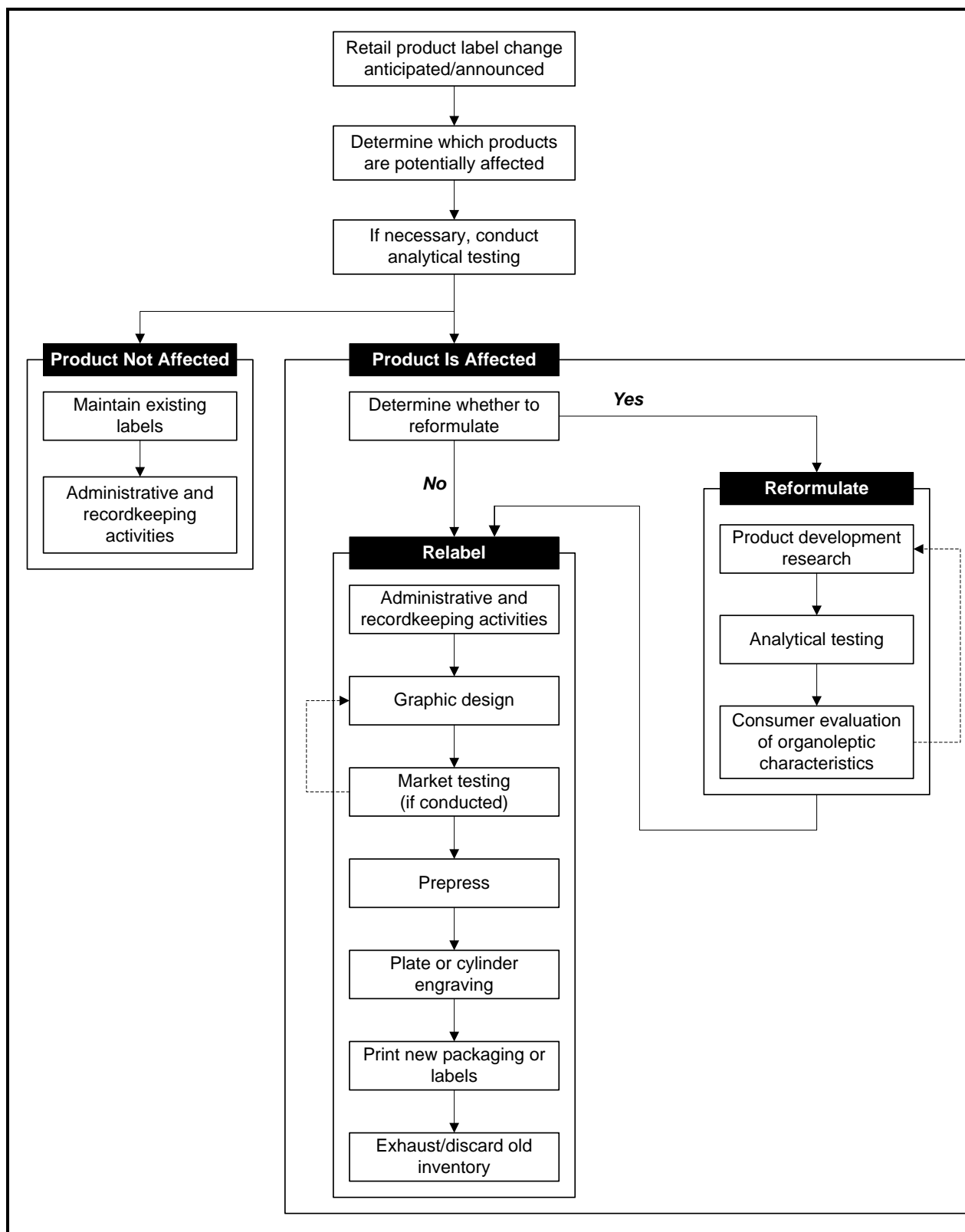
Figure 3-1 provides an overview of the process by which labeling information and graphics on consumer products included in the FDA Labeling Cost Model may be changed as a result of regulation. Once a product manufacturer has determined that a product might be affected, the manufacturer may conduct some type of analytical testing (e.g., for nutrients or contaminants) of the product. Results of the analytical tests then influence a manufacturer's decision to reformulate the product. However, in many cases, reformulation would not be a likely response to the regulatory requirements or the company may choose not to reformulate. Estimating the costs of reformulation is beyond the scope of the Labeling Cost Model; thus, we focus on the process that occurs assuming either no reformulation or that the reformulation has already occurred.

Labeling changes involve several internal departments within a company and typically involve multiple outside vendors.

Whether or not a manufacturer conducts analytical testing prior to determining its response, it will follow a number of steps to initiate the change process. In general, the steps (not necessarily in this order) are as follows:

- conduct administrative activities such as reviewing the regulation and determining a response; coordinate with the marketing, legal, and environmental departments to determine and implement the response; and work with outside vendors to change graphics and produce new packaging;
- conduct recordkeeping activities to update records of labeling information;
- conduct analytical testing to determine if a product meets the regulatory requirements or to obtain information needed for the label (not necessary for some types of changes);
- alter the graphic design to accommodate the required change;
- conduct market testing to determine whether consumers will respond favorably to the redesigned label (not necessary for minor changes);
- conduct prepress activities to convert the graphic design into the film or files that are used to engrave the printing plates, color trap the design to prevent white or black spaces between the colors, and prepare proofs for approval;

**Figure 3-1. Process of Changing Labeling Information on Consumer Products**



- engrave new plates or cylinders (typically 6 to 10 plates or cylinders);<sup>2</sup> and
- print and manufacture (convert) labels and packaging material, which includes cutting, stacking, and forming packaging materials.

In some cases, a labeling change may be extensive enough that it is necessary to re-engineer the packaging. For example, for small packages, the package size or dimensions may need to be increased to accommodate labeling information, or a peel-back label or accordion label may need to be added. If the packaging must be changed, a packaging engineer would be involved in designing the new packaging or labeling, developing engineering drawings or specifications, and testing the new packaging on the production line.

Several departments within the manufacturing firm (e.g., purchasing, marketing, legal, and regulatory) are involved in the process of making a labeling change. In this report, we refer to the combined set of activities conducted by these departments as administrative activities. In addition to the departments within the manufacturing firm, several outside entities may be involved. In some cases, a manufacturer may handle one or more of the steps in the process internally; however, it is often the case that these activities are outsourced to the following entities:

- analytical testing laboratory,
- market research company,
- graphic designer,
- packaging engineer,
- prepress company,
- plate or cylinder engraver, and
- packaging converter (the company that manufactures and prints labels and/or packaging material, which is typically the same company that engraves the plates or cylinders).

In many cases, a single vendor may handle multiple activities. In developing the cost estimates provided in Section 4, we assumed these activities are typically outsourced, but we accounted for the internal labor costs associated with

---

<sup>2</sup> In the case of digital printing, plates and cylinders are not used; therefore, engraving is not included in the list of activities.

coordinating with an outside vendor. If these activities are not outsourced, we assumed that the costs for a manufacturer to conduct these activities in house is approximately the same as the cost of using an outside vendor. In other words, the costs of outsourcing these activities is a proxy for the costs of conducting the same activities in house.

## 3.2 ESTIMATING THE FREQUENCY OF BASELINE LABELING CHANGES

For regulatory labeling changes that can be coordinated with planned labeling changes, the FDA Labeling Cost Model includes costs of administrative and recordkeeping activities but assumes other costs of changing labels are not attributable to the regulation.

The typical frequency of labeling changes factors into the calculation of costs of compliance with labeling regulations because manufacturers that can coordinate a labeling change with a planned labeling change will incur lower costs than they would otherwise. Even if manufacturers can coordinate a labeling change, the model is designed to include administrative and recordkeeping costs associated with labeling changes because manufacturers still incur costs associated with understanding the regulation, determining their responses, tracking the required change throughout the labeling change process, and reviewing and updating their records of product labels. The model assumes that other types of costs, such as prepress, graphic design, and engraving plates or cylinders, are not attributable to the regulation if the labeling change is coordinated with a planned change. In this section, we describe the reasons for and general frequency of nonregulatory labeling changes and the derivation of default estimates of the percentages of UPCs that are relabeled in a typical year for use in the model.

### 3.2.1 Reasons for and Frequency of Nonregulatory Labeling Changes

We obtained information on the reasons why labeling information is updated for nonregulatory reasons and estimates of the frequency of nonregulatory changes through structured discussions with trade associations that represent manufacturers of products regulated by FDA and with manufacturers. In conducting discussions with trade associations, we followed the list of topics identified in the project description included in Appendix A of Muth et al. (2012). The trade associations we interviewed were as follows:

- Grocery Manufacturers Association
- Natural Products Association

- Pet Foods Institute (PFI)
- Private Label Manufacturers Association
- Produce Marketing Association
- American Pet Association
- Consumer Health Products Association

We made multiple attempts to conduct interviews with other associations, including those that represent cosmetic and retail medical device manufacturers but were unable to schedule those interviews. However, the trade associations listed above provided useful information regarding issues related to changing labels for the manufacturers they represent.

In conducting discussions with product manufacturers, we used the interview guide included in Appendix A of Muth et al. (2012). We conducted discussions with a total of nine manufacturers in 2010—five food manufacturers, two OTC manufacturers, one OTC and dietary supplement manufacturer, and one pet food manufacturer—and focused primarily on the costs of each step in the labeling change process but also on types and frequency of nonregulatory labeling changes.

Based on the interviews with trade associations, products are typically relabeled every 3 to 4 years, with the exception of pet foods produced by large manufacturers, which are more typically relabeled every 1 to 2 years. The reasons for nonregulatory labeling changes include the following:

- to include promotional text or graphics (including for new products that can only be labeled “new” for 6 months after introduction)
- to update the brand image or graphics
- to accommodate packaging changes (e.g., due to changes in the type, size, or vendor)
- to reflect ingredient changes or product reformulation (for either cost reduction or product improvement purposes)
- to update the corporate contact information, distributor information, or country of origin
- to reflect updated “science” such as for dietary supplements
- to add or delete product claims

The reasons cited by manufacturers can generally be classified into one of the above reasons provided by the trade associations. Many manufacturers were unable to provide an estimate of the percentage of products changed for each of these reasons each year. However, based on the responses that were provided, the percentages of products that were relabeled in a typical year were as follows:

- 5 to 25% of products were relabeled for promotional purposes,
- 10 to 33% were relabeled to update the brand image or graphics,
- 5 to 35% were relabeled to accommodate packaging changes, and
- an unspecified small percentage to 50% were relabeled to reflect product reformulation.

The estimated percentages of products relabeled in a typical year indicate a 2- to 5-year cycle for relabeling most products for nonregulatory reasons.

Specific percentages for the other possible reasons listed above were not provided or generalizable across respondents.

However, most manufacturers that provided an overall percentage indicated that 20 to 50% of products are relabeled in any given year (indicating a 2- to 5-year cycle for relabeling all products), with the exception of a manufacturer that said that less than 1% of products are relabeled annually.

Furthermore, interview respondents noted that private-label products were less likely to be relabeled in any given year.

### 3.2.2 Derivation of Default Percentages of Nonregulatory Labeling Changes

Let  $\rho^B$  represent the proportion of uncoordinated changes for branded products and  $\rho^{PL}$  the proportion of uncoordinated changes for private-label products.<sup>3</sup> These proportions are each a function of the number of months of compliance because longer compliance periods increase the proportion of changes that can be coordinated. The model includes default values for  $\rho^B$  and  $\rho^{PL}$  from  $m = 3$  to 60, where  $m$  is the number of months provided for compliance in 3-month increments. Users of the model can modify the default values directly within the model input screens. Based on the trade association and manufacturer interviews, it is extremely unlikely that regulatory labeling changes could be coordinated with nonregulatory labeling changes for compliance periods of less than 12 months;

<sup>3</sup> The formulas in the model that incorporate  $\rho^B$  and  $\rho^{PL}$  are described in Section 4.3.

therefore, the default values  $\rho^B$  and  $\rho^{PL}$  are set to 100% for  $m = 3, 6$ , and  $9$ .

We assumed that  $\rho^B < \rho^{PL}$  because, based on information obtained from trade associations and manufacturers, branded product labels are typically updated more frequently than private-label products and, thus, are assumed to be more easily coordinated with a planned change. Furthermore, we assumed that  $\rho^B$  and  $\rho^{PL}$  vary by product type with products such as OTCs having higher  $\rho$  (a higher proportion of uncoordinated changes) and others, such as pet foods, having lower  $\rho$  (a lower proportion of uncoordinated changes) because of the typical frequency in which each product type is usually relabeled.

Many of the participants in the industry interviews stated that coordinating required labeling changes with planned changes is often difficult because of the timing of the change relative to where they are in the cycle for making planned changes. Thus, the actual proportion of labeling changes that can be coordinated is likely less than might be implied based on the typical frequency of labeling changes. Also, the ability to coordinate changes increases at an increasing rate because, with more lead time, it becomes more likely that a regulatory change could be initiated at the beginning of the cycle of a planned change rather than falling within a cycle that is already underway.

To develop the default values for  $\rho^B$  and  $\rho^{PL}$ , we made the following assumptions based on limited information available from trade associations and manufacturers:

- no labeling changes can be coordinated with planned changes for compliance periods of less than 1 year for all product categories;
- dietary supplements, OTC medications, retail medical devices, and tobacco products are assumed to require the longest time period for coordination;
- cosmetics and foods are assumed to require an intermediate time period for coordination;
- pet foods are assumed to require the shortest time period for coordination;
- private-label products are assumed to require a longer time period for coordination relative to branded products; and

- percentages of labeling changes that cannot be coordinated with a planned change are assumed to decrease at an increasing rate over time.

Table 3-1 provides the default percentages of labeling changes (on a UPC basis) that cannot be coordinated with a planned labeling change. To account for the fact that the ability to coordinate increases at an increasing rate, the model uses a square root function to estimate the percentage of labeling changes that cannot be coordinated with a planned change. Specifically, we assumed 100% of UPCs are uncoordinated for compliance periods of 9 months or less. For compliance periods of 12 months or more, the percentage of labeling changes that cannot be coordinated with a planned change was calculated based on the square root of the percentage of time remaining until all UPCs can be coordinated.<sup>4</sup> The time period at which we assumed all labeling changes can be coordinated varies by product type and for branded versus private-label products; the estimate of the time period was derived from information provided by manufacturers and vendors.

---

<sup>4</sup> For example, if we assumed that all labeling changes for a product type can be coordinated within 30 months, we first calculated the percentage of time elapsed from 3 to 30 months for each 3-month increment. We then calculated the square root of the percentage of time elapsed and rescaled it by dividing the result for each 3-month increment in time periods by the value at 9 months (since 100% of labeling changes are assumed to be uncoordinated at 9 months) and multiplying by 100.



**Table 3-1. Assumed Percentages of Changes to Branded ( $\rho^B$ ) and Private-Label ( $\rho^{PL}$ ) UPCs that Cannot be Coordinated with a Planned Change**

Compliance Period (months)	Cosmetics		Dietary Supplements		Foods		OTCs		Pet Foods		Retail Medical Devices		Tobacco Products	
	Branded	Private Label	Branded	Private Label	Branded	Private Label	Branded	Private Label	Branded	Private Label	Branded	Private Label	Branded	Private Label
3	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
6	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
9	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
12	94%	96%	96%	97%	89%	95%	96%	97%	82%	93%	96%	97%	96%	97%
15	88%	92%	92%	94%	77%	90%	92%	94%	58%	85%	92%	94%	92%	94%
18	82%	88%	88%	91%	63%	85%	88%	91%	0%	76%	88%	91%	88%	91%
21	75%	83%	83%	87%	45%	80%	83%	87%		65%	83%	87%	83%	87%
24	67%	78%	78%	84%	0%	74%	78%	84%		53%	78%	84%	78%	84%
27	58%	73%	73%	80%		67%	73%	80%		38%	73%	80%	73%	80%
30	47%	68%	68%	77%		60%	68%	77%		0%	68%	77%	68%	77%
33	33%	62%	62%	73%		52%	62%	73%			62%	73%	62%	73%
36	0%	55%	55%	69%		43%	55%	69%			55%	69%	55%	69%
39		48%	48%	64%		30%	48%	64%			48%	64%	48%	64%
42		39%	39%	59%		0%	39%	59%			39%	59%	39%	59%
45		28%	28%	54%			28%	54%			28%	54%	28%	54%
48		0%	0%	49%			0%	49%			0%	49%	0%	49%
51				42%				42%				42%		42%
54				34%				34%				34%		34%
57				24%				24%				24%		24%
60				0%				0%				0%		0%

Note: These percentages apply for (1) minor label changes, (2) major label changes, and (3) package insert changes. Extensive labeling changes are extremely unlikely to be coordinated and, thus, are assumed to be 100% uncoordinated for all compliance periods. Also, adding a package insert is by definition an uncoordinated change; thus, values are assumed to be 100% uncoordinated for all compliance periods.

# 4

# Model Structure, Data, Assumptions, and Calculations

In this section, we provide an overview of the model inputs and outputs, present the product categories and data, provide the formulas for calculating the costs of labeling changes based on user selections, and discuss some of the key assumptions and limitations of the approach.

---

## 4.1 OVERVIEW OF THE MODEL INPUTS AND OUTPUTS

The labeling cost model inputs include items that are selected from lists and drop-down boxes (e.g., product categories) and fields for entering values (e.g., analytical testing costs if not provided within the model). The model outputs include a summary of the user inputs and the cost estimates generated based on the user inputs. We list the model inputs and outputs below.

### 4.1.1 Model Inputs

The model gives users the option to save, retrieve, and revise selected sets of model inputs.

In operating the model, users will select or provide the model input as follows:

- Select the affected product type by type name (e.g., foods, OTCs, and pet foods) or by 3-digit NAICS.
- Select affected product subcategories by
  - product category based on the Nielsen ScanTrack product modules or
  - 6-digit NAICS codes.
- Indicate what percentage of products within each product subcategory are affected by a labeling requirement.

- Select whether the labeling change is minor, major, or extensive based on the definitions provided in Table 4-1.
  - If extensive change is selected, indicate whether to include annual costs of adding peel-back labels (also a proxy for increased package size) in the model output.
- Indicate whether a package insert is affected by the labeling requirement. (Alternatively, if the product subcategory does not currently have a package insert, indicate whether a package insert would have to be added).
- Indicate the type of analytical tests required (if applicable) from a list such as the following:
  - nutrients or ingredients in human food (e.g., Nutrition Facts Panel, fatty acid profile, trans fatty acids, sugar profile, soluble fiber, vitamins, minerals, iodine, caffeine, allergens),
  - bioengineered ingredients,
  - dietary supplement ingredients
  - guaranteed analysis for pet foods,
  - pathogens, and
  - contaminants.
- Enter a user-provided cost estimate for analytical tests (if applicable) on a per-formula basis.
- Indicate the type of market tests that will be needed to guide industry response to a labeling requirement (if applicable) from the following:
  - focus groups,
  - discrimination tests,
  - descriptive tests,
  - central location tests, and
  - in-home tests.

**Table 4-1. Types of Labeling Changes that May Be Required by Regulation**

Users select the type of change that most closely aligns with expected industry responses to the requirements of the regulation. Note that a user might indicate that a package insert is affected (or must be added) and select none of the types of labeling changes listed in this table.

Type of Change	Definition	Examples
Minor change	One-color changes that do not require a label redesign	<ul style="list-style-type: none"> <li>Changes to the net quantity statement</li> <li>Minimal changes to a facts panel (e.g., nutrition facts, supplement facts, or drug facts)</li> <li>Minimal changes to an ingredient list</li> <li>Addition of a toll-free number</li> <li>Minimal changes to a claim, caution statement, or disclaimer on the back or side of a package (affecting one color)</li> </ul>
Major change	Multiple-color changes that require a label redesign	<ul style="list-style-type: none"> <li>Changes to the name of the product</li> <li>Changes to the standard of identity or fanciful name for a food product</li> <li>Addition of a facts panel (e.g., nutrition facts, supplement facts, or drug facts)</li> <li>Substantial changes to an ingredient list</li> <li>Substantial changes to or elimination of a claim</li> <li>Addition of or substantial changes to a caution statement</li> <li>Addition of or substantial changes to a disclaimer</li> </ul>
Extensive change	Major format change that requires a change to the product packaging to accommodate labeling information	<ul style="list-style-type: none"> <li>Addition of a peel-back label</li> <li>Increases in the package surface area for labeling information</li> </ul>

- Enter a user-provided cost estimate for market tests (if applicable) on a per-formula basis.
- Indicate whether to include recordkeeping costs (e.g., for updating nonlabel recordkeeping materials) on a per-UPC basis.
- Modify the wage rates used in calculating costs of relabeling activities.
- Select a compliance period for implementing the regulation from 3 to 60 months (in 3-month increments), which will allow the user to view the default estimates of the percentage of labeling changes

that could be coordinated with a nonregulatory labeling change.<sup>1</sup>

- Revise, if desired, the default estimates of the percentage of labeling changes that could be coordinated with a nonregulatory labeling change.
- Specify an inflation factor relative to the stated baseline year of the model so that all costs are adjusted to the current year (users could choose to base the inflation factor on the gross domestic product deflator, consumer price index, or producer price index).

#### **4.1.2 Model Outputs**

Based on the user inputs, the model will calculate the costs of labeling changes and present the following outputs:

- summary of user-selected inputs and total summary cost estimates
- aggregate one-time cost estimates for branded and private-label products with subtotals and totals
- disaggregate one-time cost estimates for branded and private-label products, including each of the following:
  - labor
  - materials
  - inventory (discarded inventory and disposal costs)
  - other (e.g., analytical and market tests)
  - recordkeeping (labor costs), if selected by the user
- ongoing annual cost estimates for adding a peel-back label (also a proxy for increased package size)
- ongoing annual cost estimates for adding package inserts to products that currently do not include package inserts

---

<sup>1</sup> The compliance period assumptions are used to account for the fact that companies may be able to coordinate a regulatory labeling change with a voluntary labeling change, thus reducing compliance costs. However, if the regulation causes the company to switch from a voluntary minor labeling change to a regulatory major labeling change, then the model assumes that all of the costs of the major labeling change are attributable to the regulation. Likewise, if the regulation causes a company to switch from a voluntary minor labeling change to a regulatory extensive change or from a voluntary major change to a regulatory extensive change, the model assumes that all of the costs of each type of change are attributable to the regulation. In other words, the model is not able to differentiate the incremental costs associated with a regulatory labeling change relative to the costs that would have been incurred for a planned voluntary labeling change but instead attributes all of the costs to the regulation.

Note that capital costs are not included because labeling changes typically do not affect capital equipment. Printing plates are categorized as materials costs because they have a relatively short duration of use. However, extensive labeling changes that result in changes in the size of packaging or addition of package inserts to products that currently do not have package inserts may require manufacturers to incur capital equipment costs associated with modifying existing packaging and labeling equipment or possibly purchasing and installing new equipment. Subtotals by product category, grand totals, and per-UPC costs are provided. Low, midpoint (or median), and high cost estimates are provided as separate columns for each cost type and in aggregate.

---

## **4.2 PRODUCT CATEGORIES AND DATA**

The categorization of products within the labeling cost model occurs at three levels as follows:

- FDA product type or 3-digit NAICS code
- product category (based on Nielsen ScanTrack) or 6-digit NAICS code
- product subcategory (based on Nielsen ScanTrack), which includes one or more Nielsen product modules

The Nielsen ScanTrack data include sales in food stores, drug stores, and mass merchandisers; thus, in some cases, it is necessary to adjust the data to account for other types of outlets (e.g., warehouse stores, pet stores, or specialized nutrition stores). The ScanTrack data also do not capture sales of foods without UPC codes, such as fresh produce and seafood purchased at the seafood counter, but these foods do not have the type of labeling requirements addressed in the labeling cost model.

### **4.2.1 Private-Label UPC Counts**

Obtaining actual counts of private-label UPCs in the ScanTrack data is not possible because all private-label UPCs are aggregated into a single record for each product and size. Nielsen does not provide individual UPC codes or descriptions for private-label products and reports total unit sales and value of sales only for the aggregated private-label records.

In 2009, Nielsen provided a separate data file containing the number of private-label UPCs by product module to supplement the ScanTrack data. The data represented all UPCs in use over

approximately a 10-year time period. We determined adjustment factors to apply to the counts of private-label UPCs in the private-label file by calculating the proportion of active branded UPCs in the ScanTrack data assuming that all branded UPCs with zero sales in 2008 were inactive. Table 4-2 provides the calculated percentages of active UPCs derived from the branded UPC data in 2008 and 2012 (for foods, pet foods, and dietary supplements). We thus calculated an estimate of the number of active private-label UPCs by multiplying the percentages for 2008 shown in Table 4-2 by the number of private-label UPCs in the supplemental data file provided by Nielsen.

For the 2012 ScanTrack data, Nielsen was unable to provide a separate file of private-label UPCs counts as they had in 2009. Therefore, we used the ratio of private-label to branded UPCs by product category calculated from the 2008 data to estimate the number of private-label UPCs for the 2012 data for foods, dietary supplements, and pet foods. Specifically, we multiplied the proportion of private-label to branded UPCs in 2008 by the number of branded UPCs in 2012 to obtain estimates of the number of private-label UPCs in 2012 for these product types.

**Table 4-2. Assumed Percentages of Active Private-Label UPCs Based on Proportion of Inactive Branded UPCs Included in the Nielsen ScanTrack Data**

<b>FDA Type</b>	<b>% Active UPCs (2008)</b>	<b>% Active UPCs (2012)</b>
Cosmetics	71.6	n.a.
Dietary supplements	80.8	72.8 <sup>a</sup>
Foods	75.9	67.6
OTCs	71.6	n.a.
Pet foods	75.5	66.6 <sup>b</sup>
Retail medical devices	71.6	71.6
Tobacco products	79.4	n.a.

Note: The percentages for cosmetics, OTCs, and retail medical devices are based on the "Health and Beauty" category.

n.a. = not available (FDA provided 2012 ScanTrack data for foods, dietary supplements, and pet foods.)

<sup>a</sup> The percentage for diet aids in the dietary supplements category is based on 2008 data.

<sup>b</sup> The percentage for pet care in the pet foods category is based on 2008 data.

#### **4.2.2 Product Categories, Subcategories, and Adjustments to the UPC Counts and Unit Sales**

Table 4-3 provides the complete list of product types, product categories, and product subcategories to be included in the

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Cosmetics (2008)	Baby needs	Baby care—oils & lotions	325620—Toilet Preparation Manufacturing	735	949	543	701	60,241,627	20,650,483
	Baby needs	Baby care—ointments	325620—Toilet Preparation Manufacturing	409	270	267	177	47,220,890	7,770,857
	Baby needs	Baby care—powder	325620—Toilet Preparation Manufacturing	288	803	202	561	45,287,432	18,013,480
	Baby needs	Baby care products—bath soap	325611—Soap & Other Detergent Manufacturing	682	363	564	301	62,131,158	12,437,048
	Cosmetics—talc & dusting powder	Talcum & dusting powder	325620—Toilet Preparation Manufacturing	694	285	512	211	12,054,409	3,512,030
	Deodorant (nonantiperspirant)	Deodorant—aerosol	325620—Toilet Preparation Manufacturing	53	62	28	34	8,620,623	601,034
	Deodorant (nonantiperspirant)	Deodorant—cologne type	325620—Toilet Preparation Manufacturing	722	59	546	43	71,296,531	670,068
	Deodorant (nonantiperspirant)	Deodorant—roll-on	325620—Toilet Preparation Manufacturing	186	3	167	3	4,427,755	8,376
	Deodorant (nonantiperspirant)	Deodorant—stick/solid	325620—Toilet Preparation Manufacturing	1,190	118	973	96	181,402,892	851,902
	Deodorant (nonantiperspirant)	Remaining deodorants	325620—Toilet Preparation Manufacturing	112	0	90	0	2,249,196	0
	Ethnic health & beauty	Ethnic health & beauty aids	325620—Toilet Preparation Manufacturing	2,170	0	1,981	0	58,965,931	0
	Ethnic health & beauty	Ethnic home permanents	325620—Toilet Preparation Manufacturing	12	0	12	0	483,219	0
	Facial/eye/lip makeup	Cosmetic kits	325620—Toilet Preparation Manufacturing	2,809	93	1,432	47	20,017,342	320,041
	Facial/eye/lip makeup	Cosmetics—remaining	325620—Toilet Preparation Manufacturing	3,872	183	3,221	152	76,095,381	7,952,315
	Facial/eye/lip makeup	Eye makeup	325620—Toilet Preparation Manufacturing	18,219	481	15,311	403	587,166,446	767,452
	Facial/eye/lip makeup	Facial makeup	325620—Toilet Preparation Manufacturing	14,164	195	11,910	164	349,501,521	337,956
	Facial/eye/lip makeup	False eyelash and accessory	325620—Toilet Preparation Manufacturing	967	0	391	0	30,564,497	0
	Facial/eye/lip makeup	Lip remedies	325620—Toilet Preparation Manufacturing	5,816	747	4,219	543	380,756,806	49,177,185
	Facial/eye/lip makeup	Lipstick	325620—Toilet Preparation Manufacturing	29,366	753	24,608	632	364,429,825	2,805,373
	Feminine hygiene	Feminine deodorant sprays	325620—Toilet Preparation Manufacturing	71	3	65	3	14,790,271	443,024

(continued)



**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Cosmetics (2008) (continued)	Feminine hygiene	Remaining feminine hygiene	325620—Toilet Preparation Manufacturing	825	474	620	357	71,044,231	14,946,898
	Foot care	Foot preparations—remaining	325412—Pharmaceutical Preparation Manufacturing	2,703	1,482	2,238	1,228	87,580,986	31,766,692
	Fragrances	Colognes and perfumes	325620—Toilet Preparation Manufacturing	17,642	301	7,632	130	77,239,569	6,304,083
	Fragrances	Men's aftershave/ cologne/lotion	325620—Toilet Preparation Manufacturing	8,314	338	3,596	146	81,764,816	7,496,364
	Gift sets & kits	Children's cologne & gift sets	325620—Toilet Preparation Manufacturing	1,786	31	849	16	14,220,419	1,178,673
	Gift sets & kits	Fragrance gift sets—women	325620—Toilet Preparation Manufacturing	10,211	930	7,254	660	39,544,465	6,774,954
	Gift sets & kits	Men's aftershave/ cologne/lotion	325620—Toilet Preparation Manufacturing	3,568	59	1,507	25	25,022,013	1,074,965
	Hair care	Creme rinses & conditioners	325620—Toilet Preparation Manufacturing	10,636	880	7,248	601	640,321,873	12,517,419
	Hair care	Hair coloring products	325620—Toilet Preparation Manufacturing	6,563	43	5,654	37	452,041,268	1,749,621
	Hair care	Hair preparations	325620—Toilet Preparation Manufacturing	6,439	93	4,752	68	131,199,301	2,825,483
	Hair care	Hairspray	325620—Toilet Preparation Manufacturing	2,954	12	1,779	6	311,371,657	679,275
	Hair care	Home permanents	325620—Toilet Preparation Manufacturing	143	0	127	0	2,309,175	0
	Hair care	Shampoo (nonmedicated)	325620—Toilet Preparation Manufacturing	14,465	3,004	9,418	1,956	1,144,449,019	42,438,557
	Hair care	Wave setting products	325620—Toilet Preparation Manufacturing	10,205	245	7,539	180	392,050,236	4,942,408
	Nail care/manicure needs	Manicure needs	325620—Toilet Preparation Manufacturing	5,320	133	3,705	93	98,909,620	1,635,117
	Nail care/manicure needs	Nail care	325620—Toilet Preparation Manufacturing	18,172	2,182	15,962	1,916	285,455,626	49,684,673
	Oral hygiene	Breath fresheners	325620—Toilet Preparation Manufacturing	220	37	152	25	5,409,085	3,689,022
	Oral hygiene	Denture cleansers	325611—Soap & Other Detergent Manufacturing	242	37	112	19	46,240,713	14,206,804
	Oral hygiene	Tooth whiteners	325611—Soap & Other Detergent Manufacturing	229	214	195	183	23,846,102	3,904,394
	Oral hygiene	Toothpaste (nonfluoride)	325611—Soap & Other Detergent Manufacturing	2,337	229	1,429	140	876,289,437	7,945,901
	Personal soap/bath need	Bath additives—dry	325620—Toilet Preparation Manufacturing	1,761	192	1,547	167	17,198,208	2,959,415

(continued)

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Cosmetics (2008) (continued)	Personal soap/bath need	Bath additives—liquid	325620—Toilet Preparation Manufacturing	2,186	657	1,919	577	34,034,804	9,813,658
	Personal soap/bath need	Soap—bar (nondeodorant)	325620—Toilet Preparation Manufacturing	6,166	570	4,287	397	756,830,404	42,479,746
	Personal soap/bath need	Soap—liquid	325620—Toilet Preparation Manufacturing	2,790	1,401	2,471	1,240	314,395,564	81,202,079
	Personal soap/bath need	Soap—specialty	325620—Toilet Preparation Manufacturing	9,939	1,525	7,930	1,218	580,416,240	45,287,841
	Shaving needs	Depilatories	325620—Toilet Preparation Manufacturing	961	0	884	0	54,577,937	0
	Shaving needs	Shaving cream	325620—Toilet Preparation Manufacturing	1,758	543	1,228	378	351,606,523	19,006,732
	Skin care preparations	Face cream and lotions	325620—Toilet Preparation Manufacturing	7,809	1,234	7,142	1,128	454,030,607	23,328,368
	Skin care preparations	Hand cream and body lotions	325620—Toilet Preparation Manufacturing	16,117	2,753	12,781	2,182	573,740,752	63,102,227
	Skin care preparations	Suntan preparations—lotions/oils/etc.	325620—Toilet Preparation Manufacturing	1,122	245	1,045	229	29,500,462	1,579,989
	Sunburn aids	Sunburn aids	325620—Toilet Preparation Manufacturing	99	127	84	109	3,606,196	1,164,965
Dietary Supplements	Diet aids (2008)	Appetite suppressants	325412—Pharmaceutical Preparation Manufacturing	335	6	276	6	11,332,106	1,231
	Diet aids (2008)	Diet aids—complete nutritional	325412—Pharmaceutical Preparation Manufacturing	893	422	725	344	156,865,732	5,803,042
	Mineral supplements (2012)	Minerals	325412—Pharmaceutical Preparation Manufacturing	2,431	4,291	2,006	3,541	67,542,075	40,515,455
	Nutritional supplements (2012)	Complete nutritional products	325412—Pharmaceutical Preparation Manufacturing	730	824	398	449	156,597,309	10,380,960
	Nutritional supplements (2012)	Nutritional supplements	325412—Pharmaceutical Preparation Manufacturing	20,979	10,818	18,372	9,473	581,800,212	140,308,390
	Protein supplements (2012)	Protein supplements	325412—Pharmaceutical Preparation Manufacturing	1,518	230	1,173	177	53,587,076	3,080,653
	Vitamin supplements (2012)	Vitamins—remaining	325412—Pharmaceutical Preparation Manufacturing	3,945	7,939	3,333	6,707	141,470,294	69,142,278
	Vitamin supplements (2012)	Vitamins-b complex w/c	325412—Pharmaceutical Preparation Manufacturing	205	393	172	330	7,775,830	2,250,393
	Vitamin supplements (2012)	Vitamins—children—flavored chewable	325412—Pharmaceutical Preparation Manufacturing	502	887	389	687	30,629,903	7,134,387
	Vitamin supplements (2012)	Vitamins—multiple	325412—Pharmaceutical Preparation Manufacturing	2,290	3,863	1,771	2,987	89,746,848	43,651,247
	Vitamins/tonics—liquid (2012)	Vitamins/tonics—liquid & powder	325412—Pharmaceutical Preparation Manufacturing	814	70	662	57	11,204,105	2,615,279

(continued)

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Food (2012)	Baked goods	Bagels/biscuits/buns/muffins/rolls—fresh	311812—Commercial Bakeries	7,067	8,687	6,199	7,609	1,519,404,015	1,015,413,568
	Baked goods	Bagels/biscuits/buns/muffins/rolls—frozen	311812—Commercial Bakeries	398	558	368	517	115,893,652	16,326,555
	Baked goods	Baked goods—remaining—fresh	311812—Commercial Bakeries	1,126	1,128	967	968	41,174,281	22,905,784
	Baked goods	Baked goods—remaining—frozen	311812—Commercial Bakeries	454	286	393	247	71,945,937	31,171,652
	Baked goods	Bread—fresh	311812—Commercial Bakeries	10,234	9,268	9,101	8,236	2,596,281,839	1,538,840,064
	Baked goods	Bread—frozen	311812—Commercial Bakeries	428	398	392	365	158,349,033	72,333,428
	Baked goods	Breading products	311812—Commercial Bakeries	1,823	1,310	1,593	943	397,815,058	113,044,421
	Baked goods	Cakes/doughnuts/sweet rolls—fresh	311812—Commercial Bakeries	10,791	16,399	8,553	12,997	1,328,426,880	337,581,128
	Baked goods	Cakes/doughnuts/sweet rolls—frozen	311813—Frozen Cakes, Pies, & Other Pastries Manufacturing	384	126	336	111	44,605,999	2,106,516
	Baked goods	Cookies/cones	311821—Cookie & Cracker Manufacturing	14,553	9,054	11,007	6,848	1,996,151,786	428,719,393
	Baked goods	Crackers	311821—Cookie & Cracker Manufacturing	4,239	2,966	3,447	2,409	1,633,496,850	253,227,727
	Baked goods	Mexican shells/tortillas	311830—Tortilla Manufacturing	2,939	795	2,306	625	798,060,372	148,322,231
	Baking ingredients	Baking mixes	311822—Flour Mixes & Dough Mfg from Purchased Flour	3,455	1,713	2,863	1,420	1,095,051,761	95,258,925
	Baking ingredients	Baking supplies	311340—Nonchocolate Confectionery Manufacturing	3,440	1,844	2,703	1,493	686,980,643	150,247,415
	Baking ingredients	Bread/cookie/dough products—frozen	311822—Flour Mixes & Dough Mfg from Purchased Flour	237	103	217	94	13,013,358	6,032,436
	Baking ingredients	Dough products—refrigerated	311822—Flour Mixes & Dough Mfg from Purchased Flour	794	1,990	643	1,612	713,043,873	247,172,069
	Baking ingredients	Flour/corn meal	311211—Flour Milling	1,494	718	1,119	538	228,115,744	91,469,895
	Beverages	Buttermilk—refrigerated	311511—Fluid Milk Manufacturing	487	219	336	151	54,608,770	30,528,835

(continued)

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Food (2012) (continued)	Beverages	Carbonated beverages—low calorie	312111—Soft Drink Manufacturing	2,517	1,805	994	712	2,801,096,368	221,703,836
	Beverages	Carbonated beverages—regular	312111—Soft Drink Manufacturing	8,372	6,597	4,159	3,278	5,472,881,281	862,005,332
	Beverages	Cocktail mixes	312111—Soft Drink Manufacturing	1,294	105	1,008	80	50,437,145	3,388,337
	Beverages	Coffee—ground	311920—Coffee & Tea Manufacturing	5,359	2,470	4,900	2,259	699,869,811	93,929,394
	Beverages	Coffee—liquid	311920—Coffee & Tea Manufacturing	451	24	360	19	178,140,752	3,073,980
	Beverages	Coffee—soluble	311920—Coffee & Tea Manufacturing	763	655	549	472	144,268,545	15,537,773
	Beverages	Coffee—whole bean	311920—Coffee & Tea Manufacturing	2,155	794	2,051	755	49,420,832	8,353,178
	Beverages	Creamers—liquid	311511—Fluid Milk Manufacturing	379	367	242	234	508,135,386	53,509,478
	Beverages	Fruit drinks—frozen	311411—Frozen Fruit, Juice, & Vegetable Manufacturing	213	752	199	703	76,731,249	34,815,120
	Beverages	Fruit drinks—refrigerated	312111—Soft Drink Manufacturing	1,210	437	883	319	574,427,001	21,832,889
	Beverages	Fruit drinks—shelf stable	312111—Soft Drink Manufacturing	6,625	4,188	4,752	3,003	3,406,196,681	199,782,939
	Beverages	Fruit juice—frozen	311411—Frozen Fruit, Juice, & Vegetable Manufacturing	153	818	141	755	75,647,145	60,581,711
	Beverages	Fruit juice—refrigerated	311421—Fruit & Vegetable Canning	1,977	1,315	1,252	832	1,134,669,253	214,551,869
	Beverages	Fruit juice—shelf stable	311421—Fruit & Vegetable Canning	3,795	3,518	2,523	2,340	762,883,190	245,606,473
	Beverages	Fruit punch bases/syrups	311930—Flavoring Syrup & Concentrate Manufacturing	384	20	323	16	38,781,974	5,221,282
	Beverages	Ice	312113—Ice Manufacturing	759	247	535	174	229,146,138	116,354,094
	Beverages	Milk—flavored—refrigerated	311511—Fluid Milk Manufacturing	1,544	513	967	321	239,674,901	104,953,601
	Beverages	Milk—refrigerated	311511—Fluid Milk Manufacturing	4,897	4,326	2,215	1,956	1,662,033,780	3,122,925,081
	Beverages	Milk—shelf stable	311514—Dry, Condensed, & Evaporated Dairy Product Mfg	363	487	269	362	264,304,208	149,586,310
	Beverages	Milk/creamers—powdered	311514—Dry, Condensed, & Evaporated Dairy Product Mfg	241	1,465	185	1,120	66,058,635	68,721,688
	Beverages	Milk/water—additives	311514—Dry, Condensed, & Evaporated Dairy Product Mfg	1,179	753	1,025	654	170,968,445	24,562,677

(continued)

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Food (2012) (continued)	Beverages	Noncarbonated beverages— mixes	311999—All Other Miscellaneous Food Manufacturing	1,133	1,501	763	1,012	982,946,387	71,942,097
	Beverages	Shakes/drinks— remaining—nonrefrigerated	312111—Soft Drink Manufacturing	666	143	398	86	104,083,844	9,418,766
	Beverages	Shakes/drinks/eggnog— refrigerated	311514—Dry, Condensed, & Evaporated Dairy Product Mfg	951	414	659	286	319,387,656	58,847,172
	Beverages	Tea—bags/package	311920—Coffee & Tea Manufacturing	3,080	1,095	2,744	975	222,937,393	37,127,259
	Beverages	Tea—herbal	311920—Coffee & Tea Manufacturing	2,243	199	2,086	185	97,755,318	3,246,256
	Beverages	Tea—instant	311920—Coffee & Tea Manufacturing	521	747	435	624	85,320,782	17,771,380
	Beverages	Tea—liquid	311920—Coffee & Tea Manufacturing	3,534	611	2,533	439	1,189,277,215	103,010,170
	Beverages	Vegetable juice—shelf stable	311421—Fruit & Vegetable Canning	1,151	897	868	677	345,748,117	43,020,981
	Beverages	Water—bottled	312112—Bottled Water Manufacturing	4,795	3,297	2,905	1,997	2,464,522,397	993,287,424
	Beverages	Water—bottled/caloric	312111—Soft Drink Manufacturing	637	294	344	159	236,405,739	61,240,928
	Beverages	Water—bottled/low calorie	312111—Soft Drink Manufacturing	815	1,700	556	1,159	248,243,155	229,164,607
	Beverages	Wine—nonalcoholic	312130—Wineries	308	41	253	33	48,212,507	3,234,466
	Breakfast foods	Breakfast bars/pastries/powders	311340—Nonchocolate Confectionery Manufacturing	3,326	3,216	2,250	1,880	1,244,490,759	153,427,929
	Breakfast foods	Breakfasts—frozen	311412—Frozen Specialty Food Manufacturing	1,144	566	1,035	512	311,479,799	51,356,904
	Breakfast foods	Cereal —hot	311230—Breakfast Cereal Manufacturing	1,134	2,199	903	1,751	329,954,614	147,916,534
	Breakfast foods	Cereal—ready to eat	311230—Breakfast Cereal Manufacturing	3,315	6,331	2,019	3,853	2,451,470,720	411,574,719
	Breakfast foods	Waffle/pancake/French toast—frozen	311412—Frozen Specialty Food Manufacturing	452	980	393	854	343,934,224	98,517,916
	Candy & gum	Candy—chocolate	311320—Chocolate & Confectionery Mfg from Cacao Beans	19,740	2,220	13,671	1,538	4,276,902,924	64,111,513
	Candy & gum	Candy—dietetic	311340—Nonchocolate Confectionery Manufacturing	1,394	122	1,197	105	131,817,836	8,281,612

(continued)

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Food (2012) (continued)	Candy & gum	Candy—nonchocolate	311340—Nonchocolate Confectionery Manufacturing	25,036	6,203	18,994	4,707	2,254,987,477	346,323,009
	Candy & gum	Gum—low calorie	311340—Nonchocolate Confectionery Manufacturing	1,438	114	617	48	1,057,230,448	322,463
	Candy & gum	Gum—regular	311340—Nonchocolate Confectionery Manufacturing	1,396	93	965	65	188,416,854	5,331,606
	Condiments/dips/spreads	Condiments	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	2,125	2,451	1,813	2,092	451,807,481	212,095,135
	Condiments/dips/spreads	Dips—refrigerated	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	1,695	877	1,331	689	198,325,802	56,727,586
	Condiments/dips/spreads	Dips—shelf stable	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	1,124	354	1,032	325	215,192,732	19,076,190
	Condiments/dips/spreads	Extracts	311942—Spice & Extract Manufacturing	1,198	549	970	444	44,641,650	23,853,742
	Condiments/dips/spreads	Honey	311999—All Other Miscellaneous Food Manufacturing	1,904	727	1,501	573	30,650,570	51,848,406
	Condiments/dips/spreads	Jams/jellies	311421—Fruit & Vegetable Canning	3,002	2,719	2,664	2,408	197,702,687	86,952,585
	Condiments/dips/spreads	Jams/spreads—remaining	311421—Fruit & Vegetable Canning	1,180	383	1,053	341	67,900,813	11,146,338
	Condiments/dips/spreads	Marinades/tenderizers/MSG	311942—Spice & Extract Manufacturing	1,144	458	1,058	424	103,855,714	21,430,898
	Condiments/dips/spreads	Mayonnaise	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	703	1,043	480	711	451,617,536	88,656,169
	Condiments/dips/spreads	Peanut butter	311911—Roasted Nuts & Peanut Butter Manufacturing	687	1,814	480	1,268	376,440,425	117,228,156
	Condiments/dips/spreads	Pepper	311942—Spice & Extract Manufacturing	1,714	847	1,396	689	83,057,229	51,457,762
	Condiments/dips/spreads	Pickles/olives/relishes	311421—Fruit & Vegetable Canning	7,648	5,442	6,308	4,367	656,603,538	393,270,772
	Condiments/dips/spreads	Salt	311942—Spice & Extract Manufacturing	1,494	1,074	1,225	881	187,631,455	73,061,297
	Condiments/dips/spreads	Salt—substitutes	311942—Spice & Extract Manufacturing	17	0	17	0	2,176,047	0

(continued)

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Food (2012) (continued)	Condiments/dips/spreads	Sandwich spreads/horseradish/sauerkraut—refrigerated	311421—Fruit & Vegetable Canning	591	204	487	168	56,077,263	19,378,423
	Condiments/dips/spreads	Seasoning—dry	311942—Spice & Extract Manufacturing	15,309	3,484	13,341	3,035	506,099,831	137,987,797
	Condiments/dips/spreads	Spices/seasonings—remaining	311942—Spice & Extract Manufacturing	1,046	355	841	285	73,484,058	8,557,619
	Condiments/dips/spreads	Spreads—refrigerated	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	1,782	172	1,520	147	203,173,145	20,690,415
	Dairy foods	Butter	311512—Creamery Butter Manufacturing	713	641	616	554	361,620,921	415,907,744
	Dairy foods	Cheese—cottage/farmers/ricotta	311511—Fluid Milk Manufacturing	1,438	1,308	927	842	299,249,107	241,669,791
	Dairy foods	Cheese—grated/shredded	311513—Cheese Manufacturing	1,935	3,665	1,518	2,877	695,774,681	904,394,942
	Dairy foods	Cheese—natural	311513—Cheese Manufacturing	4,927	5,218	3,655	1,936	813,117,232	772,869,541
	Dairy foods	Cheese—processed	311513—Cheese Manufacturing	2,877	3,214	2,276	2,542	1,021,928,060	542,752,399
	Dairy foods	Cheese—specialty/imported	311513—Cheese Manufacturing	3,443	570	2,635	436	304,312,512	93,057,255
	Dairy foods	Cream—refrigerated	311511—Fluid Milk Manufacturing	946	631	587	392	286,655,292	231,383,051
	Dairy foods	Frozen novelties	311520—Ice Cream & Frozen Dessert Manufacturing	4,446	2,442	4,047	2,224	1,029,521,612	194,747,111
	Dairy foods	Ice cream	311520—Ice Cream & Frozen Dessert Manufacturing	6,840	6,305	5,884	5,422	1,075,964,973	455,029,540
	Dairy foods	Ice milk/sherbet/yogurt—frozen	311520—Ice Cream & Frozen Dessert Manufacturing	972	896	867	800	75,828,148	62,097,811
	Dairy foods	Ice pops—unfrozen	311520—Ice Cream & Frozen Dessert Manufacturing	357	163	231	105	54,783,523	18,968,228
	Dairy foods	Sour cream	311511—Fluid Milk Manufacturing	885	842	477	453	373,544,450	246,981,284
	Dairy foods	Whipping cream	311511—Fluid Milk Manufacturing	392	242	251	155	47,790,166	69,112,688
	Dairy foods	Yogurt—refrigerated	311511—Fluid Milk Manufacturing	3,856	4,849	3,175	3,992	4,325,146,512	984,636,444
	Dairy foods	Yogurt—shakes/drinks—refrigerated	311511—Fluid Milk Manufacturing	883	199	657	147	186,700,318	9,034,157

(continued)

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Food (2012) (continued)	Desserts	Cheesecake/pies—fresh	311812—Commercial Bakeries	2,894	3,283	1,956	2,219	215,250,136	79,281,465
	Desserts	Cheesecake/pies—frozen	311813—Frozen Cakes, Pies, & Other Pastries Manufacturing	636	113	525	94	142,746,274	3,939,181
	Desserts	Dessert—RTS single serving	311999—All Other Miscellaneous Food Manufacturing	874	1,846	738	1,558	506,827,072	144,513,354
	Desserts	Desserts/toppings—frozen	311813—Frozen Cakes, Pies, & Other Pastries Manufacturing	1,067	683	934	598	263,615,876	100,836,026
	Desserts	Gelatin/pudding—mixes—diet	311999—All Other Miscellaneous Food Manufacturing	111	422	83	314	96,360,184	22,265,356
	Desserts	Gelatin/pudding—mixes—sweetened	311999—All Other Miscellaneous Food Manufacturing	741	1,223	568	937	282,472,886	60,079,643
	Desserts	Pudding—refrigerated	311999—All Other Miscellaneous Food Manufacturing	591	464	441	346	164,232,433	9,228,817
	Desserts	Syrups/toppings—shelf stable	311999—All Other Miscellaneous Food Manufacturing	1,074	354	907	299	167,311,656	27,825,890
	Desserts	Toppings—refrigerated	311999—All Other Miscellaneous Food Manufacturing	230	398	179	308	84,283,280	50,154,528
	Dressings & sauces	Salad dressing—liquid	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	2,671	1,926	2,076	1,498	578,919,744	161,211,172
	Dressings & sauces	Salad dressing—reduced/low calorie	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	557	243	508	222	58,661,609	11,885,444
	Dressings & sauces	Salad dressing—refrigerated	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	969	140	755	109	107,552,273	1,858,527
	Dressings & sauces	Salad dressings/toppings—dry	311942—Spice & Extract Manufacturing	316	197	251	156	122,803,930	27,682,511
	Dressings & sauces	Sauce—barbecue	311421—Fruit & Vegetable Canning	2,365	971	2,013	826	285,833,457	45,331,076
	Dressings & sauces	Sauce—Mexican	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	2,958	1,465	2,673	1,324	405,989,016	96,646,358
	Dressings & sauces	Sauce—spaghetti/marinara	311421—Fruit & Vegetable Canning	2,325	1,691	2,150	1,562	797,099,880	133,301,913

(continued)



**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Food (2012) (continued)	Dressings & sauces	Sauce/gravy—mixes	311942—Spice & Extract Manufacturing	2,059	1,170	1,859	1,056	618,203,571	204,285,939
	Dressings & sauces	Sauce/gravy/glaze	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	7,867	2,094	7,118	1,894	922,291,301	148,002,578
	Dressings & sauces	Vinegar/cooking wine	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	1,760	1,322	1,394	1,048	88,382,766	98,934,468
	Eggs	Eggs—fresh	311999—All Other Miscellaneous Food Manufacturing	2,341	1,830	1,814	1,417	634,962,376	1,528,924,869
	Entrees	Combination lunches	311911—Roasted Nuts & Peanut Butter Manufacturing	309	51	277	45	546,941,214	1,889,534
	Entrees	Entrees—frozen	311412—Frozen Specialty Food Manufacturing	9,478	2,720	8,590	2,465	3,597,883,797	212,196,922
	Entrees	Entrees—refrigerated	311991—Perishable Prepared Food Manufacturing	4,599	2,932	4,150	2,646	427,165,654	240,476,380
	Entrees	Prepared foods—canned/shelf stable	311999—All Other Miscellaneous Food Manufacturing	6,594	1,659	5,681	1,428	1,111,475,873	153,029,603
	Entrees	Sandwiches—refrigerated/frozen	311999—All Other Miscellaneous Food Manufacturing	2,594	1,913	2,352	1,733	457,470,493	79,858,142
	Fats & oils	Cooking sprays	311225—Fats & Oils Refining & Blending	161	514	136	434	84,118,908	44,173,842
	Fats & oils	Lard/shortening	311613—Rendering & Meat Byproduct Processing	141	206	76	111	42,695,804	7,498,753
	Fats & oils	Margarine/spreads	311225—Fats & Oils Refining & Blending	448	821	308	565	671,413,886	97,632,689
	Fats & oils	Oils—olive/salad/cooking	311225—Fats & Oils Refining & Blending	3,569	2,766	2,156	1,670	315,109,305	247,032,414
	Fruits & vegetables	Beans—canned	311421—Fruit & Vegetable Canning	1,796	1,885	1,376	1,442	628,521,856	349,840,103
	Fruits & vegetables	Beans/peas/lentils/barley—dry	311423—Dried & Dehydrated Food Manufacturing	2,152	1,928	1,649	1,477	98,073,002	134,628,792
	Fruits & vegetables	Fruit—canned	311421—Fruit & Vegetable Canning	2,759	6,513	2,236	4,666	600,651,108	497,944,992
	Fruits & vegetables	Fruit—dried	311423—Dried & Dehydrated Food Manufacturing	4,705	2,131	3,665	1,659	538,171,465	155,851,672

(continued)

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Food (2012) (continued)	Fruits & vegetables	Fruit—fresh	111339—Other Noncitrus Fruit Farming	7,094	847	3,979	476	2,335,060,454	147,157,989
	Fruits & vegetables	Fruit/fruit salad—refrigerated	311991—Perishable Prepared Food Manufacturing	2,045	908	1,212	539	232,278,504	38,513,429
	Fruits & vegetables	Fruits—frozen	311411—Frozen Fruit, Juice, & Vegetable Manufacturing	708	1,411	630	1,253	45,621,278	116,648,787
	Fruits & vegetables	Garlic/herbs—fresh	111219—Other Vegetable (except Potato) & Melon Farming	1,989	277	1,652	229	115,241,337	44,488,996
	Fruits & vegetables	Leafy greens—fresh	111219—Other Vegetable (except Potato) & Melon Farming	477	68	386	55	988,427,219	170,635,063
	Fruits & vegetables	Potatoes—canned	311421—Fruit & Vegetable Canning	199	599	164	493	50,189,972	52,927,566
	Fruits & vegetables	Potatoes—dehydrated	311423—Dried & Dehydrated Food Manufacturing	459	757	333	549	271,408,036	38,716,510
	Fruits & vegetables	Potatoes—fresh	111211—Potato Farming	1,663	161	1,057	101	482,623,817	305,903,569
	Fruits & vegetables	Potatoes—frozen	311411—Frozen Fruit, Juice, & Vegetable Manufacturing	1,152	2,078	1,005	1,811	506,030,431	239,817,445
	Fruits & vegetables	Tomatoes—canned	311421—Fruit & Vegetable Canning	1,862	3,083	1,515	2,509	895,446,380	735,239,604
	Fruits & vegetables	Vegetables—canned	311421—Fruit & Vegetable Canning	4,472	6,518	3,672	5,344	1,172,376,790	1,266,014,019
	Fruits & vegetables	Vegetables—fresh	111219—Other Vegetable (except Potato) & Melon Farming	8,520	1,674	6,643	1,306	2,359,798,535	863,389,702
	Fruits & vegetables	Vegetables—frozen	311411—Frozen Fruit, Juice, & Vegetable Manufacturing	2,526	7,876	2,106	6,559	733,194,949	853,745,575
	Fruits & vegetables	Vegetables—precut salad mix—fresh	311991—Perishable Prepared Food Manufacturing	771	422	613	168	1,060,970,813	275,187,077
	Infant foods	Baby food	311422—Specialty Canning	1,701	421	1,551	383	1,041,449,518	32,238,788
	Infant foods	Infant formulas	311514—Dry, Condensed, & Evaporated Dairy Product Mfg	374	323	246	106	225,859,808	7,222,015
	Infant foods	Juices—baby	311421—Fruit & Vegetable Canning	90	3	66	1	24,919,117	764,728
	Meat & poultry	Meat—frozen	311612—Meat Processed from Carcasses	833	307	665	245	69,480,590	24,763,469

(continued)

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Food (2012) (continued)	Meat & poultry	Meat/poultry—canned	311422—Specialty Canning	2,741	1,437	2,204	578	1,265,888,253	188,505,045
	Meat & poultry Pizza	Poultry—frozen	311615—Poultry Processing	459	326	382	271	92,345,984	68,423,148
		Pizza—frozen	311412—Frozen Specialty Food Manufacturing	2,359	1,675	2,110	1,497	1,137,708,303	192,669,739
	Pizza	Pizza—refrigerated	311991—Perishable Prepared Food Manufacturing	305	156	273	139	22,064,092	15,830,692
	Seafood	Fish—frozen	311712—Fresh & Frozen Seafood Processing	1,765	892	1,453	734	158,564,685	60,388,780
	Seafood	Seafood—canned	311711—Seafood Canning	3,464	855	2,853	704	1,036,473,011	256,973,541
	Seafood	Seafood—refrigerated	311711—Seafood Canning	1,667	187	1,383	155	68,200,369	15,910,941
	Seafood	Seafood—remaining—frozen	311712—Fresh & Frozen Seafood Processing	918	120	830	108	17,083,497	7,960,049
	Seafood	Shrimp—frozen	311712—Fresh & Frozen Seafood Processing	2,666	1,279	1,565	751	68,015,794	91,363,940
	Side dishes & starches	Hors d'oeuvres/snacks—frozen	311412—Frozen Specialty Food Manufacturing	2,246	993	1,966	870	345,841,294	47,652,391
	Side dishes & starches	Pasta/noodles—dry	311823—Dry Pasta Manufacturing	6,973	4,865	6,166	4,302	1,234,031,347	474,241,421
	Side dishes & starches	Prepared foods—dry mixes	311823—Dry Pasta Manufacturing	2,773	2,911	2,493	2,616	1,787,574,006	294,395,472
	Side dishes & starches	Prepared foods—remaining—frozen/refrigerated	311412—Frozen Specialty Food Manufacturing	3,732	1,544	3,361	1,389	240,813,964	97,629,091
	Side dishes & starches	Ready-made salads	311991—Perishable Prepared Food Manufacturing	2,390	2,446	1,827	1,870	218,194,579	186,280,682
	Side dishes & starches	Rice—instant/packaged	311212—Rice Milling	1,859	1,503	1,324	1,069	229,004,296	125,908,423
	Side dishes & starches	Vegetables—formulated/breaded—frozen	311411—Frozen Fruit, Juice, & Vegetable Manufacturing	354	315	309	274	243,767,266	17,290,934
	Snack foods	Nuts—cans/jars	311911—Roasted Nuts & Peanut Butter Manufacturing	3,114	3,385	2,517	2,736	258,602,994	191,713,824
	Snack foods	Nuts—cello wrapped	311911—Roasted Nuts & Peanut Butter Manufacturing	6,402	1,692	5,095	1,346	463,754,852	134,646,709
	Snack foods	Nuts—unshelled	311911—Roasted Nuts & Peanut Butter Manufacturing	596	171	356	102	49,965,975	11,440,117
	Snack foods	Popcorn—unpopped	311999—All Other Miscellaneous Food Manufacturing	942	1,589	581	979	265,020,869	84,426,073

(continued)

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Food (2012) (continued)	Snack foods	Snacks—caramel corn/popped popcorn	311919—Other Snack Food Manufacturing	2,383	238	1,695	171	190,986,109	19,817,279
	Snack foods	Snacks—health bars & sticks	311919—Other Snack Food Manufacturing	1,939	41	1,182	13	516,896,226	9,441,670
	Snack foods	Snacks—meat	311612—Meat Processed from Carcasses	3,042	363	2,631	315	160,598,882	17,320,968
	Snack foods	Snacks—remaining	311919—Other Snack Food Manufacturing	5,743	886	4,691	723	808,577,448	59,639,658
	Snack foods	Snacks—salty	311919—Other Snack Food Manufacturing	14,773	5,163	10,048	3,506	4,841,094,191	541,006,893
	Snack foods	Snacks—trail mixes	311919—Other Snack Food Manufacturing	2,555	750	2,048	600	76,051,619	65,854,079
	Soups	Soup—canned	311421—Fruit & Vegetable Canning	2,556	4,446	2,223	3,867	2,344,623,940	541,914,461
	Soups	Soup—dry	311423—Dried & Dehydrated Food Manufacturing	3,004	552	2,663	488	1,472,224,183	42,735,204
	Sweeteners	Sugar	311311—Sugarcane Mills	791	1,274	648	1,043	303,139,372	411,112,839
	Sweeteners	Sugar—substitutes	325199—All Other Basic Organic Chemical Manufacturing	484	520	330	353	111,874,342	25,600,387
	Sweeteners	Table syrups/molasses	311999—All Other Miscellaneous Food Manufacturing	1,620	1,405	1,179	1,022	158,500,357	87,058,640
	OTCs (2008)	Acne remedies	325412—Pharmaceutical Preparation Manufacturing	669	146	589	129	72,485,538	5,036,634
	Cough and cold remedies	Cold remedies—adult	325412—Pharmaceutical Preparation Manufacturing	1,859	4,043	1,284	2,792	308,264,804	132,012,814
	Cough and cold remedies	Cold remedies—children	325412—Pharmaceutical Preparation Manufacturing	396	640	302	489	53,150,238	10,612,885
	Cough and cold remedies	Cough and cold throat sprays	325412—Pharmaceutical Preparation Manufacturing	56	136	48	115	6,202,146	2,919,599
	Cough and cold remedies	Cough drops lozenges	325412—Pharmaceutical Preparation Manufacturing	678	909	458	613	184,594,269	63,262,188
	Cough and cold remedies	Cough syrups and tablets	325412—Pharmaceutical Preparation Manufacturing	514	1,061	386	798	75,997,912	27,119,212
	Cough and cold remedies	Nasal products	325412—Pharmaceutical Preparation Manufacturing	405	571	333	470	57,753,720	25,101,061
	Cough and cold remedies	Sinus remedies	325412—Pharmaceutical Preparation Manufacturing	168	428	143	364	20,793,650	10,469,211
	Deodorant (antiperspirant)	Deodorant—aerosol (OTC)	325620—Toilet Preparation Manufacturing	141	0	106	0	24,479,267	0
	Deodorant (antiperspirant)	Deodorant—roll-on (OTC)	325620—Toilet Preparation Manufacturing	148	52	101	35	22,464,074	302,718

(continued)

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
OTCs (2008) (continued)	Deodorant (antiperspirant)	Deodorant—stick/solid (OTC)	325620—Toilet Preparation Manufacturing	1,537	62	1,056	42	327,144,936	945,687
	Deodorant (antiperspirant)	Remaining deodorants (OTC)	325620—Toilet Preparation Manufacturing	419	0	300	0	69,573,470	0
	Eye care	Contact lens solution	325412—Pharmaceutical Preparation Manufacturing	207	395	150	286	69,863,189	19,098,170
	Eye care	Eye care—remaining	325412—Pharmaceutical Preparation Manufacturing	108	143	90	119	7,324,612	2,453,990
	Eye care	Eye drops & lotions	325412—Pharmaceutical Preparation Manufacturing	343	326	245	232	67,188,380	9,947,897
	Feminine hygiene	Remaining feminine hygiene (OTC)	325620—Toilet Preparation Manufacturing	125	265	105	223	16,479,007	7,959,830
	First aid	Adhesive bandages (medicated)	339113—Surgical Appliance & Supplies Manufacturing	50	36	49	35	8,100,869	1,113,393
	First aid	First aid—germicidal antiseptics	325412—Pharmaceutical Preparation Manufacturing	427	1,121	315	825	12,485,157	96,944,666
	First aid	First aid—hydrocortisones	325412—Pharmaceutical Preparation Manufacturing	157	332	97	204	17,458,655	16,736,454
	First aid	First aid—treatments	325412—Pharmaceutical Preparation Manufacturing	1,158	676	914	533	59,493,843	15,951,837
	Hair care	Hair growth products	325620—Toilet Preparation Manufacturing	78	164	42	88	2,040,795	1,392,483
	Hair care	Shampoo (medicated)	325620—Toilet Preparation Manufacturing	25	24	22	21	645,585	551,690
	Oral hygiene	Denture adhesives	325620—Toilet Preparation Manufacturing	112	49	90	39	48,937,169	1,693,675
	Oral hygiene	Oral care combinations— OTC	325620—Toilet Preparation Manufacturing	98	45	70	32	7,339,692	1,979,436
	Oral hygiene	Oral rinse and antiseptic	325620—Toilet Preparation Manufacturing	1,002	1,516	505	764	208,774,574	53,226,088
	Oral hygiene	Toothpaste (fluoride)	325611—Soap & Other Detergent Manufacturing	833	27	571	18	253,588,287	268,225
	Pain remedies	Pain remedies	325412—Pharmaceutical Preparation Manufacturing	2,351	6,401	1,133	3,084	388,073,094	148,830,599
	Pain remedies	Pain remedies—children's	325412—Pharmaceutical Preparation Manufacturing	161	749	133	619	42,154,689	18,841,756
	Pain remedies	Pain remedies—urinary tract	325412—Pharmaceutical Preparation Manufacturing	39	22	25	14	4,247,158	1,359,879
	Pain remedies	Tranquilizers/calmatives	325412—Pharmaceutical Preparation Manufacturing	32	0	27	0	236,421	0
	Personal soap/bath need	Hand cleaners and hand sanitizers	325620—Toilet Preparation Manufacturing	725	210	542	157	48,276,042	33,658,176

(continued)

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
OTCs (continued)	Preparations/ remedies	Analgesic & chest rubs	325412—Pharmaceutical Preparation Manufacturing	648	409	512	323	66,398,958	10,789,502
	Preparations/ remedies	Antacids	325412—Pharmaceutical Preparation Manufacturing	1,106	2,551	610	1,408	169,254,240	48,413,053
	Preparations/ remedies	Antigas products	325412—Pharmaceutical Preparation Manufacturing	169	304	101	181	23,327,230	7,591,143
	Preparations/ remedies	Antisleep products	325412—Pharmaceutical Preparation Manufacturing	77	115	56	84	4,262,489	3,080,818
	Preparations/ remedies	Antismoking products	325412—Pharmaceutical Preparation Manufacturing	286	634	165	367	8,527,578	9,265,455
	Preparations/ remedies	Bronchial remedies	325412—Pharmaceutical Preparation Manufacturing	20	60	15	48	4,962,800	1,802,620
	Preparations/ remedies	Dairy digestive aids	325412—Pharmaceutical Preparation Manufacturing	52	168	38	123	3,322,992	2,049,334
	Preparations/ remedies	Diarrhea remedies	325412—Pharmaceutical Preparation Manufacturing	164	385	70	165	23,585,870	10,497,560
	Preparations/ remedies	Diuretic remedies	325412—Pharmaceutical Preparation Manufacturing	50	1	41	1	2,619,114	7,160
	Preparations/ remedies	Ear drops	325412—Pharmaceutical Preparation Manufacturing	112	101	85	77	9,764,588	2,337,399
	Preparations/ remedies	Foot preparations— athlete's foot	325412—Pharmaceutical Preparation Manufacturing	265	307	213	246	19,298,763	8,414,528
	Preparations/ remedies	Ipecac product	325412—Pharmaceutical Preparation Manufacturing	11	20	10	17	67,040	10,333
	Preparations/ remedies	Jock itch products	325412—Pharmaceutical Preparation Manufacturing	39	27	34	22	4,924,798	1,051,977
	Preparations/ remedies	Laxatives	325412—Pharmaceutical Preparation Manufacturing	1,078	2,234	743	1,541	93,226,921	69,102,207
	Preparations/ remedies	Lip remedies—cold sore/fever blister	325412—Pharmaceutical Preparation Manufacturing	90	15	70	13	27,795,165	622,370
	Preparations/ remedies	Medicated products	325412—Pharmaceutical Preparation Manufacturing	329	630	231	442	44,328,210	18,973,042
	Preparations/ remedies	Motion sickness preventatives	325412—Pharmaceutical Preparation Manufacturing	91	116	46	59	8,212,512	2,282,776
	Preparations/ remedies	Petroleum jelly	325412—Pharmaceutical Preparation Manufacturing	102	302	74	217	16,002,076	11,767,969
	Preparations/ remedies	Psoriasis & eczema treatments	325412—Pharmaceutical Preparation Manufacturing	50	0	46	0	2,140,218	0
	Preparations/ remedies	Rectal medication	325412—Pharmaceutical Preparation Manufacturing	181	398	112	246	21,099,882	8,463,360
	Preparations/ remedies	Sleeping aids	325412—Pharmaceutical Preparation Manufacturing	225	309	140	192	16,065,497	10,483,767

(continued)

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
OTCs (continued)	Preparations/ remedies	Tooth & gum analgesics	325412—Pharmaceutical Preparation Manufacturing	235	45	186	35	27,717,878	2,641,416
	Preparations/ remedies	Vaporizing products	325412—Pharmaceutical Preparation Manufacturing	49	29	35	21	6,490,281	896,777
	Skin care preparations	Skin bleaching/toning products	325620—Toilet Preparation Manufacturing	168	6	153	6	4,036,312	6,483
Pet Foods	Skin care preparations	Suntan preparations— sunscreens & sunblock	325620—Toilet Preparation Manufacturing	1,492	732	1,303	640	71,330,098	13,998,566
	Pet care (2008)	Flea products	325320—Pesticide & Other Agricultural Chemical Manufacturing	649	19	500	15	24,049,740	77,282
	Pet care (2008)	Pet incontinence product	325412—Pharmaceutical Preparation Manufacturing	193	21	113	13	10,980,033	1,563,219
	Pet care (2008)	Pet treatments external	325412—Pharmaceutical Preparation Manufacturing	993	11	968	11	10,332,437	121,208
	Pet care (2008)	Pet treatments internal	325412—Pharmaceutical Preparation Manufacturing	1,016	19	861	17	36,198,895	468,065
	Pet food (2012)	Cat food—dry	311111—Dog & Cat Food Manufacturing	1,368	1,045	643	491	241,951,082	26,036,291
	Pet food (2012)	Cat food—moist/wet	311111—Dog & Cat Food Manufacturing	1,658	3,156	1,341	2,553	1,944,215,597	196,648,354
	Pet food (2012)	Dog food—dry	311111—Dog & Cat Food Manufacturing	2,824	2,532	1,590	1,426	251,223,464	36,585,112
	Pet food (2012)	Dog food—moist/wet	311111—Dog & Cat Food Manufacturing	1,501	2,466	1,269	2,085	808,288,808	121,804,411
	Pet food (2012)	Domestic bird food	311119—Other Animal Food Manufacturing	646	24	586	21	6,246,331	931,309
	Pet food (2012)	Other pet food	311119—Other Animal Food Manufacturing	1,301	43	1,072	35	13,521,294	555,656
	Pet food (2012)	Pet treats	311111—Dog & Cat Food Manufacturing	3,741	1,631	3,067	1,338	558,073,045	41,196,371
	Adult incontinence	Adult incontinence	322121—Paper (except Newsprint) Mills	477	1,344	393	1,107	64,249,191	29,615,879
Retail Medical Devices (2008)	Baby needs	Baby and nursing accessories	326299—All Other Rubber Product Manufacturing	1,119	83	955	70	37,894,266	2,943,345
	Baby needs	Baby bottles & nipples	326299—All Other Rubber Product Manufacturing	822	266	638	207	34,834,068	5,468,529
	Breathing aids— external	Breathing aids—external	339113—Surgical Appliance & Supplies Manufacturing	210	160	176	134	12,815,443	2,171,341
	Enemas—ready to use	Enemas—ready to use	325412—Pharmaceutical Preparation Manufacturing	38	161	29	125	9,686,057	6,581,190

(continued)

**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Retail Medical Devices (2008) (continued)	Family planning	Contraceptives—female	325412—Pharmaceutical Preparation Manufacturing	35	0	22	0	4,513,160	0
	Family planning	Contraceptives—male	325412—Pharmaceutical Preparation Manufacturing	343	25	209	15	39,182,906	75,853
	Family planning	Family planning test kits	325413—In-Vitro Diagnostic Substance Manufacturing	150	350	111	259	18,380,747	10,906,237
	Feminine hygiene	Douches	325412—Pharmaceutical Preparation Manufacturing	130	423	85	277	13,172,979	4,218,395
	Feminine hygiene	Remaining feminine hygiene (medical device)	325620—Toilet Preparation Manufacturing	32	8	28	7	246,075	160,756
	Feminine hygiene	Sanitary belts/panties/napkins	322121—Paper (except Newsprint) Mills	939	1,932	514	1,057	273,536,750	57,902,768
	Feminine hygiene	Tampons	322121—Paper (except Newsprint) Mills	617	1,033	259	434	143,020,346	21,805,298
	First aid	Adhesive bandages—liquid—powder—PA	339113—Surgical Appliance & Supplies Manufacturing	38	36	29	28	3,860,203	737,614
	First aid	Adhesive bandages (nonmedicated)	339113—Surgical Appliance & Supplies Manufacturing	825	1,309	694	1,102	85,170,994	50,019,782
	First aid	First aid—gauze & tape	339113—Surgical Appliance & Supplies Manufacturing	515	673	381	498	42,320,417	29,217,521
	First aid	First aid—ice and heat pack	339113—Surgical Appliance & Supplies Manufacturing	753	206	581	158	29,070,790	7,430,707
	First aid	First aid—thermometers	339112—Surgical & Medical Instrument Manufacturing	378	337	363	323	8,003,390	7,339,499
	Foot care	Foot comfort products	339113—Surgical Appliance & Supplies Manufacturing	916	141	648	101	21,191,778	2,647,030
	Foot care	Foot preparations—remaining (medical device)	339113—Surgical Appliance & Supplies Manufacturing	447	304	396	270	16,642,528	7,410,521
	Insulin syringes	Insulin syringes	339112—Surgical & Medical Instrument Manufacturing	113	146	74	95	3,838,603	1,784,880
	Medical accessory—remaining	Medical accessory—remaining	339113—Surgical Appliance & Supplies Manufacturing	2,689	708	1,918	505	33,738,375	19,021,122

(continued)



**Table 4-3. Product Category Data for the Labeling Cost Model: Estimated Number of UPCs, Formulas, and Sales Units, 2008 and 2012 (continued)**

FDA Type	Model Category	Model Subcategory (i)	6-Digit NAICS	No. of UPCs		No. of Formulas		No. of Sales Units	
				Branded	PL	Branded	PL	Branded	PL
				UPC <sup>B</sup>	UPC <sup>PL</sup>	FORM <sup>B</sup>	FORM <sup>PL</sup>	UNIT <sup>B</sup>	UNIT <sup>PL</sup>
Retail Medical Devices (2008) (continued)	Medical wrap and brace	Medical wrap and brace	339113—Surgical Appliance & Supplies Manufacturing	2,159	511	1,786	423	22,425,736	14,761,183
	Oral hygiene	Dental accessories	339114—Dental Equipment & Supplies Manufacturing	237	53	193	43	24,507,713	1,193,954
	Oral hygiene	Dental floss	325620—Toilet Preparation Manufacturing	409	767	323	608	78,781,500	26,142,306
	Oral hygiene	Oral care combinations—medical device	335211—Electric Housewares & Household Fan Manufacturing	118	13	90	10	6,157,322	1,124,502
	Oral hygiene	Oral hygiene appliance and accessory	335211—Electric Housewares & Household Fan Manufacturing	511	69	322	43	40,300,774	1,074,219
	Oral hygiene	Oral hygiene brushes	339994—Broom, Brush, & Mop Manufacturing	1,683	1,774	1,434	1,511	201,095,698	52,955,903
	Test kits	Blood pressure kit and accessory	339112—Surgical & Medical Instrument Manufacturing	210	144	140	97	1,509,945	1,250,791
	Test kits	Blood urine stool test products	339113—Surgical Appliance & Supplies Manufacturing	371	354	255	244	11,235,850	2,263,405
Tobacco Products (2008)	Tobacco & accessories	Cigarette and cigar paper	322121—Paper (except Newsprint) Mills	273	0	209	0	127,646,055	0
	Tobacco & accessories	Cigarettes	312221—Cigarette Manufacturing	3,789	523	1,574	217	7,993,315,003	10,879,661
	Tobacco & accessories	Cigars	312229—Other Tobacco Product Manufacturing	1,709	68	1,102	44	521,923,709	6,189,762
	Tobacco & accessories	Tobacco—chewing	312229—Other Tobacco Product Manufacturing	982	0	456	0	512,869,443	0
	Tobacco & accessories	Tobacco—smoking	312229—Other Tobacco Product Manufacturing	208	22	185	20	44,495,658	2,287,092

model along with the counts of branded and private-label UPCs; formulas; and sales units. The estimated numbers of UPCs total 816,823 for branded products and 406,362 for private-label products, for a grand total of 1,223,185 across all categories. In addition to the adjustments to the private-label UPC counts noted in Section 4.2.1, we adjusted the numbers of UPCs, formulas, and sales units to account for sales in outlets not represented in the Nielsen ScanTrack data for 2012 (foods, dietary supplements, and pet foods) and for 2009 (all other product categories).

Based on our assessment, we adjusted the Nielsen ScanTrack counts of UPCs and formulas and estimates of sales units as described in Table 4-4.

**Table 4-4. Adjustments to UPCs, Formulas, and Sales Units to Account for Nonrepresentation in the Nielsen ScanTrack Data**

FDA Type	Adjustment Factor		Justification
	UPCs and Formulas	Sales Units	
Cosmetics (2008 data)	3.1	3.1	Many cosmetic products are sold in department stores; thus, sales of these products are not tracked in the ScanTrack data. We assumed the same adjustment for dietary supplements as for cosmetics using the 2008 data under the assumption that cosmetics are sold at a similarly wide range of outlets (see Muth et al. [2012] for further explanation).
Dietary supplements (2012 data)	2.2	2.2	The ScanTrack data for dietary supplements do not capture sales in independent nutrition stores, through multilevel marketing, on the Internet, and through practitioners. According to the National Institutes of Health's (NIH's) Office of Dietary Supplements, approximately 55,000 dietary supplements are on the market. <sup>a</sup> We assumed this count represents unique formulas for both branded and private-label products and therefore calculated the adjustment as $(55,000/24,421 = 2.2)$ , where 24,421 is the estimate of branded and private-label formulas in the ScanTrack data. We assumed the same adjustment for UPC counts and sales units.

(continued)

**Table 4-4. Adjustments to UPCs, Formulas, and Sales Units to Account for Nonrepresentation in the Nielsen ScanTrack Data (continued)**

FDA Type	Adjustment Factor		Justification
	UPCs and Formulas	Sales Units	
Foods (2012 data)	1.4	1.4	The 2012 ScanTrack data include supermarkets, drug stores, and mass merchandisers and excludes Wal-Mart sales. Wal-Mart typically has unique UPCs for branded products based on their own specifications. According to Economic Research Service (ERS) data on sales of food at home by type of outlet, <sup>b</sup> 65.8% of food sales were in supermarkets, other grocery, and mass merchandisers, and 91.4% of sales were in retail outlets (excludes home deliveries and direct sales) in 2012. The ratio of all retail sales to sales in the ScanTrack data is $(91.4/65.8 = 1.4)$ . We applied this ratio to UPC counts, formula counts, and sales units.
OTCs (2008 data)	1.4	1.4	We assumed the same adjustment as for foods because they are sold in similar stores.
Pet foods (2012 data)	1.9	1.9	The PFI estimates that the number of branded and private-label pet food products is 15,000 to 17,000; we assumed this estimate represents cat and dog food formulas and excludes treats. We calculated the ratio of the midpoint of PFI's estimate to the estimate of branded and private-label cat and dog food formulas in the ScanTrack data as $(16,000/8,207 = 1.9)$ . We applied this ratio to UPC counts, formula counts, and sales units.
Retail medical devices (2008 data)	1.4	1.4	We assumed the same adjustment as for foods because they are sold in similar stores.
Tobacco products (2008 data)	0	6.7	Based on Nielsen scanner data, about 15% of tobacco sales are in grocery stores, drugs stores, and mass merchandisers represented in the scanner data; at least 85% are sold in convenience stores and other outlets. We assumed the number of UPCs vary only slightly across outlets and, therefore, are not adjusted.

<sup>a</sup> See NIH press release in June 2013: <http://www.nih.gov/news/health/jun2013/nlm-17.htm> (NIH, 2013).

<sup>b</sup> See Table 14 on the ERS Web site: [http://www.ers.usda.gov/data-products/food-expenditures.aspx#.U\\_83JFfco\\_8](http://www.ers.usda.gov/data-products/food-expenditures.aspx#.U_83JFfco_8) (USDA, 2014).

In Appendix Table B-1, we provide further detail regarding the specific Nielsen product modules included within each product type, category, and subcategory. The detail regarding the Nielsen product modules can be helpful in determining the appropriate product subcategory for a regulated product. Note that in some cases, Nielsen product modules were split into

multiple product subcategories to ensure that products are correctly associated. For example, bandages without an antibiotic are classified as a medical device, while those with an antibiotic are classified as an OTC; dandruff shampoo is classified as an OTC, while regular shampoo is classified as a cosmetic; and toothpaste with fluoride is classified as an OTC, while toothpaste without fluoride is classified as a cosmetic.

---

### **4.3 FORMULAS FOR CALCULATING THE COSTS OF LABELING CHANGES**

In this section, we describe the formulas used for calculating the costs of changing product labels in response to FDA regulation. We begin with a description of the core calculations and then describe how the costs will be adjusted for short compliance periods and for inflation. We also describe the method for addressing uncertainty in the cost estimates. Finally, we describe the conceptual framework for estimating the proportion of required labeling changes that can be coordinated with a planned (nonregulatory) labeling change.

#### **4.3.1 Costs of Changing Product Labels**

For each product subcategory  $i$  affected by a labeling requirement, the costs of labeling changes are incurred at the following three levels:

- Per-UPC basis—labor and materials costs for administrative activities, graphic design, prepress activities, printing plates, and recordkeeping activities
- Per-formulation (or product) basis—analytical testing and market testing costs
- Per-sales unit basis—discarded inventory and disposal costs for labels or printed packages that become obsolete as a result of the labeling requirement, annual costs of peel-back label or increased package size, and annual costs of package inserts if the regulation requires adding a package insert

The units in the model are the numbers of UPCs, unique formulations, and units sold calculated from Nielsen scanner data. These units are adjusted based on the (1) user-supplied proportion of affected products for the product subcategory,  $\alpha_i$ , and (2) assumed percentages of required changes that cannot be coordinated with a planned change,  $\rho^B$  and  $\rho^{PL}$ .

Within each cost category, the calculations were conducted separately for the low, midpoint, and high cost estimates. With the exception of the annual costs including package inserts to products that do not currently have them, the costs of labeling changes were assumed to be one-time costs.

Let  $\alpha_i$  represent the user-entered percentage of the product subcategory affected by the labeling requirement. Assuming that manufacturers *cannot coordinate the required labeling change with a planned labeling change*, the numbers of affected units used at each level in the calculations for product subcategory  $i$  are calculated as follows. The **number of affected UPCs** is calculated as

$$X_i = \alpha_i (UPC_i^B + UPC_i^{PL}),$$

where  $UPC_i^B$  and  $UPC_i^{PL}$  are the annual numbers of unique branded and private-label UPCs in product subcategory  $i$ . The **number of affected formulations** (or unique products) is calculated as

$$Y_i = \alpha_i (FORM_i^B + FORM_i^{PL}),$$

where  $FORM_i^B$  and  $FORM_i^{PL}$  are the annual numbers of unique formulations for branded and private-label products in product subcategory  $i$ . Finally, the **number of affected sales units** is calculated as

$$Z_i = \alpha_i (UNIT_i^B + UNIT_i^{PL}),$$

where  $UNIT_i^B$  and  $UNIT_i^{PL}$  are the annual numbers of units of branded and private-label products sold in product subcategory  $i$ .

Depending on the compliance period, the number of affected UPCs, formulations, and sales units are adjusted to reflect that some manufacturers can coordinate the required labeling change with planned labeling changes for some UPCs. Let  $\rho^B$  represent the proportion of uncoordinated changes for branded products and  $\rho^{PL}$  represent the proportion of uncoordinated changes for private-label products.<sup>1</sup> For extensive changes and for addition of a package insert, the model assumes  $\rho^B = \rho^{PL} = 100\%$  because these types of changes do not occur on a routine basis; thus, it is extremely unlikely that a regulatory

<sup>1</sup> The estimation of  $\rho^B$  and  $\rho^{PL}$  is discussed in Section 3.

change could coincide with a voluntary change of this magnitude.

Thus, the **adjusted number of affected UPCs** (i.e., the number of UPC changes that cannot be coordinated with a scheduled change) is calculated as

$$X_i^A = \alpha_i (\rho^B \bullet \text{UPC}_i^B + \rho^{PL} \bullet \text{UPC}_i^{PL}),$$

the **adjusted number of affected formulations** (or unique products) is calculated as

$$Y_i^A = \alpha_i (\rho^B \bullet \text{FORM}_i^B + \rho^{PL} \bullet \text{FORM}_i^{PL}), \text{ and}$$

the **adjusted number of affected sales units** is calculated as

$$Z_i^A = \alpha_i (\rho^B \bullet \text{UNIT}_i^B + \rho^{PL} \bullet \text{UNIT}_i^{PL}).$$

Note that the assumed values for  $\rho^B$  and  $\rho^{PL}$  are applied to all product subcategories based on default values provided in the model or user-supplied inputs. Although these proportions may vary by product subcategory, information for making separate adjustments for each product subcategory is typically not available; thus, the values are assumed to be the same. When used in the model calculations for short compliance periods, the estimate of  $Z_i^A$  is further reduced based on the portion of remaining inventory that would be discarded and the volume of products that would need to have a sticker applied.

Note that, although other printing methods are used occasionally, offset lithography, flexography, and rotogravure are used for the vast majority of products. Digital printing is on the increase but typically used only for very small runs.

Let  $j$  indicate the type of change required by regulation as follows:

- $j = 1$  for a minor change,
- $j = 2$  for a major change,
- $j = 3$  for an extensive change,
- $j = 4$  for updating a package insert, and
- $j = 5$  for adding a package insert for products that do not currently have them.

Note that a product subcategory can be affected by a minor, major, or extensive labeling change; a package insert change; or both a labeling change and a package insert change.

Let  $k$  represent the printing method used for the product subcategory as follows:

- $k = 1$  for offset lithography,

$k = 2$  for flexography,

$k = 3$  for rotogravure, and

$k = 4$  for digital.

We assumed that each product subcategory  $i$  is associated with a representative labeling method (e.g., paper label, shrink wrap label, printed carton, or printed plastic bottle) in which the proportions of each printing method,  $k$ , associated with the labeling method are based on representative industry data. As an illustrative example, we might assume all products in product subcategory  $i$  are packaged in a paperboard carton, and 80% of paperboard cartons are printed using lithography, 15% are printed using flexography, and 5% are printed using rotogravure. The cost estimates that vary by printing method are then calculated as a weighted average of the costs associated with lithography, flexography, and rotogravure.

In cases in which the product subcategory typically has labeling on both outer and inner packaging (e.g., a paperboard carton and a paper label on a bottle), we include the costs for changing each part of the labeling information. Furthermore, in cases in which the product subcategory typically has a package insert, we include the costs of changing the package insert if the user selects this option or adding a package insert to a product subcategory that typically does not include packaging inserts. Thus, the costs of changing a label for a particular subcategory may have up to three components: outer packaging, inner packaging, and a packaging insert. The costs of changing each part are estimated separately using the formulas below and added together to obtain a total cost estimate for the product category.

The types of costs included in **per-UPC costs of compliance**, for type of change,  $j$ , incurred for product subcategory,  $i$ , are defined as follows:

- $AC_j$  are the administrative labor costs (labor hours times hourly wage rate with benefits and overhead) associated with administrative activities that are incurred for UPCs in the product subcategory that cannot be coordinated with a scheduled change, and  $C\_AC_j$  are the administrative labor costs associated with administrative activities for UPCs that can be coordinated with a scheduled change.

- $LC_j$  are the labor costs (labor hours times hourly wage rate with benefits and overhead) associated with graphic design and prepress activities incurred by either the manufacturer's employees or outside vendors or consultants.<sup>2</sup>
- $\sum_{k=1}^4 \beta_k \cdot PC_{jk}$  are the weighted average printing plate costs where  $\beta_k$  represents the proportion of UPCs printed using each printing method,  $k$ , and  $PC_{jk}$  represents the plate costs for each printing method. (Note that because the number of plates affected varies by the type of change  $j$ , the plate costs also depend on the type of change.)<sup>3</sup>
- $OMC_j$  are the other materials costs associated with graphic design and prepress activities.
- $RC_j$  are recordkeeping costs associated with changing label information (i.e., labor hours associated with updating records to reflect the change times hourly wage rate with benefits and overhead) for UPCs that cannot be coordinated with a scheduled change, and  $C\_RC_j$  are the recordkeeping costs associated with updating records for UPCs that can be coordinated (i.e., labor costs associated with updating records to reflect the review of the requirement and making a notation in the record).

Thus, the **total cost of compliance associated with per-UPC costs** for type of change,  $j$ , incurred for *uncoordinated* product subcategory,  $i$ , is

$$TC\_UPC_{ij} = (AC_j + RC_j + LC_j + \sum_{k=1}^4 \beta_k \cdot PC_{jk} + OMC_j) \cdot X_i^A,$$

and the **total cost of compliance associated with per-UPC costs** for type of change,  $j$ , incurred for *coordinated* product subcategory,  $i$ , is

$$C\_TC\_UPC_{ij} = (C\_AC_j + C\_RC_j) \cdot (X_i - X_i^A).$$

<sup>2</sup> We assumed that if employees of the manufacturer conduct graphic design and prepress activities, the costs are similar to hiring an outside consultant for those activities.

<sup>3</sup> Digital printing does not require printing plates; therefore, the costs associated with preparing new printing plates is set to zero.



The types of costs included in **per-formulation costs of compliance** are defined as follows:

- ATC represents the sum of all selected or entered analytical test costs, including the cost of selecting and preparing and shipping samples, and laboratory fees and supplies (1 hour of labor at the relevant wage rate with benefits and overhead).
- MTC represents the sum of all selected or entered market testing costs, including focus groups or quantitative tests assumed to be conducted by manufacturers in preparation for the labeling change.

Both ATC and MTC are based on user selections for which default cost estimates are available in the model or separate cost estimates inputted by the model user. For minor labeling changes, ATC and MTC are likely to be 0, but for major and extensive changes, both values are likely to be positive. The **total costs of compliance associated with per-formulation costs** incurred for product subcategory  $i$  are

$$TC\_FORM_i = (ATC + MTC) \bullet Y_i^A.$$

The types of costs included in **per-sales unit costs of compliance** are defined as follows:

- $PLC_i$  represents the per-sales unit cost of printed packages or labels for product subcategory  $i$  based on the representative packaging or labeling method for the product category.<sup>4</sup>

Let  $\phi_{i,t}^B$  and  $\phi_{i,t}^{PL}$  represent the annual portion of remaining branded and private-label packaging or label inventory that would need to be discarded for product subcategory  $i$  for compliance period  $t$ . The values of  $\phi_{i,t}^B$  and  $\phi_{i,t}^{PL}$  depend on the type of packaging or label material used and whether it is low, medium, or high bulkiness because manufacturers are likely to have larger inventories on hand for materials with lower bulkiness. Furthermore, inventories tend to be higher for private-label UPCs because label designs are less frequently updated and manufacturers can, therefore, order a relatively larger quantity of materials with each order.

---

<sup>4</sup> Note that additional costs may be incurred if the manufacturer has to pay a fee to retailers to remove products from shelves. However, because these costs would be difficult to estimate in a general manner, they are not included in the model calculations.

Note that we assumed that no printed packages or labels are discarded for the first year following the regulation because all products are assumed to have stickers applied. Thus, discarded inventory costs are the same for 3-, 6-, 9-, and 12-month compliance periods and then decrease for longer compliance periods.

The **total cost of compliance associated with per-sales unit costs** incurred for product subcategory  $i$  is

$$TC\_UNIT_i = PLC_i \cdot \alpha_i (\phi_{i,t}^B \cdot \rho^B \cdot UNIT_i^B + \phi_{i,t}^{PL} \cdot \rho^{PL} \cdot UNIT_i^{PL}).$$

Finally, the total cost of compliance is calculated as the summation of the above costs. For uncoordinated product subcategories, the costs are summed as follows:

$$ALLCOSTS_{ij} = TC\_UPC_{ij} + TC\_FORM_i + TC\_UNIT_i.$$

For coordinated product subcategories, the costs are simply

$$ALLCOSTS_{ij} = C\_TC\_UPC_{ij}.$$

As noted above, for product categories that have both outer and inner packaging (e.g., 12-pack soda cartons with labeling on the carton and on the individual cans),  $TC\_UPC_{ij}$  and  $TC\_UNIT_i$  are calculated separately based on the printing and packaging methods for the outer and inner packaging and then summed for a total cost before adding the costs over all products in the product subcategory. Furthermore, if a product category has a package insert or will have a package insert added, these costs are also calculated separately and summed with the outer and inner packaging costs.

In cases where package inserts are to be added to products that do not currently have them, manufacturers incur not only the one-time costs represented in  $ALLCOSTS_{ij}$  but also the annual costs of package inserts for all subsequent years. The annual costs of package inserts are calculated as

$$AC\_UNIT_i = PLC_i \cdot \alpha_i (UNIT_i^B + UNIT_i^{PL}).$$

For extensive changes, manufacturers incur annual costs for adding peel-back labels or increased package size for subsequent years. The annual costs of peel-back labels are calculated as

$$AC\_UNIT_i = PBL \cdot \tau_i \cdot \alpha_i (UNIT_i^B + UNIT_i^{PL})$$

where PBL is the per-sales unit value of a peel-back label, which also serves as a proxy for increased package size, and  $\tau_i$  is the portion of product subcategory  $i$  that will require the addition of a peel-back label to accommodate label information.

#### 4.3.2 Adjustments for Short Compliance Periods

If the compliance period for making changes to labels is particularly short, manufacturers incur costs beyond those described above. Specifically, manufacturers

- will likely incur overtime and rush charges for completing all of the label change activities on a faster than usual schedule and
- may also incur costs for applying stickers to existing labels if there is insufficient time to print new labels before the change must be implemented.

We assumed that a labeling change requires a minimum of 15 months to fully implement; thus, any change that must be incorporated in less time requires one or both of these charges.

To account for overtime and rush charges, we multiplied  $TC\_UPC_{ij}$  and  $TC\_FORM_i$  by an escalation factor. Based on information provided by manufacturers during the industry interviews, we assumed an escalation factor of 40% for compliance periods of 15 months or less. Note that the escalation factor does not apply to per-sales unit costs.

To account for the costs of applying stickers, in addition to  $PC_i$  above, **per-sales unit costs of compliance** also include the following:

- $SC_i$ , which represents the per-sales unit sticker costs, including the costs of purchasing printed stickers and the labor costs for applying stickers (labor hours times hourly wage rate with benefits and overhead), for product subcategory  $i$ .

Thus, in the case of short compliance periods, the **total cost of compliance associated with per-sales unit costs** incurred for product subcategory  $i$  is modified as follows:

$$TC\_UNIT_i = PLC_i \cdot \alpha_i (\phi_{i,t}^B \cdot \rho^B \cdot UNIT_i^B + \phi_{i,t}^{PL} \cdot \rho^{PL} \cdot UNIT_i^{PL}) + SC_i \cdot \gamma_i Z_i^A,$$

where  $\gamma_i$  represents the proportion of annual sales volume that would need to be stickered for product subcategory  $i$ . Because

of the high costs associated with applying stickers, we assumed that they will only be applied for compliance periods of 9 or fewer months.

To summarize, for each compliance period of 15 or fewer months, the model applies additional costs based on the following assumptions:

- 3-month compliance—apply stickers to 9 months' worth of unit sales and incur overtime and rush charges to complete the labeling change
- 6-month compliance—apply stickers to 6 months' worth of unit sales and incur overtime and rush charges to complete the labeling change
- 9-month compliance—apply stickers to 3 months' worth of unit sales and incur overtime and rush charges to complete the labeling change
- 12-month compliance—incur overtime and rush charges to complete the labeling change
- 15-month compliance—incur overtime and rush charges to complete the labeling change

However, we note that based on the industry interviews, for some FDA product types, such as OTC medications, manufacturers typically do not apply stickers and would instead accelerate the label change process with overtime labor and rush charges. Furthermore, it is unlikely that changes to product inserts would be addressed through use of stickers and instead would be reprinted under an accelerated schedule.

In addition to overtime labor and rush charges and the costs of stickers, manufacturers will also incur higher discarded inventory costs under short compliance periods. These costs will be accounted for in the calculation of affected unit sales,  $Z_i^A$ , that is multiplied by the per-unit cost of labeling or packaging.

#### **4.3.3 Adjustments for Inflation**

Users have the option of indicating an inflation adjustment factor to account for the differences in costs that have occurred between 2014, the base year for the costs, and the year in which the analysis is conducted. Thus, users enter a value for the cumulative inflation rate,  $r$ , relative to 2014. The costs are inflated by calculating  $(1 + r) \cdot \text{ALLCOSTS}_{ij}$ . To allow for

complete flexibility in using the model,  $r$  is permitted to fall in the range of 0.5 to 10.0. By permitting values less than 1.0, the model allows for the possibility of deflation or for estimating costs for an earlier time period.

---

## **4.4 COST CALCULATION DATA INCLUDED IN THE MODEL**

As described in Section 4.3, the costs of labeling changes are incurred on a UPC, formula, or sales unit basis. In this section, we present the cost estimates included in the model and describe the assumptions underlying the estimates. The estimates were developed through interviews with product manufacturers and graphic design and package/label printing vendors. In addition, information obtained from the trade associations was used to inform the development of appropriate assumptions.

### **4.4.1 Per-UPC Cost Calculation Data**

Table 4-5 presents a summary of the estimated internal labor hours, consultant costs, and materials costs associated with uncoordinated labeling changes, and Table 4-6 presents the corresponding estimates for coordinated labeling changes.<sup>5</sup> To develop these estimates, we provided the estimates from the previous model presented in Muth et al. (2012) to five food manufacturers and two vendors and conducted teleconferences to discuss whether the estimates were reasonable or needed to be adjusted. In most cases, the respondents indicated that their estimates would fall within the ranges provided in the previous model. In addition, PTIS also reviewed the estimates and provided revisions based on their experience and discussions with two additional vendors. According to PTIS, the labor hours for some activities have declined from the previous estimates because of increased efficiencies associated with modern digital print processes.

---

<sup>5</sup> If manufacturers conduct graphic design and prepress activities internally, we assumed that the costs are similar to those for using an outside consultant. Both sets of costs must be included to develop an estimate of the total costs of changing a label.

**Table 4-5. Estimated Labor Hours and Materials Costs Associated with Uncoordinated Labeling Changes, 2014**

	Minor Change (j=1)			Major Change (j=2)			Extensive Change (j=3)			Package Insert Change (j=4)			Package Insert Added (j=5)		
	5th P	Mean	95th P	5th P	Mean	95th P	5th P	Mean	95th P	5th P	Mean	95th P	5th P	Mean	95th P
<b>Hours Per UPC</b>															
Labor hours—administrative (internal)	6.1	11.8	17.4	13.9	24.5	35.1	18.6	32.3	44.7	6.1	11.8	17.4	13.9	24.5	35.1
Labor hours—graphic design (internal)	2.1	4.6	7.3	7.2	15.3	25.2	12.3	26.7	42.4	2.1	4.5	6.9	5.9	16.1	28.8
Labor hours—prepress (internal)	2.9	5.3	8.4	3.4	6.7	10.3	4.0	8.7	13.6	1.7	3.1	4.4	3.4	6.7	10.3
Labor hours—recordkeeping (internal)	1.7	2.0	2.3	1.7	2.0	2.3	1.7	2.0	2.3	2.2	2.8	3.6	2.2	2.8	3.6
<b>Costs (\$/UPC)</b>															
Consultant labor costs—graphic design	\$347	\$583	\$863	\$1,044	\$1,600	\$2,208	\$1,632	\$3,000	\$4,367	\$347	\$583	\$863	\$1,044	\$1,600	\$2,208
Consultant labor costs—prepress	\$548	\$900	\$1,304	\$964	\$1,350	\$1,788	\$1,274	\$1,917	\$2,646	\$548	\$900	\$1,304	\$964	\$1,350	\$1,788
Materials—flexography	\$427	\$833	\$1,283	\$1,302	\$2,600	\$4,206	\$2,866	\$4,833	\$6,975	\$185	\$267	\$357	\$695	\$900	\$1,105
Materials—offset	\$93	\$143	\$214	\$363	\$500	\$637	\$463	\$600	\$737	\$93	\$143	\$214	\$363	\$500	\$637
Materials—gravure	\$1,082	\$1,467	\$1,834	\$5,047	\$6,333	\$7,792	\$5,401	\$7,500	\$9,859	\$1,082	\$1,467	\$1,834	\$5,048	\$6,333	\$7,792
Materials—digital	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Materials—other	\$51	\$65	\$79	\$154	\$195	\$236	\$257	\$325	\$393	\$51	\$65	\$79	\$154	\$195	\$236

Table 4-6. Estimated Labor Hours Associated with Coordinated Labeling Changes, 2014

Hours per UPC	Minor Change (j=1)			Major Change (j=2)			Extensive Change (j=3)			Package Insert Change (j=4)			Package Insert Added (j=5)		
	5th P	Mean	95th P	5th P	Mean	95th P	5th P	Mean	95th P	5th P	Mean	95th P	5th P	Mean	95th P
Labor hours—administrative (internal)	3.1	5.9	8.7	6.9	12.2	17.5	—	—	—	3.1	5.9	8.7	—	—	—
Labor hours—recordkeeping (internal)	0.8	1.0	1.2	0.8	1.0	1.2	—	—	—	1.1	1.4	1.8	—	—	—

Note: Extensive changes and additions of product inserts are assumed to be uncoordinated changes in all cases; thus, costs are not estimated for coordinated changes for these two cases.

Materials costs are associated with printing plates and other miscellaneous materials. Note that the typical number of printing plates for a printed package or label is 6, but it may range from 5 to 10. Although a minor change affects only one plate, a major change affects all plates. Because of volume discounts, the cost of cutting all new plates is typically less than the cost of cutting one new plate multiplied by the number of plates.

We used @Risk to regenerate the 5th percentile, mean, and 95th percentile of the estimated internal labor hours, consultant costs, and materials costs. The wage rates used to calculate the labor costs associated with internal labor hours are shown in Table 4-7. The wage rates are shown for the 10th and 90th rather than 5th and 95th percentiles because the Bureau of Labor Statistics (BLS) publishes these values as the endpoints.

**Table 4-7. Hourly Wage Rates for Activities Conducted in Changing Product Labels, 2014**

BLS Labor Category	Labeling Change Activity	10th Percentile	Mean	90th Percentile
Graphic designers	Graphic design	\$12.38	\$21.36	\$33.32
	Prepress			
Weighers, measurers, checkers, and samplers, recordkeeping	Recordkeeping	\$9.83	\$15.84	\$23.69
Helpers—Production workers	Analytical testing	\$8.69	\$12.92	\$18.38
	Sticker application			
Advertising and promotion managers	Administrative	\$26.85	\$52.13	\$82.09

Source: BLS downloaded from [http://www.bls.gov/oes/current/naics2\\_31-33.htm](http://www.bls.gov/oes/current/naics2_31-33.htm). Wage rates apply to NAICS code 31-33 for manufacturing in May 2014.

Note: In the model, these rates are multiplied by 2 to account for an estimated combined benefits and overhead rate of 100%.

In developing these estimates, we assumed the following:

- Materials costs for an extensive change (specifically, printing plates and other miscellaneous materials) were assumed to be typically 25% more than for a major change for offset and gravure. Adjustments to this percentage were provided by PTIS.
- The costs for administrative and recordkeeping activities for a change that is coordinated with a planned change are 50% of the costs of an uncoordinated change based on information provided by industry respondents.



- The cost of changing a package insert is assumed to be similar to the cost of a minor labeling change, and the cost of adding a package inserts is assumed to be similar to the cost of a major labeling change. Extensive changes and additions of product inserts are not able to be coordinated with a planned change.

For materials costs, the model calculates a weighted average cost for materials across printing methods used with the type of packaging typical for each product subcategory. Table 4-8 shows the estimated percentages of each package type that are printed using each printing method. We based these percentages on data published in Shulman and Elred's *Trends in Package Printing* published in 2007; these estimates were initially reviewed and, in some cases, modified by PTIS based on its understanding of current industry practices in 2010. PTIS also reviewed and updated these estimates in 2014.

**Table 4-8. Estimated Percentages of UPCs Printed Using Each Printing Method by Package Label Type, 2014 (%)**

Package-Label Type	Bulkiness	Flexography ( $\beta_1$ )	Offset ( $\beta_2$ )	Gravure ( $\beta_3$ )	Digital ( $\beta_4$ )
Aluminum can	High	0%	100%	0%	0%
Aseptic carton	High	0%	100%	0%	0%
Foam carton	High	100%	0%	0%	0%
Foil-backed paper	Medium	29%	51%	20%	0%
Foil-backed paper—blister pack	Medium	29%	51%	20%	0%
Foil-backed paper—pouch	Medium	78%	2%	20%	0%
Foil—bag	Medium	78%	2%	20%	0%
Foil—top	Low	78%	2%	20%	0%
Foil—tube	High	78%	2%	20%	0%
Gable top carton	High	29%	51%	20%	0%
Paper	Medium	29%	51%	20%	0%
Paper backed—blister pack	Medium	0%	100%	0%	0%
Paper—bag	Medium	75%	20%	5%	0%
Paper—label	Low	40%	50%	5%	5%
Paper—pouch	Medium	2%	73%	25%	0%
Paperboard—carton	Medium	20%	78%	2%	0%
Paperboard—cigarette carton	Medium	5%	0%	95%	0%
Paperboard—molded	High	100%	0%	0%	0%

(continued)

**Table 4-8. Estimated Percentages of UPCs Printed Using Each Printing Method by Package Label Type, 2014 (%) (continued)**

Package-Label Type	Bulkiness	Flexography ( $\beta_1$ )	Offset ( $\beta_2$ )	Gravure ( $\beta_3$ )	Digital ( $\beta_4$ )
Paperboard—sheet	Medium	25%	73%	2%	0%
Paperboard—sleeve	Medium	29%	51%	20%	0%
Plastic bag—clear	Medium	95%	0%	5%	0%
Plastic bag—opaque	Medium	85%	0%	15%	0%
Plastic bag—resealable	Medium	73%	2%	25%	0%
Plastic—carton	High	0%	100%	0%	0%
Plastic—label	Low	40%	20%	40%	0%
Plastic—molded	High	20%	60%	20%	0%
Plastic—sheet	Medium	78%	2%	20%	0%
Plastic—tube	High	0%	100%	0%	0%
Tin steel container	High	0%	100%	0%	0%
Package inserts	Low	50%	50%	0%	0%
Peel-back labels	Low	100%	0%	0%	0%

Source: Shulman and Elred (2007) with revisions provided by PTIS in 2010 and 2014.

#### 4.4.2 Per-Formulation Cost Calculation Data

Per-formulation costs include analytical testing and market testing costs, both of which are optional to include in the model. The model allocates these costs to a per-UPC basis by dividing the per-formula cost by the ratio of the number of UPCs to the number of formulas in the product subcategory. Table 4-9 shows estimated analytical testing costs for a list of common tests, and Table 4-10 shows estimated market testing costs for focus groups and quantitative tests. In both tables, the low estimates correspond to the 5th percentiles and the high estimates correspond to the 95th percentiles of the probability ranges, assuming a triangular distribution.

**Table 4-9. Estimated Analytical Testing Costs in the Labeling Cost Model, 2014 (\$/Formula)**

Type of Test	5th Percentile	Mean	95th Percentile
	ATC_LO	ATC_MEAN	ATC_HI
Cosmetics—microbes and contaminants	69	99	129
Dietary supplements—vitamins	97	168	256
Dietary supplements—amino acids	258	275	292
Food—NFP based on laboratory test	742	845	968
Food—NFP based on database	111	188	262
Food—fat composition	122	168	208
Food—trans fatty acids	122	172	225
Food—sugar profile	87	104	122
Food—total fiber	132	194	265
Food—soluble or insoluble fiber	155	212	272
Food—vitamins	93	169	257
Food—vitamin D	179	243	309
Food—minerals	23	42	64
Food—iodine	55	107	170
Food—potassium	22	40	63
Food—sodium chloride	19	29	37
Food—pH, brix, Aw	13	20	27
Food—proximate analysis	66	108	161
Food—pathogens	34	77	126
Food—caffeine	74	102	128
Food—acrylamide	216	227	239
Food—allergens	85	125	175
Food—bioengineered ingredients	147	276	414
OTCs—microbes and contaminants	79	88	96
Pet Foods—whole pet food label	136	213	289
Pet foods—proximate assay	30	52	84
Pet foods—microbiology	42	74	105
Pet foods—vitamin assay	96	157	226
Pet foods—amino acid assay	141	185	229
Pet foods—contaminants	90	192	299

Note: The total test costs included in the model assume two tests: \$25.30 for 1 hour of labor to prepare the samples, and \$75.35 for overnight shipment to the testing lab.

**Table 4-10. Estimated Market Testing Costs in the Labeling Cost Model, 2014 (\$/Formula)**

Type of Test	5th Percentile	Mean	95th Percentile
	ATC_LO	ATC_MID	ATC_HI
Focus groups	6,158	6,500	6,842
Discrimination test	4,973	6,300	7,784
Descriptive test	8,594	13,058	16,534
Central location test	24,733	31,950	39,162
In-home test	21,776	27,350	32,922

Estimated analytical testing costs were based on published prices from testing laboratories,<sup>1</sup> and estimated market testing costs were based on information provided by vendors. For both types of tests, users have the option of including additional testing costs other than the specific selections in the model.

In developing the costs of analytical tests, we assumed the following:

- Two samples per formula are tested.
- Labor costs to prepare samples are estimated by assuming 1 hour of labor for a production worker.
- Testing the samples requires shipping one 2-pound package overnight by FedEx at a cost of \$75.35 (based on the assumption of 8:00 AM delivery and a shipment distance of 301 to 600 miles).

Thus, the total cost per sample is two times the cost per test shown in Table 4-9 plus labor and shipping. However, the exception is the use of a nutrition database for the NFP. In this case, testing costs are estimated as one test with no labor or shipping costs.

<sup>1</sup> Analytical test costs were obtained from The National Food Lab, Midwest Laboratories, Microbac Laboratories, Inc., Medallion Labs, RL Food Testing Laboratory, EMSL Food Testing, Nutrilabel, NutriData, Food Lab, Shakti BioResearch, Celplor, LLC, CGIBD Advanced Analytics Core, Barrow-Agee Laboratories, LLC, Great Lakes Scientific, Inc., Litchfield Analytical Services and BioProfile Testing Laboratories. To combine these estimates, we first discarded outlier values. Then we identified the minimum and maximum values from the range of estimates. We calculated the “most likely” value as an average of the remaining values. If we had only two estimates (minimum and maximum), we calculated the mid-point and used this as the “most likely” value.

We developed estimates of the market testing costs shown in Table 4-10 using information provided by three companies that conduct a variety of studies for manufacturers. The key assumptions underlying these estimates are as follows:

- Focus groups—three groups with 8 to 10 consumers each, 3 products per group, 1.5 hours per group
- Discrimination test—one location with 30 to 100 consumers and 1 to 3 products per test
- Descriptive test—one location 12 to 100 consumers and 3 to 4 products per test
- Central location test—3 to 5 locations with 100 consumers per location and 3 to 5 products per test
- In-home test—5 locations with 100 consumers per location (or distributed across a broader area through direct shipment) and 5 products per test

When multiple products are included in a test, we divided the costs for the entire test by the number of products to determine a per-formula cost for use in the model. An additional test that may be conducted for major national brands is an alienation test with frequent users of the products. However, estimates of the costs of this test and the information on the scenarios in which these tests would be run were not available.

#### **4.4.3 Per-Sales Unit Cost Calculation Data**

Per-sales unit costs include the

- one-time costs of applying stickers for short compliance periods,
- one-time costs of discarded inventory for short compliance periods,
- annual costs of adding peel-back labels (or increased package size) to products, and
- annual costs of including package inserts for products that do not currently have them.

Table 4-11 shows the low, medium, and high estimates of the costs of printing and applying stickers, adding peel-back labels, and adding package inserts for all product subcategories.

For application time for stickers, we assumed 300 (minimum cost), 200 (midpoint), and 100 (maximum costs) pieces per hour. These labor hour estimates were multiplied by the wage rate (including benefits and overhead) for helpers—production

**Table 4-11. Estimated Sticker Costs, Sticker Application Time, Peel-Back Label Costs, and Package Insert Costs on a Per-Sales Unit Basis, 2014**

Type of Cost	Low	Medium	High
	SC_LO	SC_MID	SC_HI
Sticker cost	\$0.015	\$0.006	\$0.150
Application time (minutes)	0.2	0.3	0.6
Peel-back label cost	\$0.025	\$0.050	\$0.070
Package insert	\$0.035	\$0.045	\$0.055

Source: Cost estimates were provided by PTIS in 2014.

workers. We assumed that 12 months of packaging or printing materials are on hand or on order at the time a labeling requirement is announced. Thus, if the compliance period is 3 months, then 9 months of material (75% of annual sales units) will need to be stickered. Likewise, if the compliance period is 6 months, then 6 months of material (50% of annual sales units) will need to be stickered. Finally, if the compliance period is 9 months, then 3 months of material (25% of annual sales units) will need to be stickered.

To calculate discarded inventory costs, we estimated the cost per unit of each printed package or label and multiplied this value by the estimated remaining inventory based on the compliance period as shown in Table 4-12. Table 4-13 shows the per-sales unit cost of printed packaging or labels for each product subcategory in the model as obtained from PTIS. The estimates of remaining inventory for branded and private-label UPCs, which are based on the bulkiness of the material, are shown in Table 4-8.

**Table 4-12. Assumed Remaining Percentages of Package-Label Inventory Based on Compliance Period**

Compliance Period (months)	Low Bulkiness		Medium Bulkiness		High Bulkiness	
	Branded Sales Units	PL Sales Units	Branded Sales Units	PL Sales Units	Branded Sales Units	PL Sales Units
3 <sup>a</sup>	10%	150%	0%	10%	0%	0%
6 <sup>a</sup>	10%	150%	0%	10%	0%	0%
9 <sup>a</sup>	10%	150%	0%	10%	0%	0%
12	10%	150%	0%	10%	0%	0%
15	8%	125%	0%	8%	0%	0%
18	5%	100%	0%	5%	0%	0%
21	3%	75%	0%	3%	0%	0%

(continued)

**Table 4-12. Assumed Remaining Percentages of Package-Label Inventory Based on Compliance Period (continued)**

Compliance Period (months)	Low Bulkiness		Medium Bulkiness		High Bulkiness	
	Branded Sales Units	PL Sales Units	Branded Sales Units	PL Sales Units	Branded Sales Units	PL Sales Units
24	0%	50%	0%	0%	0%	0%
27	0%	40%	0%	0%	0%	0%
30	0%	30%	0%	0%	0%	0%
33	0%	20%	0%	0%	0%	0%
36	0%	10%	0%	0%	0%	0%
39	0%	8%	0%	0%	0%	0%
42	0%	5%	0%	0%	0%	0%
45	0%	3%	0%	0%	0%	0%
48						
51						
54	All values from 4 years and beyond are assumed to be 0%.					
57						
60						

<sup>a</sup> For 3-, 6-, and 9-month compliance periods, a portion of products is assumed to have stickers applied until reprinted materials are available 12 months after the labeling requirement is effective. Thus, the remaining inventory that will be discarded is the same for all compliance periods of 12 or fewer months.

Note: We assumed that bulkiness is the key driver for inventory storage rather than product type. All products likely have limited storage because of the need to maintain sanitary storage conditions until use.

Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Cosmetics	Baby needs	Baby care—oils & lotions	Plastic-label	\$0.020	\$0.025	\$0.030					No
	Baby needs	Baby care—ointments	Paperboard-carton	\$0.020	\$0.025	\$0.030	Plastic-tube	\$0.320	\$0.340	\$0.360	No
	Baby needs	Baby care—powder	Plastic-molded	\$0.060	\$0.080	\$0.100					No
	Baby needs	Baby care products—bath soap	Plastic-label	\$0.020	\$0.025	\$0.030					No
	Cosmetics—talc & dusting powder	Talcum & dusting powder	Plastic-label	\$0.020	\$0.023	\$0.026					No
	Deodorant (nonantiperspirant)	Deodorant—aerosol	Tin steel container	\$0.180	\$0.200	\$0.220					No
	Deodorant (nonantiperspirant)	Deodorant—cologne type	Aluminum can	\$0.150	\$0.170	\$0.190					No
	Deodorant (nonantiperspirant)	Deodorant—roll-on	Paper-label	\$0.015	\$0.020	\$0.025					No
	Deodorant (nonantiperspirant)	Deodorant—stick/solid	Plastic-label	\$0.012	\$0.015	\$0.018					No
	Deodorant (nonantiperspirant)	Remaining deodorants	Plastic-label	\$0.012	\$0.014	\$0.016					No
	Ethnic health & beauty	Ethnic health & beauty aids	Paper-label	\$0.016	\$0.018	\$0.020					Yes
	Ethnic health & beauty	Ethnic home permanents	Paperboard-carton	\$0.040	\$0.045	\$0.050	Paper-label	\$0.014	\$0.016	\$0.018	Yes
	Facial/eye/lip makeup	Cosmetic kits	Paperboard-carton	\$0.025	\$0.035	\$0.045	Plastic-sheet	\$0.010	\$0.020	\$0.030	No
	Facial/eye/lip makeup	Cosmetics—remaining	Paperboard-sleeve	\$0.020	\$0.025	\$0.030	Paper-label	\$0.010	\$0.012	\$0.014	No
	Facial/eye/lip makeup	Eye makeup	Paperboard-sheet	\$0.015	\$0.020	\$0.025	Plastic-label	\$0.010	\$0.013	\$0.016	No
	Facial/eye/lip makeup	Facial makeup	Paperboard-sheet	\$0.015	\$0.020	\$0.025	Plastic-label	\$0.014	\$0.017	\$0.020	No
	Facial/eye/lip makeup	False eyelash and accessory	Paperboard-sheet	\$0.010	\$0.015	\$0.020					No
	Facial/eye/lip makeup	Lip remedies	Plastic-label	\$0.005	\$0.010	\$0.015					No

(continued)



Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Cosmetics (cont'd)	Facial/eye/lip makeup	Lipstick	Plastic—label	\$0.005	\$0.010	\$0.015					No
	Feminine hygiene	Feminine deodorant sprays	Aluminum can	\$0.100	\$0.120	\$0.140					No
	Feminine hygiene	Remaining feminine hygiene	Paperboard-carton	\$0.020	\$0.025	\$0.030	Foil-tube	\$0.120	\$0.140	\$0.160	No
	Foot care	Foot preparations—remaining	Paperboard-sheet	\$0.015	\$0.020	\$0.025	Paperboard-sheet	\$0.030	\$0.040	\$0.050	Yes
	Fragrances	Colognes and perfumes	Paper-label	\$0.020	\$0.023	\$0.026					No
	Fragrances	Men's aftershave/cologne/lotion	Paper-label	\$0.006	\$0.008	\$0.010					No
	Gift sets & kits	Children's cologne & gift sets	Paperboard-carton	\$0.025	\$0.035	\$0.045	Plastic-label	\$0.020	\$0.025	\$0.030	No
	Gift sets & kits	Fragrance gift sets—women	Paperboard-carton	\$0.040	\$0.045	\$0.050	Plastic-tube	\$0.120	\$0.140	\$0.160	No
	Gift sets & kits	Men's aftershave/cologne/lotion	Paperboard—carton	\$0.040	\$0.045	\$0.050	Paper—label	\$0.010	\$0.012	\$0.014	No
	Hair care	Creme rinses & conditioners	Plastic-label	\$0.020	\$0.025	\$0.030					No
	Hair care	Hair coloring products	Paperboard-carton	\$0.025	\$0.030	\$0.035	Paper-label	\$0.010	\$0.012	\$0.014	Yes
	Hair care	Hair preparations	Plastic-label	\$0.030	\$0.035	\$0.040					No
	Hair care	Hairspray	Tin steel container	\$0.180	\$0.200	\$0.220					No
	Hair care	Home permanents	Paperboard-carton	\$0.035	\$0.040	\$0.045	Paper-label	\$0.012	\$0.014	\$0.016	Yes
	Hair care	Shampoo (nonmedicated)	Plastic-label	\$0.020	\$0.025	\$0.030					No
	Hair care	Wave setting products	Paperboard-carton	\$0.035	\$0.040	\$0.045	Plastic-tube	\$0.380	\$0.400	\$0.420	No
	Nail care/manicure needs	Manicure needs	Paperboard—carton	\$0.025	\$0.035	\$0.045					No
	Nail care/manicure needs	Nail care	Paper-label	\$0.014	\$0.017	\$0.020					No
	Oral hygiene	Breath fresheners	Plastic-label	\$0.005	\$0.010	\$0.015					No

(continued)

Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Cosmetics (cont'd)	Oral hygiene	Denture cleansers	Paperboard-carton	\$0.025	\$0.030	\$0.035	Foil backed paper-pouch	\$0.010	\$0.015	\$0.020	No
	Oral hygiene	Tooth whiteners	Paperboard-carton	\$0.020	\$0.025	\$0.030	Plastic-sheet	\$0.010	\$0.015	\$0.020	Yes
	Oral hygiene	Toothpaste (nonfluoride)	Paperboard-carton	\$0.023	\$0.028	\$0.033	Plastic-tube	\$0.380	\$0.400	\$0.420	No
	Personal soap/bath need	Bath additives—dry	Paperboard-carton	\$0.035	\$0.040	\$0.045					No
	Personal soap/bath need	Bath additives—liquid	Paper-label	\$0.010	\$0.013	\$0.016					No
	Personal soap/bath need	Soap—bar (nondeodorant)	Plastic-sheet	\$0.020	\$0.025	\$0.030					No
	Personal soap/bath need	Soap—liquid	Plastic-label	\$0.015	\$0.020	\$0.025					No
	Personal soap/bath need	Soap—specialty	Plastic-label	\$0.015	\$0.020	\$0.025					No
	Shaving needs	Depilatories	Paperboard-carton	\$0.020	\$0.025	\$0.030	Plastic-sheet	\$0.020	\$0.030	\$0.040	Yes
	Shaving needs	Shaving cream	Tin steel container	\$0.170	\$0.190	\$0.210					No
	Skin care preparations	Face cream and lotions	Plastic-label	\$0.020	\$0.025	\$0.030					No
	Skin care preparations	Hand cream and body lotions	Paper-label	\$0.024	\$0.027	\$0.030					No
	Skin care preparations	Suntan preparations—lotions/oils/etc.	Plastic-label	\$0.020	\$0.025	\$0.030					No
	Sunburn aids	Sunburn aids	Plastic-label	\$0.030	\$0.035	\$0.040					No
Dietary Supplements	Diet aids	Appetite suppressants	Paperboard-carton	\$0.030	\$0.035	\$0.040	Paper-label	\$0.008	\$0.010	\$0.012	Yes
	Diet aids	Diet aids—complete nutritional	Plastic-sheet	\$0.065	\$0.070	\$0.075	Paper-label	\$0.045	\$0.050	\$0.055	No
	Mineral supplements	Minerals	Paper-label	\$0.020	\$0.025	\$0.030					No
	Nutritional supplements	Complete nutritional products	Paperboard-carton	\$0.100	\$0.110	\$0.120	Aluminum can	\$0.070	\$0.090	\$0.110	No
	Nutritional supplements	Nutritional supplements	Plastic sheet	\$0.007	\$0.009	\$0.011					No

(continued)

Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Dietary Supplements (cont'd)	Protein supplements	Protein supplements	Plastic sheet	\$0.060	\$0.065	\$0.070					No
	Vitamin supplements	Vitamins—B complex w/C	Paper-label	\$0.010	\$0.012	\$0.014					No
	Vitamin supplements	Vitamins—children-flavored chewable	Paperboard-carton	\$0.030	\$0.035	\$0.040	Paper-label	\$0.008	\$0.010	\$0.012	No
	Vitamin supplements	Vitamins—multiple	Paperboard-carton	\$0.030	\$0.035	\$0.040	Paper-label	\$0.008	\$0.010	\$0.012	No
	Vitamin supplements	Vitamins—remaining	Plastic bag-resealable	\$0.060	\$0.080	\$0.100					No
	Vitamins/tonics—liquid	Vitamins/tonics—liquid & powder	Paperboard-carton	\$0.040	\$0.045	\$0.050	Paper-label	\$0.010	\$0.012	\$0.014	No
Foods	Baked goods	Bagels/biscuits/buns/muffins/rolls—fresh	Plastic bag-clear	\$0.035	\$0.040	\$0.045	Paperboard—carton	\$0.025	\$0.030	\$0.035	No
	Baked goods	Bagels/biscuits/buns/muffins/rolls—frozen	Plastic bag-clear	\$0.035	\$0.040	\$0.045					No
	Baked goods	Baked goods—remaining—fresh	Paperboard-carton	\$0.075	\$0.080	\$0.085					No
	Baked goods	Baked goods—remaining—frozen	Paperboard-carton	\$0.075	\$0.080	\$0.085					No
	Baked goods	Bread—fresh	Plastic bag-clear	\$0.040	\$0.045	\$0.050					No
	Baked goods	Bread—frozen	Paperboard-carton	\$0.060	\$0.065	\$0.070					No
	Baked goods	Breading products	Paperboard-carton	\$0.050	\$0.055	\$0.060					No
	Baked goods	Cakes/doughnuts/sweet rolls—fresh	Paperboard-carton	\$0.075	\$0.080	\$0.085					No
	Baked goods	Cakes/doughnuts/sweet rolls—frozen	Paperboard-carton	\$0.075	\$0.080	\$0.085					No
	Baked goods	Cookies/cones	Plastic bag-opaque	\$0.055	\$0.060	\$0.065					No

(continued)

Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (cont'd)	Baked goods	Crackers	Paperboard-carton	\$0.075	\$0.080	\$0.085					No
	Baked goods	Mexican shells/tortillas	Plastic bag-resealable	\$0.100	\$0.110	\$0.120					No
	Baking ingredients	Baking mixes	Paperboard-carton	\$0.040	\$0.045	\$0.050					No
	Baking ingredients	Baking supplies	Foil-backed paper-pouch	\$0.020	\$0.025	\$0.030	Plastic bag-opaque	\$0.020	\$0.025	\$0.030	No
	Baking ingredients	Bread/cookie/dough products—frozen	Plastic bag-clear	\$0.040	\$0.050	\$0.060					No
	Baking ingredients	Dough products—refrigerated	Paper-label	\$0.050	\$0.060	\$0.070					No
	Baking ingredients	Flour/corn meal	Paper-bag	\$0.050	\$0.055	\$0.060					No
	Beverages	Buttermilk—refrigerated	Gable-top carton	\$0.100	\$0.110	\$0.120					No
	Beverages	Carbonated beverages—low calorie	Plastic-label	\$0.030	\$0.035	\$0.040					No
	Beverages	Carbonated beverages—regular	Plastic-label	\$0.030	\$0.035	\$0.040					No
	Beverages	Cocktail mixes	Paper-label	\$0.050	\$0.060	\$0.070					No
	Beverages	Coffee—ground	Plastic-molded	\$0.200	\$0.230	\$0.260					No
	Beverages	Coffee—liquid	Aluminum can	\$0.080	\$0.090	\$0.100					No
	Beverages	Coffee—soluble	Paper-label	\$0.025	\$0.030	\$0.035					No
	Beverages	Coffee—whole bean	Foil-bag	\$0.120	\$0.140	\$0.160					No
	Beverages	Creamers—liquid	Plastic-label	\$0.055	\$0.060	\$0.065					No
	Beverages	Fruit drinks—frozen	Paper-label	\$0.055	\$0.060	\$0.065					No
	Beverages	Fruit drinks—refrigerated	Plastic-label	\$0.035	\$0.040	\$0.045					No
	Beverages	Fruit drinks—shelf stable	Plastic-label	\$0.040	\$0.045	\$0.050					No
	Beverages	Fruit juice—frozen	Paper-label	\$0.055	\$0.060	\$0.065					No
	Beverages	Fruit juice—refrigerated	Plastic-label	\$0.035	\$0.040	\$0.045					No
	Beverages	Fruit juice—shelf stable	Paper-label	\$0.050	\$0.060	\$0.070					No
	Beverages	Fruit punch bases/syrups	Plastic-label	\$0.015	\$0.018	\$0.020					No

(continued)

Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (cont'd)	Beverages	Ice	Plastic bag-clear	\$0.060	\$0.065	\$0.070					No
	Beverages	Milk—flavored—refrigerated	Plastic-label	\$0.040	\$0.045	\$0.050					No
	Beverages	Milk—refrigerated	Paper-label	\$0.030	\$0.040	\$0.050					No
	Beverages	Milk—shelf stable	Aseptic carton	\$0.080	\$0.090	\$0.100					No
	Beverages	Milk/creamers—powdered	Plastic-label	\$0.055	\$0.060	\$0.065					No
	Beverages	Milk/water—additives	Paperboard-carton	\$0.020	\$0.025	\$0.030	Foil-backed paper-pouch	\$0.005	\$0.006	\$0.007	No
	Beverages	Noncarbonated beverages—mixes	Paper-pouch	\$0.010	\$0.020	\$0.030					No
	Beverages	Shakes/drinks—remaining—nonrefrigerated	Aluminum can	\$0.080	\$0.090	\$0.100					No
	Beverages	Shakes/drinks/eggnog—refrigerated	Gable-top carton	\$0.120	\$0.130	\$0.140					No
	Beverages	Tea—bags/package	Paperboard-carton	\$0.030	\$0.035	\$0.040	Paper-pouch	\$0.002	\$0.003	\$0.004	No
	Beverages	Tea—herbal	Paperboard-carton	\$0.030	\$0.035	\$0.040	Paper-pouch	\$0.002	\$0.003	\$0.004	No
	Beverages	Tea—instant	Plastic-label	\$0.040	\$0.045	\$0.050					No
	Beverages	Tea—liquid	Aluminum can	\$0.080	\$0.090	\$0.100					No
	Beverages	Vegetable juice—shelf stable	Paper-label	\$0.060	\$0.080	\$0.100					No
	Beverages	Water—bottled	Plastic-label	\$0.020	\$0.030	\$0.040					No
	Beverages	Water—bottled/caloric	Plastic-label	\$0.040	\$0.045	\$0.050					No
	Beverages	Water—bottled/low calorie	Plastic-label	\$0.040	\$0.045	\$0.050					No
	Beverages	Wine—nonalcoholic	Paper-label	\$0.040	\$0.045	\$0.050					No
	Breakfast foods	Breakfast bars/pastries/powders	Paperboard-carton	\$0.060	\$0.070	\$0.080	Foil-backed paper-pouch	\$0.015	\$0.020	\$0.025	No
	Breakfast foods	Breakfasts—frozen	Gable-top carton	\$0.100	\$0.110	\$0.120					No
	Breakfast foods	Cereal—hot	Paper-label	\$0.060	\$0.080	\$0.100					No

(continued)

Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (cont'd)	Breakfast foods	Cereal—ready to eat	Paperboard-carton	\$0.100	\$0.110	\$0.120					No
	Breakfast foods	Waffle/pancake/French toast—frozen	Paperboard-carton	\$0.060	\$0.065	\$0.070					No
	Candy & gum	Candy—chocolate	Paper-bag	\$0.020	\$0.025	\$0.030					No
	Candy & gum	Candy—dietetic	Tin steel container	\$0.110	\$0.130	\$0.150					No
	Candy & gum	Candy—nonchocolate	Plastic bag-clear	\$0.045	\$0.050	\$0.055					No
	Candy & gum	Gum—low calorie	Paper-label	\$0.020	\$0.025	\$0.030					No
	Candy & gum	Gum—regular	Paper-label	\$0.020	\$0.025	\$0.030					No
	Condiments/dips/spreads	Condiments	Paper-label	\$0.040	\$0.045	\$0.050					No
	Condiments/dips/spreads	Dips—refrigerated	Plastic-molded	\$0.050	\$0.060	\$0.070					No
	Condiments/dips/spreads	Dips—shelf stable	Paper-label	\$0.030	\$0.035	\$0.040					No
	Condiments/dips/spreads	Extracts	Paperboard-carton	\$0.010	\$0.015	\$0.020	Paper-label	\$0.005	\$0.006	\$0.007	No
	Condiments/dips/spreads	Honey	Paper-label	\$0.020	\$0.025	\$0.030					No
	Condiments/dips/spreads	Jams/jellies	Paper-label	\$0.040	\$0.045	\$0.050					No
	Condiments/dips/spreads	Jams/spreads—remaining	Paper-label	\$0.040	\$0.045	\$0.050					No
	Condiments/dips/spreads	Marinades/tenderizers/MSG	Foil-backed paper	\$0.030	\$0.035	\$0.040					No
	Condiments/dips/spreads	Mayonnaise	Paper-label	\$0.050	\$0.055	\$0.060					No
	Condiments/dips/spreads	Peanut butter	Paper-label	\$0.050	\$0.055	\$0.060					No
	Condiments/dips/spreads	Pepper	Tin steel container	\$0.090	\$0.110	\$0.130					No
	Condiments/dips/spreads	Pickles/olives/relishes	Paper-label	\$0.040	\$0.050	\$0.060					No
	Condiments/dips/spreads	Salt	Paper-label	\$0.025	\$0.030	\$0.035					No

(continued)

Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (cont'd)	Condiments/dips/spreads	Salt—substitutes	Paperboard-molded	\$0.020	\$0.025	\$0.030					No
	Condiments/dips/spreads	Sandwich spreads/horseradish/sauerkraut—refrigerated	Plastic bag-clear	\$0.045	\$0.050	\$0.055					No
	Condiments/dips/spreads	Seasoning—dry	Paper-label	\$0.020	\$0.025	\$0.030					No
	Condiments/dips/spreads	Spices/seasonings—remaining	Paper-label	\$0.020	\$0.025	\$0.030					No
	Condiments/dips/spreads	Spreads—refrigerated	Paper-label	\$0.035	\$0.040	\$0.045					No
	Dairy foods	Butter	Paperboard-carton	\$0.030	\$0.035	\$0.040					No
	Dairy foods	Cheese—cottage/farmers/ricotta	Plastic-molded	\$0.030	\$0.040	\$0.050					No
	Dairy foods	Cheese—grated/shredded	Plastic bag-resealable	\$0.070	\$0.080	\$0.090					No
	Dairy foods	Cheese—natural	Plastic sheet	\$0.030	\$0.040	\$0.050					No
	Dairy foods	Cheese—processed	Paperboard-carton	\$0.025	\$0.030	\$0.035					No
	Dairy foods	Cheese—specialty/imported	Plastic sheet	\$0.035	\$0.045	\$0.055					No
	Dairy foods	Cream—refrigerated	Gable-top carton	\$0.110	\$0.120	\$0.130					No
	Dairy foods	Frozen novelties	Paperboard-carton	\$0.040	\$0.045	\$0.050					No
	Dairy foods	Ice cream	Paperboard-molded	\$0.085	\$0.090	\$0.095					No
	Dairy foods	Ice milk/sherbet/yogurt—frozen	Paperboard-molded	\$0.075	\$0.080	\$0.085					No
	Dairy foods	Ice pops—unfrozen	Paperboard-carton	\$0.060	\$0.065	\$0.070					No
	Dairy foods	Sour cream	Plastic-molded	\$0.030	\$0.040	\$0.050					No
	Dairy foods	Whipping cream	Aseptic carton	\$0.080	\$0.090	\$0.100					No

(continued)

Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (cont'd)	Dairy foods	Yogurt—refrigerated	Plastic-molded	\$0.025	\$0.030	\$0.035					No
	Dairy foods	Yogurt—shakes/drinks—refrigerated	Paperboard-carton	\$0.050	\$0.055	\$0.060	Plastic-label	\$0.070	\$0.080	\$0.090	No
	Desserts	Cheesecake/pies—fresh	Paper-pouch	\$0.020	\$0.025	\$0.030					No
	Desserts	Cheesecake/pies—frozen	Paperboard-carton	\$0.035	\$0.040	\$0.045					No
	Desserts	Dessert—RTS single serving	Paperboard-carton	\$0.030	\$0.040	\$0.050	Plastic-label	\$0.007	\$0.009	\$0.011	No
	Desserts	Desserts/toppings—frozen	Plastic-molded	\$0.060	\$0.070	\$0.080					No
	Desserts	Gelatin/pudding—mixes—diet	Paperboard-carton	\$0.015	\$0.018	\$0.020					No
	Desserts	Gelatin/pudding—mixes—sweetened	Paperboard-carton	\$0.015	\$0.018	\$0.020					No
	Desserts	Pudding—refrigerated	Plastic-molded	\$0.040	\$0.045	\$0.050					No
	Desserts	Syrups/toppings—shelf stable	Plastic-molded	\$0.120	\$0.140	\$0.160					No
	Desserts	Toppings—refrigerated	Plastic-label	\$0.040	\$0.045	\$0.050					No
	Dressings & sauces	Salad dressing—liquid	Paper-label	\$0.035	\$0.040	\$0.045					No
	Dressings & sauces	Salad dressing—reduced/low calorie	Paper-label	\$0.035	\$0.040	\$0.045					No
	Dressings & sauces	Salad dressing—refrigerated	Plastic-label	\$0.050	\$0.055	\$0.060					No
	Dressings & sauces	Salad dressings/toppings—dry	Paper-label	\$0.020	\$0.025	\$0.030					No
	Dressings & sauces	Sauce—barbecue	Paper-label	\$0.035	\$0.040	\$0.045					No
	Dressings & sauces	Sauce—Mexican	Paper-label	\$0.035	\$0.040	\$0.045					No
	Dressings & sauces	Sauce—spaghetti/marinara	Paper-label	\$0.050	\$0.055	\$0.060					No
	Dressings & sauces	Sauce/gravy—mixes	Foil-backed paper	\$0.035	\$0.040	\$0.045					No
	Dressings & sauces	Sauce/gravy/glaze	Paper-label	\$0.035	\$0.040	\$0.045					No
	Dressings & sauces	Vinegar/cooking wine	Paper-label	\$0.040	\$0.045	\$0.050					No
	Eggs	Eggs—fresh	Foam carton	\$0.020	\$0.030	\$0.040					No
	Entrees	Combination lunches	Paper-label	\$0.030	\$0.040	\$0.050					No

(continued)



Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (cont'd)	Entrees	Entrees—frozen	Paperboard-carton	\$0.040	\$0.045	\$0.050					No
	Entrees	Entrees—refrigerated	Paperboard-carton	\$0.050	\$0.055	\$0.060					No
	Entrees	Prepared foods—canned/shelf stable	Paper-label	\$0.007	\$0.009	\$0.010					No
	Entrees	Sandwiches—refrigerated/frozen	Paperboard-carton	\$0.040	\$0.050	\$0.060					No
	Fats & oils	Cooking sprays	Tin steel container	\$0.180	\$0.200	\$0.220					No
	Fats & oils	Lard/shortening	Paper-label	\$0.075	\$0.085	\$0.095					No
	Fats & oils	Margarine/spreads	Paperboard-carton	\$0.030	\$0.035	\$0.040					No
	Fats & oils	Oils—olive/salad/cooking	Paper-label	\$0.020	\$0.025	\$0.030					No
	Fruits & vegetables	Beans—canned	Paper-label	\$0.008	\$0.009	\$0.010					No
	Fruits & vegetables	Beans/peas/lentils/barley—dry	Plastic bag-clear	\$0.045	\$0.050	\$0.055					No
	Fruits & vegetables	Fruit—canned	Paper-label	\$0.008	\$0.010	\$0.012					No
	Fruits & vegetables	Fruit—dried	Paperboard-carton	\$0.040	\$0.045	\$0.050	Foil-backed paper—pouch	\$0.015	\$0.020	\$0.025	No
	Fruits & vegetables	Fruit—fresh	Paper-label	\$0.005	\$0.007	\$0.009					No
	Fruits & vegetables	Fruit/fruit salad—refrigerated	Plastic-label	\$0.040	\$0.045	\$0.050					No
	Fruits & vegetables	Fruits—frozen	Plastic bag-resealable	\$0.080	\$0.100	\$0.120					No
	Fruits & vegetables	Garlic/herbs—fresh	Paperboard-sleeve	\$0.020	\$0.030	\$0.040					No
	Fruits & vegetables	Leafy greens—fresh	Plastic-sheet	\$0.030	\$0.035	\$0.040					No
	Fruits & vegetables	Potatoes—canned	Paper-label	\$0.008	\$0.009	\$0.010					No
	Fruits & vegetables	Potatoes—dehydrated	Paperboard-carton	\$0.080	\$0.090	\$0.100					No
	Fruits & vegetables	Potatoes—fresh	Plastic bag-opaque	\$0.150	\$0.170	\$0.190					No

(continued)

Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (cont'd)	Fruits & vegetables	Potatoes—frozen	Paperboard-sleeve	\$0.050	\$0.060	\$0.070					No
	Fruits & vegetables	Tomatoes—canned	Paper-label	\$0.008	\$0.009	\$0.010					No
	Fruits & vegetables	Vegetables—canned	Paper-label	\$0.008	\$0.009	\$0.010					No
	Fruits & vegetables	Vegetables—fresh	Paper-label	\$0.010	\$0.011	\$0.012					No
	Fruits & vegetables	Vegetables—frozen	Plastic bag-opaque	\$0.050	\$0.060	\$0.070					No
	Fruits & vegetables	Vegetables—precut salad mix—fresh	Plastic bag-clear	\$0.070	\$0.080	\$0.090					No
	Infant foods	Baby food	Paper-label	\$0.005	\$0.007	\$0.009					No
	Infant foods	Infant formulas	Paper-label	\$0.060	\$0.070	\$0.080					No
	Infant foods	Juices—baby	Paper-label	\$0.050	\$0.060	\$0.070					No
	Meat & poultry	Meat—frozen	Paperboard-carton	\$0.050	\$0.060	\$0.070					No
	Meat & poultry	Meat/poultry—canned	Paper-label	\$0.008	\$0.009	\$0.010					No
	Meat & poultry	Poultry—frozen	Plastic-sheet	\$0.040	\$0.050	\$0.060					No
	Pizza	Pizza—frozen	Paperboard-carton	\$0.070	\$0.080	\$0.090					No
	Pizza	Pizza—refrigerated	Paper-label	\$0.010	\$0.012	\$0.014					No
	Seafood	Fish—frozen	Plastic bag-opaque	\$0.090	\$0.100	\$0.110					No
	Seafood	Seafood—canned	Paper-label	\$0.008	\$0.009	\$0.010					No
	Seafood	Seafood—refrigerated	Plastic bag-resealable	\$0.070	\$0.080	\$0.090					No
	Seafood	Seafood—remaining—frozen	Paperboard-carton	\$0.050	\$0.060	\$0.070					No
	Seafood	Shrimp—frozen	Paperboard-carton	\$0.050	\$0.060	\$0.070					No
	Side dishes & starches	Hors d'oeuvres/snacks—frozen	Paperboard-carton	\$0.100	\$0.110	\$0.120					No
	Side dishes & starches	Pasta/noodles—dry	Paperboard-carton	\$0.050	\$0.060	\$0.070					No
	Side dishes & starches	Prepared foods—dry mixes	Plastic-molded	\$0.050	\$0.055	\$0.060					No
	Side dishes & starches	Prepared foods—remaining—frozen/refrigerated	Paperboard-carton	\$0.120	\$0.140	\$0.160					No

(continued)

Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (cont'd)	Side dishes & starches	Ready-made salads	Foil-top	\$0.040	\$0.050	\$0.060					No
	Side dishes & starches	Rice—instant/package	Paperboard-carton	\$0.050	\$0.060	\$0.070					No
	Side dishes & starches	Vegetables—formulated/breaded—frozen	Paperboard-carton	\$0.045	\$0.050	\$0.055					No
	Snack foods	Nuts—cans/jars	Paper-label	\$0.010	\$0.020	\$0.030					No
	Snack foods	Nuts—cello wrapped	Plastic bag-clear	\$0.010	\$0.020	\$0.030					No
	Snack foods	Nuts—unshelled	Plastic bag-clear	\$0.050	\$0.060	\$0.070					No
	Snack foods	Popcorn—unpopped	Paperboard-carton	\$0.040	\$0.045	\$0.050	Paper-pouch	\$0.020	\$0.025	\$0.030	No
	Snack foods	Snacks—caramel corn/popped popcorn	Paperboard-carton	\$0.020	\$0.030	\$0.040					No
	Snack foods	Snacks—health bars & sticks	Foil-backed paper	\$0.030	\$0.035	\$0.040					No
	Snack foods	Snacks—meat	Plastic bag-resealable	\$0.070	\$0.080	\$0.090					No
	Snack foods	Snacks—remaining	Plastic bag-opaque	\$0.060	\$0.070	\$0.080					No
	Snack foods	Snacks—salty	Plastic bag-opaque	\$0.060	\$0.070	\$0.080					No
	Snack foods	Snacks—trail mixes	Paperboard-carton	\$0.030	\$0.035	\$0.040	Foil-bag	\$0.005	\$0.007	\$0.009	No
	Soups	Soup—canned	Paper-label	\$0.007	\$0.008	\$0.009					No
	Soups	Soup—dry	Paperboard-sleeve	\$0.008	\$0.010	\$0.012					No
	Sweeteners	Sugar	Paper-bag	\$0.055	\$0.060	\$0.065					No
	Sweeteners	Sugar—substitutes	Paperboard-carton	\$0.040	\$0.045	\$0.050	Paper-pouch	\$0.002	\$0.003	\$0.004	No
	Sweeteners	Table syrups/molasses	Paper-label	\$0.030	\$0.040	\$0.050					No

(continued)

Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
OTCs	Acne remedies	Acne remedies	Plastic-Carton	\$0.030	\$0.040	\$0.050	Plastic-label	\$0.015	\$0.020	\$0.025	No
	Cough and cold remedies	Cold remedies—adult	Paperboard-carton	\$0.015	\$0.020	\$0.025	Foil backed paper-blister pack	\$0.010	\$0.020	\$0.030	Yes
	Cough and cold remedies	Cold remedies—children	Paperboard-carton	\$0.030	\$0.035	\$0.040	Paper-label	\$0.008	\$0.010	\$0.012	Yes
	Cough and cold remedies	Cough and cold throat sprays	Paper-label	\$0.008	\$0.010	\$0.012					No
	Cough and cold remedies	Cough drops lozenges	Plastic bag-resealable	\$0.040	\$0.045	\$0.050					No
	Cough and cold remedies	Cough syrups and tablets	Paperboard-carton	\$0.015	\$0.020	\$0.025	Foil backed paper-blister pack	\$0.010	\$0.020	\$0.030	Yes
	Cough and cold remedies	Nasal products	Paperboard-sheet	\$0.015	\$0.020	\$0.025	Plastic-sheet	\$0.014	\$0.017	\$0.020	Yes
	Cough and cold remedies	Sinus remedies	Paperboard-carton	\$0.020	\$0.025	\$0.030	Foil backed paper-blister pack	\$0.020	\$0.030	\$0.040	Yes
	Deodorant (antiperspirant)	Deodorant—aerosol (OTC)	Tin steel container	\$0.180	\$0.200	\$0.220					No
	Deodorant (antiperspirant)	Deodorant—roll-on (OTC)	Plastic-label	\$0.015	\$0.020	\$0.025					No
	Deodorant (antiperspirant)	Deodorant—stick/solid (OTC)	Plastic-label	\$0.015	\$0.020	\$0.025					No
	Deodorant (antiperspirant)	Remaining deodorants (OTC)	Plastic-label	\$0.012	\$0.017	\$0.022					No
	Eye care	Contact lens solution	Paperboard-carton	\$0.035	\$0.040	\$0.045	Paper-label	\$0.010	\$0.012	\$0.014	Yes
	Eye care	Eye care—remaining	Paperboard-carton	\$0.010	\$0.015	\$0.020	Plastic-label	\$0.010	\$0.013	\$0.016	No
	Eye care	Eye drops & lotions	Paperboard-carton	\$0.010	\$0.015	\$0.020	Paper-label	\$0.003	\$0.005	\$0.007	Yes
	Feminine hygiene	Remaining feminine hygiene (OTC)	Paperboard-carton	\$0.030	\$0.035	\$0.040	Plastic-tube	\$0.120	\$0.140	\$0.160	Yes
	First aid	Adhesive bandages (medicated)	Paperboard-carton	\$0.020	\$0.025	\$0.030	Paper	\$0.010	\$0.015	\$0.020	No

(continued)

Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
OTCs (cont'd)	First aid	First aid—germicidal antiseptics	Paper-label	\$0.040	\$0.045	\$0.050	Foil backed paper-pouch	\$0.010	\$0.015	\$0.020	No
	First aid	First aid—hydrocortisones	Paperboard-carton	\$0.020	\$0.025	\$0.030	Plastic-tube	\$0.100	\$0.120	\$0.140	No
	First aid	First aid—treatments	Paperboard-carton	\$0.020	\$0.025	\$0.030	Plastic-tube	\$0.100	\$0.120	\$0.140	No
	Hair care	Hair growth products	Plastic-sheet	\$0.100	\$0.120	\$0.140	Aluminum can	\$0.100	\$0.120	\$0.140	Yes
	Hair care	Shampoo (medicated)	Plastic-label	\$0.020	\$0.025	\$0.030					No
	Oral hygiene	Denture adhesives	Paperboard-carton	\$0.015	\$0.020	\$0.025	Plastic-tube	\$0.180	\$0.200	\$0.220	Yes
	Oral hygiene	Oral care combinations—OTC	Plastic-tube	\$0.015	\$0.020	\$0.025	Paperboard-sheet	\$0.100	\$0.120	\$0.140	No
	Oral hygiene	Oral rinse and antiseptic	Plastic-label	\$0.006	\$0.009	\$0.012					No
	Oral hygiene	Toothpaste (fluoride)	Paperboard-carton	\$0.025	\$0.030	\$0.035	Plastic-tube	\$0.380	\$0.400	\$0.420	No
	Pain remedies	Pain remedies	Paperboard-carton	\$0.015	\$0.020	\$0.025	Paper-label	\$0.008	\$0.010	\$0.012	Yes
	Pain remedies	Pain remedies—children's	Paperboard-carton	\$0.030	\$0.035	\$0.040	Paper-label	\$0.008	\$0.010	\$0.012	Yes
	Pain remedies	Pain remedies—urinary tract	Paperboard-carton	\$0.025	\$0.030	\$0.035	Paper-label	\$0.008	\$0.010	\$0.012	Yes
	Pain remedies	Tranquilizers/calmatives	Paperboard-carton	\$0.030	\$0.035	\$0.040	Paper-label	\$0.008	\$0.010	\$0.012	No
	Personal soap/bath need	Hand cleaners and hand sanitizers	Plastic-label	\$0.015	\$0.020	\$0.025					No
	Preparations/ remedies	Analgesic & chest rubs	Paperboard-carton	\$0.015	\$0.020	\$0.025	Paper-label	\$0.008	\$0.010	\$0.012	No
	Preparations/ remedies	Antacids	Paperboard-carton	\$0.015	\$0.020	\$0.025	Foil backed paper-blister pack	\$0.010	\$0.020	\$0.030	No
	Preparations/ remedies	Antigas products	Paperboard-carton	\$0.015	\$0.020	\$0.025	Foil backed paper-blister pack	\$0.010	\$0.020	\$0.030	No
	Preparations/ remedies	Antisleep products	Paperboard-carton	\$0.030	\$0.035	\$0.040	Paper-label	\$0.008	\$0.010	\$0.012	Yes

(continued)

**Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)**

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
OTCs (cont'd)	Preparations/ remedies	Antismoking products	Paperboard-carton	\$0.035	\$0.040	\$0.045	Foil backed paper-blister pack	\$0.010	\$0.020	\$0.030	Yes
	Preparations/ remedies	Bronchial remedies	Paperboard-carton	\$0.015	\$0.020	\$0.025	Paper-label	\$0.005	\$0.007	\$0.009	Yes
	Preparations/ remedies	Dairy digestive aids	Paperboard-carton	\$0.035	\$0.040	\$0.045	Foil backed paper-blister pack	\$0.020	\$0.030	\$0.040	Yes
	Preparations/ remedies	Diarrhea remedies	Paperboard-carton	\$0.020	\$0.025	\$0.030	Foil backed paper-blister pack	\$0.010	\$0.020	\$0.030	Yes
	Preparations/ remedies	Diuretic remedies	Paperboard-carton	\$0.025	\$0.030	\$0.035	Foil backed paper-blister pack	\$0.020	\$0.030	\$0.040	Yes
	Preparations/ remedies	Ear drops	Paperboard-carton	\$0.010	\$0.015	\$0.020	Paper-label	\$0.003	\$0.005	\$0.007	Yes
	Preparations/ remedies	Foot preparations—athlete's foot	Tin steel container	\$0.120	\$0.140	\$0.160					No
	Preparations/ remedies	Ipecac product	Paperboard-carton	\$0.030	\$0.035	\$0.040	Paper-label	\$0.008	\$0.010	\$0.012	Yes
	Preparations/ remedies	Jock itch products	Paperboard-carton	\$0.020	\$0.025	\$0.030	Plastic-tube	\$0.100	\$0.120	\$0.140	Yes
	Preparations/ remedies	Laxatives	Paper-label	\$0.018	\$0.021	\$0.024					No
	Preparations/ remedies	Lip remedies—cold sore/fever blister	Plastic-tube	\$0.020	\$0.030	\$0.040					No
	Preparations/ remedies	Medicated products	Paperboard-carton	\$0.020	\$0.025	\$0.030	Plastic-tube	\$0.100	\$0.120	\$0.140	No
	Preparations/ remedies	Motion sickness preventatives	Paperboard-carton	\$0.010	\$0.015	\$0.020	Foil backed paper-blister pack	\$0.010	\$0.020	\$0.030	No
	Preparations/ remedies	Petroleum jelly	Plastic-label	\$0.016	\$0.021	\$0.026					No
	Preparations/ remedies	Psoriasis & eczema treatments	Paperboard-carton	\$0.025	\$0.030	\$0.035	Plastic-tube	\$0.100	\$0.120	\$0.140	Yes
	Preparations/ remedies	Rectal medication	Paperboard-carton	\$0.015	\$0.020	\$0.025	Plastic-tube	\$0.120	\$0.140	\$0.160	Yes

(continued)

Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
OTCs (cont'd)	Preparations/ remedies	Sleeping aids	Paperboard-carton	\$0.020	\$0.025	\$0.030	Paper-label	\$0.008	\$0.010	\$0.012	Yes
	Preparations/ remedies	Tooth & gum analgesics	Paperboard-sheet	\$0.010	\$0.015	\$0.020	Plastic-tube	\$0.100	\$0.120	\$0.140	No
	Preparations/ remedies	Vaporizing products	Paperboard-carton	\$0.030	\$0.035	\$0.040	Paper-label	\$0.010	\$0.012	\$0.014	No
	Skin care preparations	Skin bleaching/toning products	Paperboard-carton	\$0.040	\$0.045	\$0.050	Foil-tube	\$0.180	\$0.200	\$0.220	No
	Skin care preparations	Suntan preparations—sunscreens & sunblock	Plastic-tube	\$0.120	\$0.140	\$0.160					No
Pet Foods	Pet care	Flea products	Paper-label	\$0.024	\$0.027	\$0.030					Yes
	Pet care	Pet incontinence product	Plastic-sheet	\$0.060	\$0.070	\$0.080					No
	Pet care	Pet treatments external	Paper-label	\$0.020	\$0.023	\$0.026					No
	Pet care	Pet treatments internal	Plastic bag-resealable	\$0.080	\$0.100	\$0.120					No
	Pet food	Cat food—dry	Paper-bag	\$0.160	\$0.165	\$0.170					No
	Pet food	Cat food—moist/wet	Paper-label	\$0.004	\$0.006	\$0.008					No
	Pet food	Dog food—dry	Plastic bag-opaque	\$0.450	\$0.550	\$0.650					No
	Pet food	Dog food—moist/wet	plastic-molded	\$0.030	\$0.040	\$0.050					No
	Pet food	Domestic bird food	Plastic bag-clear	\$0.080	\$0.090	\$0.100					No
	Pet food	Other pet food	Plastic-label	\$0.010	\$0.012	\$0.014					No
	Pet food	Pet treats	Paperboard-carton	\$0.080	\$0.085	\$0.090					No
Retail Medical Devices	Adult incontinence	Adult incontinence	Plastic bag-opaque	\$0.060	\$0.070	\$0.080					No
	Baby needs	Baby and nursing accessories	Paperboard-sheet	\$0.020	\$0.025	\$0.030					No
	Baby needs	Baby bottles & nipples	Paperboard-carton	\$0.030	\$0.035	\$0.040					No
	Breathing aids—external	Breathing aids—external	Paperboard-carton	\$0.015	\$0.020	\$0.025	Paper	\$0.010	\$0.015	\$0.020	Yes
	Enemas—ready to use	Enemas—ready to use	Paperboard-carton	\$0.025	\$0.030	\$0.035	Plastic-label	\$0.010	\$0.013	\$0.016	Yes

(continued)

**Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)**

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Retail Medical Devices (cont'd)	Family planning	Contraceptives—female	Paperboard-carton	\$0.015	\$0.020	\$0.025	Plastic-sheet	\$0.020	\$0.030	\$0.040	Yes
	Family planning	Contraceptives—male	Paperboard-carton	\$0.015	\$0.020	\$0.025	Foil backed paper-pouch	\$0.010	\$0.020	\$0.030	Yes
	Family planning	Family planning test kits	Paperboard-carton	\$0.020	\$0.025	\$0.030	Foil backed paper-pouch	\$0.030	\$0.040	\$0.050	Yes
	Feminine hygiene	Douches	Paperboard-carton	\$0.025	\$0.030	\$0.035	Plastic-label	\$0.018	\$0.021	\$0.024	Yes
	Feminine hygiene	Remaining feminine hygiene (medical device)	Paperboard-carton	\$0.050	\$0.055	\$0.060	Plastic-label	\$0.010	\$0.012	\$0.014	No
	Feminine hygiene	Sanitary belts/panties/napkins	Plastic-sheet	\$0.060	\$0.070	\$0.080					No
	Feminine hygiene	Tampons	Paperboard-carton	\$0.030	\$0.035	\$0.040					No
	First aid	Adhesive bandages—liquid—powder—PA	Paperboard-carton	\$0.010	\$0.015	\$0.020	Paper-label	\$0.005	\$0.007	\$0.009	No
	First aid	Adhesive bandages (nonmedicated)	Paperboard-carton	\$0.020	\$0.025	\$0.030	Paper	\$0.010	\$0.015	\$0.020	No
	First aid	First aid—gauze & tape	Paperboard-sheet	\$0.015	\$0.020	\$0.025	Plastic-molded	\$0.030	\$0.040	\$0.050	No
	First aid	First aid—ice and heat pack	Paperboard-carton	\$0.035	\$0.040	\$0.045	Foil backed paper-pouch	\$0.030	\$0.040	\$0.050	Yes
	First aid	First aid—thermometers	Paperboard-sheet	\$0.015	\$0.020	\$0.025					No
	Foot care	Foot comfort products	Tin steel container	\$0.120	\$0.140	\$0.160					No
	Foot care	Foot preparations—remaining (medical device)	Plastic bag-clear	\$0.010	\$0.015	\$0.020					No
	Insulin syringes	Insulin syringes	Paperboard-carton	\$0.040	\$0.045	\$0.050	Paper	\$0.010	\$0.020	\$0.030	Yes
	Medical accessory—remaining	Medical accessory—remaining	Paperboard—carton	\$0.040	\$0.050	\$0.060					No

(continued)



Table 4-13. Per-Unit Label Costs for the Labeling Cost Model, 2014 (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit			Secondary Package Label	Secondary Cost per Unit			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Retail Medical Devices (cont'd)	Medical wrap and brace	Medical wrap and brace	Paperboard—carton	\$0.040	\$0.050	\$0.060					No
	Oral hygiene	Dental accessories	Paperboard-sheet	\$0.010	\$0.015	\$0.020					No
	Oral hygiene	Dental floss	Paper-label	\$0.005	\$0.001	\$0.015	Plastic-molded	\$0.060	\$0.070	\$0.080	No
	Oral hygiene	Oral care combinations—medical device	Plastic-tube	\$0.015	\$0.020	\$0.025					No
	Oral hygiene	Oral hygiene appliance and accessory	Paperboard-sheet	\$0.015	\$0.020	\$0.025					No
	Oral hygiene	Oral hygiene brushes	Paperboard-sheet	\$0.030	\$0.035	\$0.040					No
	Test kits	Blood pressure kit and accessory	Paperboard-carton	\$0.040	\$0.050	\$0.060					Yes
	Test kits	Blood urine stool test products	Paperboard-carton	\$0.030	\$0.035	\$0.040	Paper backed-blister pack	\$0.020	\$0.030	\$0.040	Yes
Tobacco Products	Tobacco & accessories	Cigarette and cigar paper	Paperboard—carton	\$0.025	\$0.030	\$0.035					No
	Tobacco & accessories	Cigarettes	Paperboard-cigarette carton	\$0.025	\$0.030	\$0.035					No
	Tobacco & accessories	Cigars	Paperboard-carton	\$0.015	\$0.020	\$0.025					No
	Tobacco & accessories	Tobacco—chewing	Paper-label	\$0.004	\$0.006	\$0.008					No
	Tobacco & accessories	Tobacco—smoking	Paperboard-carton	\$0.015	\$0.020	\$0.025					No

Source: Cost estimates were provided by PTIS in 2014.

#### **4.4.4 Accounting for Uncertainty in the Cost Estimates**

In the sections above, we noted the assumptions regarding the interpretation of the low, middle, and high cost estimates for each component of costs in the model. Because the model allows users the option of revising wage rates directly in the model, it does not jointly simulate the final cost ranges by drawing from the distribution of all costs in the model. However, the distribution of individual cost components is accounted for in a manner consistent with previous versions of the model.

To recap the discussions in this section, the probability ranges of each component of costs are as follows:

- Per-UPC label change costs represent 5th percentile, mean, and 95th percentile estimates simulated using a triangular distribution in @Risk.
- Per-formulation costs (analytical tests and market tests) represent 5th percentile, mean, and 95th percentile estimates simulated using a triangular distribution in @Risk.
- Wage rates represent 10th percentile, mean, and 90th percentile estimates as reported directly by BLS.
- Per-unit costs of printed labels and packaging; peel-back labels; and stickers represent low, medium, and high estimates. Probability ranges were not generated for these values because the values are small; thus, rounding the simulated values to the nearest cents would have resulted in similar values to the original estimates.

---

### **4.5 ASSUMPTIONS AND LIMITATIONS OF THE METHODOLOGY**

In the previous sections, we described assumptions and limitations in developing the structure of the model and the data for the calculations. To summarize, key operational assumptions and limitations for the labeling cost model include the following:

- The number of UPCs and sales volumes calculated from the scanner data for 2008 and 2012 (based on product category) are assumed to be representative of a typical year.
- Costs incurred on a per-UPC basis include administrative, graphic design, prepress, plate cutting, and recordkeeping.

- Administrative costs are incurred to some extent for all affected UPCs even if the manufacturer can coordinate the change with a planned change because of the time required to interpret and respond to the labeling change requirement.
- The proportion of labeling changes that cannot be coordinated with a planned labeling change is lower for branded versus private-label products.
- The proportion of labeling changes that cannot be coordinated with a planned labeling change is the same for minor changes, major changes, and changes to package inserts.
- Extensive labeling changes and addition of package inserts cannot be coordinated with planned labeling changes.
- Costs incurred on a per-formulation basis include analytical and market testing costs.
- Stickers are applied in the case of extremely short compliance periods (in contrast to possibly discontinuing sales until new labels or packages can be printed).
- Costs of making changes for private-label and branded products are somewhat similar (within the range of the cost estimates provided).
- Costs of making changes for small and large companies are somewhat similar (within the range of the cost estimates provided).
- Costs do not account for efficiencies that may occur when manufacturers relabel multiple UPCs at the same time.

# 5 Instructions for Using the Labeling Cost Model

In this section, we provide a brief overview of the structure of the FDA Labeling Cost Model, provide instructions for selecting the model inputs, and describe the model's output.

## 5.1 AN OPERATIONAL OVERVIEW OF THE MODEL

In addition to data updates, the major changes to the model compared with the most recent version are the

- option to save and retrieve scenarios and
- option to alter wage rates.

The FDA Labeling Cost Model is a stand-alone program and thus can be run on any computer with Microsoft Excel 2010. The model contains aggregated Nielsen ScanTrack data as well as cost estimates compiled from interviews with manufacturers from industries represented in the model and PTIS. These cost estimates include labor and materials expenses associated with the various steps in making labeling changes to consumer products under FDA's jurisdiction. Users must select the product categories affected by a regulatory change (by model category/subcategory or by NAICS code), the type of labeling change, and the compliance period. The other user inputs are optional, including adjusting the percentage of affected products, analytical testing costs, market testing costs, recordkeeping costs, wage rates, and inflation factor. Users have the option of running the model with the existing input data or modifying any of the default values. When users run the model, it generates estimates of the costs of industry compliance per UPC and overall.

The model was developed in Microsoft Excel with Visual Basic components. It contains several tabs (worksheets) representing the user inputs, data sheets, and model outputs. The input and data worksheets (COLOR tabs in the model) are as follows:

- **Start:** Directs the user to the main menu to select or enter inputs in the model

- **Product:** Contains the UPC counts, formulas, and package-label types used to drive the model
- **Label Change Costs:** Contains the specific cost estimates for each type of change used to calculate industrywide costs
- **Print Method:** Contains estimates of the percentage distribution of printing method across each package-label type for calculating a weighted average cost of labeling changes across printing methods used for the label or package material
- **Coordination:** Contains default estimates of the percentage of regulatory labeling changes that cannot be coordinated with planned changes by FDA category (can be modified by the user)
- **Package:** Contains package-label types and respective cost estimates for each subcategory according to the package-label type identified as the subcategory's top-selling product (used for calculating discarded inventory costs)
- **Package Inserts:** Contains sales information for each subcategory and stores calculated costs
- **Peel-Back Labels:** Contains sales information for each subcategory and cost estimates for peel-back labels (proxy for increased package size) and stores calculated costs
- **Analytical Costs:** Contains cost estimates for analytical tests conducted by manufacturers
- **Market Test Costs:** Contains cost estimates for market testing by manufacturers, including focus groups and quantitative testing
- **Inventory:** Contains percentage estimates of materials on hand based on the selected compliance period for a regulation by branded products versus private-label products
- **Labor Costs:** Contains labor hours and consultant costs for each type of change

The output worksheets are as follows:

- **Summary:** Provides a summary of the user inputs for the model run
- **Detailed Costs:** Provides cost breakdowns for each selected subcategory detailed by private-label versus branded products, including the following:

- Numbers of UPCs, formulas, and sales units delineated by whether the change could be coordinated with a planned change
- Range of cost estimates for each type of cost incurred per coordinated and uncoordinated UPC
- **Aggregate Costs:** Provides range of cost estimates for each type of cost incurred for each subcategory selected in the model inputs
- **Package Insert Costs:** Provide range of annual cost estimates for adding package inserts to products that previously did not have them (if applicable)
- **Peel-Back Label Costs:** Provides range of annual cost estimates for adding peel-back labels to products that previously did not have them (if applicable)
- **Data:** Provides detailed data for each subcategory selected in the model by branded products versus private-label products (provided in the event that the user would prefer to summarize costs differently than the output summaries included in the model)

---

## 5.2 SELECTING MODEL INPUTS AND RUNNING THE MODEL

To run the Labeling Cost Model, open the Excel file **FDA Labeling Cost Model 2014.xlsm**. If a warning about macros appears, click **Enable Macros**. The file will open to the Main Menu selection screen (see Figure 5-1).

Note that you may click **Exit** at any time on the Main Menu screen to exit the model, and you may click **Reset All Selections** to clear all of your selections on every menu. The **More Info** buttons on the right side of the Main Menu or at the bottom of each input menu can be used to obtain additional instructions or information for each of the model inputs.

Figure 5-1. Main Menu Selection Screen

**FDA Labeling Cost Model**

The FDA Labeling Cost Model provides estimates of the costs of changing labeling information on retail products under FDA's jurisdiction. Data on the number of labels and unit sales are based on 2012 Nielsen scanner data for foods, dietary supplements, and pet foods and 2008 Nielsen scanner data for cosmetics, OTC medications, retail medical devices, and tobacco products and accessories. Cost data are based on industry-provided data obtained in 2014.

**Instructions:**  
Follow each step below to select the model inputs that most closely correspond to the required labeling change.

**Load Saved Scenario**

**Part 1. Select products and type of change**

a. Affected products (required).....	<input type="button" value="Select by Type"/> or <input type="button" value="Select by NAICS"/>	<input type="button" value="More Info"/>
b. Percentages of affected products within product subcategories (optional).....	<input type="button" value="Enter Percentages"/>	<input type="button" value="More Info"/>
c. Type of labeling change (required) .....	<input type="button" value="Select Change"/>	<input type="button" value="More Info"/>

**Part 2. Select cost assumptions**

a. Analytical and market testing costs (optional).....	<input type="button" value="Enter Testing Costs"/>	<input type="button" value="More Info"/>
b. Wage rates (optional).....	<input type="button" value="Enter Wage Rates"/>	<input type="button" value="More Info"/>

**Part 3. Select compliance period assumptions for coordinating a labeling change (required).....**

	<input type="button" value="Select Compliance Period"/>	<input type="button" value="More Info"/>
--	---	--



**Part 4. Enter an inflation factor relative to 2014 (0.5 - 10.0) (optional).....**

	<input type="text" value="1.00"/>	<input type="button" value="More Info"/>
--	-----------------------------------	--

**Part 5. After selecting all inputs.....**

	<input type="button" value="Calculate Costs"/>	<input type="button" value="More Info"/>
--	--	--

Model results will be output to an Excel spreadsheet

### 5.2.1 Selection of Affected Products

#### Step 1 (required).

Select product categories and subcategories affected by the labeling regulation (by product type or by NAICS code).

The first step in running the model is to select the products affected by the regulatory labeling change. This can be done either by selecting product subcategories by type of product (e.g., foods, dietary supplements, cosmetics) or by NAICS code.

To choose the affected product subcategories by Product Type:

- On the Main Menu screen, click **Select by Type**.
- When the Affected Products by Type worksheet opens (see Figure 5-2), select **Product Type** from the drop-down menu at the top of the screen. The Product Category list will then populate with the product categories within the selected product type.
  - To select all product categories in a Product Type, click **Add All Subcategories** (see Figure 5-3).

OR

- To select individual product categories within the selected Product Type:
  - Select the desired Product Category.
  - Select **Add Entire List** to add all product subcategories within the selected Product Category.

OR

- Select individual product subcategories and click **Add Subcategory** (or double-click on each desired product subcategory).

The selected category(s) will appear in the "User Selections" list to the right.



**Figure 5-2. Affected Products by Type Selection Screen—Drop-Down Menu for Product Type**

Product Categories (by Type)

Instructions: Select a Product Type in the top window. Product categories will display for the selected Product Type. Select individual Product Subcategories or entire Product Categories by double-clicking on the selection or single-clicking on the selection and then "Add Subcategory" or "Add All Subcategories."

Product Type

- Cosmetics
- Dietary Supplements
- Foods
- Medical Devices
- OTCs
- Pet Foods
- Tobacco Products

Product Category

Product Subcategory

User Selections

Add Subcategory >>

<< Remove Subcategory

Add Entire List >>

Add All Subcategories>>

Save and Return to Main Menu

Clear Selections

More Info

**Figure 5-3. Affected Products by Type Selection Screen—Selecting Entire List of Product Subcategories**

Product Categories (by Type)

Instructions: Select a Product Type in the top window. Product categories will display for the selected Product Type. Select individual Product Subcategories or entire Product Categories by double-clicking on the selection or single-clicking on the selection and then "Add Subcategory" or "Add All Subcategories."

Product Type

Cosmetics

Product Category

- Baby needs
- Cosmetics - talc & dusting powder
- Deodorant (nonantiperspirant)
- Ethnic health & beauty
- Facial/eye/lip makeup
- Feminine hygiene
- Foot care
- Fragrances
- Gift sets & kits
- Hair care
- Nailcare/manicure needs
- Oral hygiene
- Personal soap/bath need
- Shaving needs
- Skin care preparations

Product Subcategory

- Baby care products - bath soap
- Baby care - oils & lotions
- Baby care - ointments
- Baby care - powder

User Selections

Add Subcategory >>

<< Remove Subcategory

Add Entire List >>

Add All Subcategories>>

Save and Return to Main Menu

Clear Selections

More Info

You may also choose the affected product subcategories by NAICS code. To do so, follow the steps below:

- On the Main Menu screen, click **Select by NAICS**.
- When the Affected Products by NAICS worksheet opens (see Figure 5-4), select the 3-digit NAICS code representing the products affected by the labeling regulation from the drop-down menu at the top of the screen.
- The 6-digit NAICS list will then populate with the product subcategories within the selected 6-digit NAICS code.
  - To select all products within a 6-digit NAICS, click **Add All Subcategories**.

OR

- To select individual product subcategories within the selected 6-digit NAICS (see Figure 5-5):
  - Select the desired 6-digit NAICS.
  - Select **Add Entire List** to add all product subcategories within the selected 6-digit NAICS.

OR

- Select individual Product Subcategories and click **Add Subcategory** (or double-click on each desired product subcategory).

The selected category(s) will appear in the “User Selections” list to the right.

After selecting all desired product subcategories, click **Save and Return to Main Menu** to save your selections and return to the Main Menu screen.

**Figure 5-4. Affected Products by NAICS Selection Screen—Selecting 3-Digit NAICS from a Drop-Down Menu**

The screenshot shows the 'FDA Labeling Cost Model' window. At the top, it says 'Product Categories (by NAICS)'. Below this is an instruction: 'Instructions: Select a 3-digit NAICS in the top window. 6-digit NAICS will display for the selected 3-digit NAICS. Select individual Product Subcategories or entire 6-Digit NAICS by double-clicking on the selection or single-clicking on the selection and then "Add Subcategory" or "Add All Subcategories."'.

The main area is divided into three sections:

- 3-Digit NAICS:** A dropdown menu showing '325 - Chemical Manufacturing'.
- 6-Digit NAICS:** A list of 6-digit NAICS codes and their descriptions:
  - 325199 - All Other Basic Organic Chemical Manufacturing
  - 325320 - Pesticide & Other Agricultural Chemical Manufacturing
  - 325412 - Pharmaceutical Preparation Manufacturing
  - 325413 - In-Vitro Diagnostic Substance Manufacturing
  - 325611 - Soap & Other Detergent Manufacturing
  - 325620 - Toilet Preparation Manufacturing
- Product Subcategory:** An empty box.
- User Selections:** An empty box.

Between the 6-Digit NAICS and Product Subcategory boxes is a double arrow '>>'. Between the Product Subcategory and User Selections boxes is a double arrow '>>'. Below the 6-Digit NAICS list is a double arrow '>>'. Below the Product Subcategory box is a double arrow '>>'. Below the User Selections box is a double arrow '>>'. Below the double arrows are three buttons: 'Add Subcategory >>', '<< Remove Subcategory', 'Add Entire List >>', and 'Add All Subcategories>>'. At the bottom are three buttons: 'Save and Return to Main Menu', 'Clear Selections', and 'More Info'.

**Figure 5-5. Affected Products by NAICS Selection Screen—Selecting and Adding 6-Digit NAICS and Product Subcategories**

The screenshot shows the 'FDA Labeling Cost Model' window. At the top, it says 'Product Categories (by NAICS)'. Below this is an instruction: 'Instructions: Select a 3-digit NAICS in the top window. 6-digit NAICS will display for the selected 3-digit NAICS. Select individual Product Subcategories or entire 6-Digit NAICS by double-clicking on the selection or single-clicking on the selection and then "Add Subcategory" or "Add All Subcategories."'.

The main area is divided into three sections:

- 3-Digit NAICS:** A dropdown menu showing '325 - Chemical Manufacturing'.
- 6-Digit NAICS:** A list of 6-digit NAICS codes and their descriptions:
  - 325199 - All Other Basic Organic Chemical Manufacturing
  - 325320 - Pesticide & Other Agricultural Chemical Manufacturing
  - 325412 - Pharmaceutical Preparation Manufacturing
  - 325413 - In-Vitro Diagnostic Substance Manufacturing
  - 325611 - Soap & Other Detergent Manufacturing
  - 325620 - Toilet Preparation Manufacturing
- Product Subcategory:** A list of product subcategories:
  - Baby care products -bath soap
  - Denture cleansers
  - Tooth whiteners
  - Toothpaste (fluoride)
  - Toothpaste (nonfluoride)
- User Selections:** An empty box.

Between the 6-Digit NAICS and Product Subcategory boxes is a double arrow '>>'. Between the Product Subcategory and User Selections boxes is a double arrow '>>'. Below the 6-Digit NAICS list is a double arrow '>>'. Below the Product Subcategory box is a double arrow '>>'. Below the User Selections box is a double arrow '>>'. Below the double arrows are three buttons: 'Add Subcategory >>', '<< Remove Subcategory', 'Add Entire List >>', and 'Add All Subcategories>>'. At the bottom are three buttons: 'Save and Return to Main Menu', 'Clear Selections', and 'More Info'.

On both the Product Categories by Type and Product Categories by NAICS screens, you also have the option of clearing all selections and starting over.

### 5.2.2 Percentage of Affected Products Modification (Optional)

**Step 2 (optional).**

Indicate the percentage of UPCs affected by the labeling regulation if not all UPCs are affected.

The model allows users to modify, if desired, the percentage of products affected by a labeling regulation. By default, the model assumes 100% of the UPCs in the product subcategories selected in the previous step will be affected by the regulation. To adjust the costs for a specific percentage of products in product subcategories selected in the previous step, from the Main Menu screen:

- Click **Enter Percentages** in the field for “Percentages of affected products applied to all product subcategories.”
  - Apply a percentage to all subcategories selected in the previous step by entering a percentage in whole numbers in the first box at the top right (see Figure 5-6).

OR

- Click the cell to the left of each product subcategory that you want to change and enter a percentage in whole numbers for each (see Figure 5-7).

**Figure 5-6. Percentage of Affected Products Screen—Entering a Percentage to Apply to All Subcategories Previously Selected**

FDA Labeling Cost Model

Percentage of Affected Products

Instructions: For each of the selected product categories, enter a percentage of affected products (UPC basis) from 0.0 to 100.0 percent. Alternatively you may enter a percentage of affected products that applies to the entire list of products.

Percentage of affected products applied to all product subcategories..... 90

90	Baby care products - bath soap
90	Baby care - oils & lotions
90	Baby care - ointments
90	Baby care - powder

Save and Return to Main Menu    Restore Default    More Info

**Figure 5-7. Percentage of Affected Products Screen—Entering a Percentage for Each Subcategory**

**FDA Labeling Cost Model**

**Percentage of Affected Products**

Instructions: For each of the selected product categories, enter a percentage of affected products (UPC basis) from 0.0 to 100.0 percent. Alternatively you may enter a percentage of affected products that applies to the entire list of products.

Percentage of affected products applied to all product subcategories..... 100

95	Baby care products - bath soap
100	Baby care - oils & lotions
80	Baby care - ointments
100	Baby care - powder

Save and Return to Main Menu    Restore Default    More Info

After you have specified the percentages of affected products, click **Save and Return to Main Menu**.

### 5.2.3 Type of Labeling Change Selection

**Step 3 (required).**

Select the type of labeling change (minor, major, or extensive) and whether package inserts are affected.

On the Main Menu screen, click **Select Change** to the right of “Type of Labeling Change” to indicate the type of labeling change required by the regulation. This screen allows you to select minor, major, or extensive change and briefly defines each type of labeling change (see Figure 5-8).

When selecting an extensive change, you may also include recurring annual costs of peel-back labels and enter the percentage of products with peel-back labels (see Figure 5-9).

After you have selected the percentage of products with peel-back labels, click **Save and Return to Menu**.

If you need further clarification or examples, click **Examples**.

**Figure 5-8. Type of Labeling Change—Selecting Type of Labeling Change and Whether Package Inserts Are Affected**

**FDA Labeling Cost Model**

**Type of Labeling Change**

Instructions: Select the Type of Labeling Change that most closely aligns with expected industry response to the regulation. If only package inserts are affected, skip this selection and select package inserts below.

[Examples](#)

☐ Minor change: one-color changes that typically do not require a label redesign

☐ Major change: multiple color changes that require a label redesign

☒ Extensive change: major format change that requires a change to the product packaging to accommodate labeling information

☐ For extensive changes, include recurring annual costs of peel-back labels?

---

Instructions: Select whether package inserts are affected by the change.

Package inserts are affected by the change? ☐ Yes ☒ No

If yes, include costs of adding package inserts if product subcategory does not already have them? ☐ Yes ☒ No

---

**Recordkeeping costs**

Instructions: Select "Yes" to include recordkeeping costs on a per-UPC basis in the output of the model. (Default value is "No.")

Include recordkeeping costs (per-UPC)? ☐ Yes ☒ No

[Save and Return to Menu](#) [Clear Selections](#) [More Info](#)

**Figure 5-9. Type of Labeling Change—Extensive Labeling Change and Percentage of Products with Peel-Back Labels**

The screenshot shows a dialog box titled "FDA Labeling Cost Model" with a close button in the top right corner. The main heading is "Percentage of Products with Peel-Back Labels". Below this is a block of instructions: "Instructions: For each of the selected product categories, enter a percentage of products (UPC basis) from 0.0 to 100.0 percent. Alternatively you may enter a percentage of products that applies to the entire list of products." Below the instructions is a label "Percentage of products applied to all product subcategories....." followed by a text input field containing the value "100". Below this is a scrollable list box containing four items, each with a text input field to its left: "Baby care products - bath soap" (empty), "Baby care - oils & lotions" (100), "Baby care - ointments" (100), and "Baby care - powder" (100). At the bottom of the dialog are three buttons: "Save and Return to Main Menu", "Restore Default", and "More Info".

This screen also allows you to select whether package inserts are affected by the change. For products that do not already have package inserts, you may also specify whether to include costs of adding package inserts.

Finally, this screen allows you to select whether recordkeeping costs are affected by the change. (Note: By default, the model will not include recordkeeping costs unless "Yes" is selected from this dialogue box.)

After you have selected the type of labeling change and whether package inserts are affected by the change, click **Save and Return to Menu**.



#### 5.2.4 Analytical and Market Testing Costs Selection

**Step 4 (optional).**  
Specify or enter (1)  
analytical testing costs  
and (2) market testing  
costs.

Some labeling regulations may require manufacturers to conduct analytical or market tests on each formula affected by the regulation. To include either of these types of costs in the Labeling Cost Model:

- From the Main Menu screen: click **Enter Testing Costs** to the right of "Analytical and Market Testing Costs." A screen listing analytical tests and market tests will open (see Figure 5-10).
- To include costs of analytical testing in the model, under the heading "Analytical Tests," enter a cost estimate or select from a list of tests as follows:
  - Enter the total analytical test cost per formula in the first box (numeric values only). (Note: The model will automatically add labor costs for sample preparation and shipping costs to the analytical test cost.)
  - Select one or more of the analytical tests by double-clicking on the test name or single-clicking the test name and "Add Analytical Test." (Note: In general, analytical tests are categorized by the product type on which they are used.)
  - Enter the number of samples to be tested. (Note: The default number of samples to be tested is two.)

Note that you may enter an analytical test cost estimate, select one or more analytical tests from the list, or both.

**Figure 5-10. Selecting Analytical Tests**

The screenshot shows the 'FDA Labeling Cost Model' window. It is divided into two main sections: 'Analytical Tests' and 'Market Tests'.

**Analytical Tests Section:**

- Instructions:** Enter a total analytical test cost per sample: . AND/OR select one or more analytical tests by double-clicking on the test name or single-clicking the test name and "Add Analytical Test."
- Analytical Tests Table:**

Analytical Tests	Cost (Mean)
Foods-NFP (laboratory test)	\$845
Foods-NFP (nutrition database)	\$188
Foods-acrylamide	\$227
Foods-allergens	\$125
Foods-bioengineered ingredients	\$276
Foods-caffeine	\$102
Foods-fat composition	\$168
Foods-iodine	\$107
Foods-microbiological	\$77
Foods-minerals	\$42
- User Selections:** A large empty box for selected tests.
- Buttons:** "Add Analytical Test >>" and "<< Remove Analytical Test".
- Additional Input:** Enter the number of samples tested (applies to user-entered testing costs and selected analytical tests): .

**Market Tests Section:**

- Instructions:** Enter a total market test cost per formula: . AND/OR select one or more market tests by double-clicking on the test name or single-clicking the test name and "Add Market Test."
- Market Tests Table:**

Market Tests	Cost (Mean)
Focus group	\$6,500
Discrimination test	\$6,300
Central location test	\$31,950
Descriptive test	\$13,058
In-home test	\$27,350
- User Selections:** A large empty box for selected tests.
- Buttons:** "Add Market Test >>" and "<< Remove Market Test".

**Bottom Buttons:** "Save and Return to Menu", "Clear Selections", and "More Info".

- To include costs of market testing in the model, under the heading "Market Tests":
  - Enter the total market testing cost per formula in the first box (numeric values only).
  - Select one or more of the market tests by double-clicking on the test name or single-clicking the test name and "Add Market Test" (see Figure 5-11).

Note that you may enter a market test cost, select focus groups, or select multiple quantitative tests, including discrimination, central location, descriptive, and in-home tests, or both.

After you have entered or selected analytical and market test costs, click **Save and Return to Menu**.

Figure 5-11. Selecting Market Tests

**FDA Labeling Cost Model**

**Analytical Tests**

Instructions: Enter a total analytical test cost per sample:

\$xxx.xx

AND/OR select one or more analytical tests by double-clicking on the test name or single-clicking the test name and "Add Analytical Test."

Analytical Tests	Cost (Mean)
Foods-NFP (laboratory test)	\$845
Foods-NFP (nutrition database)	\$188
Foods-acrylamide	\$227
Foods-allergens	\$125
Foods-bioengineered ingredients	\$276
Foods-caffeine	\$102
Foods-fat composition	\$168
Foods-iodine	\$107
Foods-microbiological	\$77
Foods-minerals	\$42

Add Analytical Test >>

<< Remove Analytical Test

User Selections

Enter the number of samples tested (applies to user-entered testing costs and selected analytical tests): 2

---

**Market Tests**

Instructions: Enter a total market test cost per formula:

\$x,xxx.xx

AND/OR select one or more market tests by double-clicking on the test name or single-clicking the test name and "Add Market Test."

Market Tests	Cost (Mean)
Focus group	\$6,500
Discrimination test	\$6,300
Central location test	\$31,950
Descriptive test	\$13,058
In-home test	\$27,350

Add Market Test >>

<< Remove Market Test

User Selections

Focus group

Save and Return to Menu   Clear Selections   More Info

### 5.2.5 Wage Rates Selection

**Step 5 (optional).**  
Adjust the wage rates used in the model.

The model includes default wage rates obtained from BLS for the relevant labor categories included in the model. To update or modify the wage rates included by default, click **Enter Wage Rates** from the Main Menu screen. A screen will open where you enter new hourly wage rates by occupation (see Figure 5-12). You must enter wage rates for the 10th percentile, mean, and 90th percentile to allow for calculation of cost ranges.

After you have entered new wage rates, click **Save and Return to Menu**.

Figure 5-12. Viewing and Editing Hourly Wage Rates

**FDA Labeling Cost Menu**

**Wage Rates**

Instructions: Hourly wage rates including estimated benefits and overhead of 100% are displayed for relevant labor categories based on 2014 BLS data for NAICS 31 - 33 Manufacturing. To update these data to a later year, enter the new wage rates with benefits, enter the year of the data, and click Save and Return to Menu.

	10th Percentile	Mean	90th Percentile
Advertising and Promotions Managers	53.70	104.26	164.18
Graphic Designers	24.76	42.72	66.64
Helpers-Production Workers	17.38	25.84	36.76
Weighers, Measurers, Checkers, and Samplers, Recordkeeping	19.66	31.68	47.38
Year of wage rate values	2014		

Save and Return to Menu    Reset Default Values    More Info

### 5.2.6 Compliance Period Selection

**Step 6 (required).**

Select a compliance period and modify, if desired, the default percentages of UPCs that cannot be coordinated.

On the Main Menu screen, click **Select Compliance Period** to the right of “Select compliance period assumptions for coordinating a labeling change” to indicate the amount of time before the regulation is to take effect. This screen allows you to select the number of months manufacturers have to comply with the regulation (see Figure 5-13).

This screen also allows you to accept the default percentages of UPCs for which the required labeling change cannot be coordinated with a planned change. The default percentages of uncoordinated labeling changes by product type vary by product type (see Figure 5-14). The product types that you selected in Step 1 will be shown in bold and can be modified; the product types that you did not select will display but cannot be modified.

After you have specified the compliance period and modified the percentages (if desired), click **Save and Return to Menu**.

**Figure 5-13. Compliance Period Selection Screen—Select Amount of Time Manufacturers Will Have to Comply with the Labeling Regulation**

**Compliance Period**

Instructions: Select the number of months that manufacturers will have to comply with the labeling regulation from "3 months" to "60 months." The default estimates of the percentages of labeling changes that cannot be coordinated with a scheduled labeling change will display. Enter new percentages or retain the default estimates.

Compliance period:

Percentages of labeling change:

Cosmetics:

Dietary Supplements:

Foods:

Medical Devices:

OTCs:

Pet Food:

Tobacco Products:

Label UPCs (%):

Note: Values for selected products are shown in bold.

**Figure 5-14. Compliance Period Selection Screen—Modify the Percentages of Changes That Cannot Be Coordinated with a Scheduled Change**

**FDA Labeling Cost Model**

**Compliance Period**

Instructions: Select the number of months that manufacturers will have to comply with the labeling regulation from "3 months" to "60 months." The default estimates of the percentages of labeling changes that cannot be coordinated with a scheduled labeling change will display. Enter new percentages or retain the default estimates.

Compliance period:

Percentages of labeling changes that cannot be coordinated:

	Branded UPCs (%)	Private Label UPCs (%)
Cosmetics	<b>67</b>	<b>78</b>
Dietary Supplements	78	84
Foods	0	74
Medical Devices	78	84
OTCs	78	84
Pet Food	0	53
Tobacco Products	78	84

Note: Values for selected products are shown in bold.

Save and Return to Menu    Clear Selections    More Info

### 5.2.7 Inflation Factor Modification (optional)

**Step 7 (optional).**  
Enter an inflation factor.

From the Main Menu Screen, you can enter a price adjustment factor to account for inflation since 2014. If the costs are being estimated in a year beyond 2014, an inflation factor is necessary to more accurately reflect the present value of cost estimates. To obtain this factor, go to the BLS Web site (found at [http://www.bls.gov/data/inflation\\_calculator.htm](http://www.bls.gov/data/inflation_calculator.htm)) and use the CPI Inflation Calculator to calculate the inflation factor since 2014. The default inflation factor is 1.0 (see Figure 5-15). The possible range for this value is 0.5 to 10.0. Values less than 1.0 can be used to estimate costs for a baseline prior to 2014 or to allow for the possibility of deflation.

**Figure 5-15. Inflation Factor Modification**

The screenshot shows the 'FDA Labeling Cost Model' window. At the top, a text box explains the model's purpose: 'The FDA Labeling Cost Model provides estimates of the costs of changing labeling information on retail products under FDA's jurisdiction. Data on the number of labels and unit sales are based on 2012 Nielsen scanner data for foods, dietary supplements, and pet foods and 2008 Nielsen scanner data for cosmetics, OTC medications, retail medical devices, and tobacco products and accessories. Cost data are based on industry-provided data obtained in 2014.' Below this is an 'Instructions' section: 'Follow each step below to select the model inputs that most closely correspond to the required labeling change.' A 'Load Saved Scenario' button is in the top right.

The interface is divided into five parts:

- Part 1. Select products and type of change**
  - a. Affected products (required)..... [Select by Type] or [Select by NAICS] [More Info]
  - b. Percentages of affected products within product subcategories (optional)..... [Enter Percentages] [More Info]
  - c. Type of labeling change (required) ..... [Select Change] [More Info]
- Part 2. Select cost assumptions**
  - a. Analytical and market testing costs (optional)..... [Enter Testing Costs] [More Info]
  - b. Wage rates (optional)..... [Enter Wage Rates] [More Info]
- Part 3. Select compliance period assumptions for coordinating a labeling change (required).....** [Select Compliance Period] [More Info]
- Part 4. Enter an inflation factor relative to 2014 (0.5 - 10.0) (optional).....** [1.00] [More Info]. A blue arrow points to the '1.00' input field.
- Part 5. After selecting all inputs.....** [Calculate Costs] [More Info]

At the bottom, a message states 'Model results will be output to an Excel spreadsheet'. There are 'Reset All Selections' and 'Exit' buttons. Logos for 'IRTI INTERNATIONAL' and 'FDA' are at the bottom left and right respectively.

### 5.2.8 Running the Model Using Input Values

**Step 8.** Run the model and view the output.

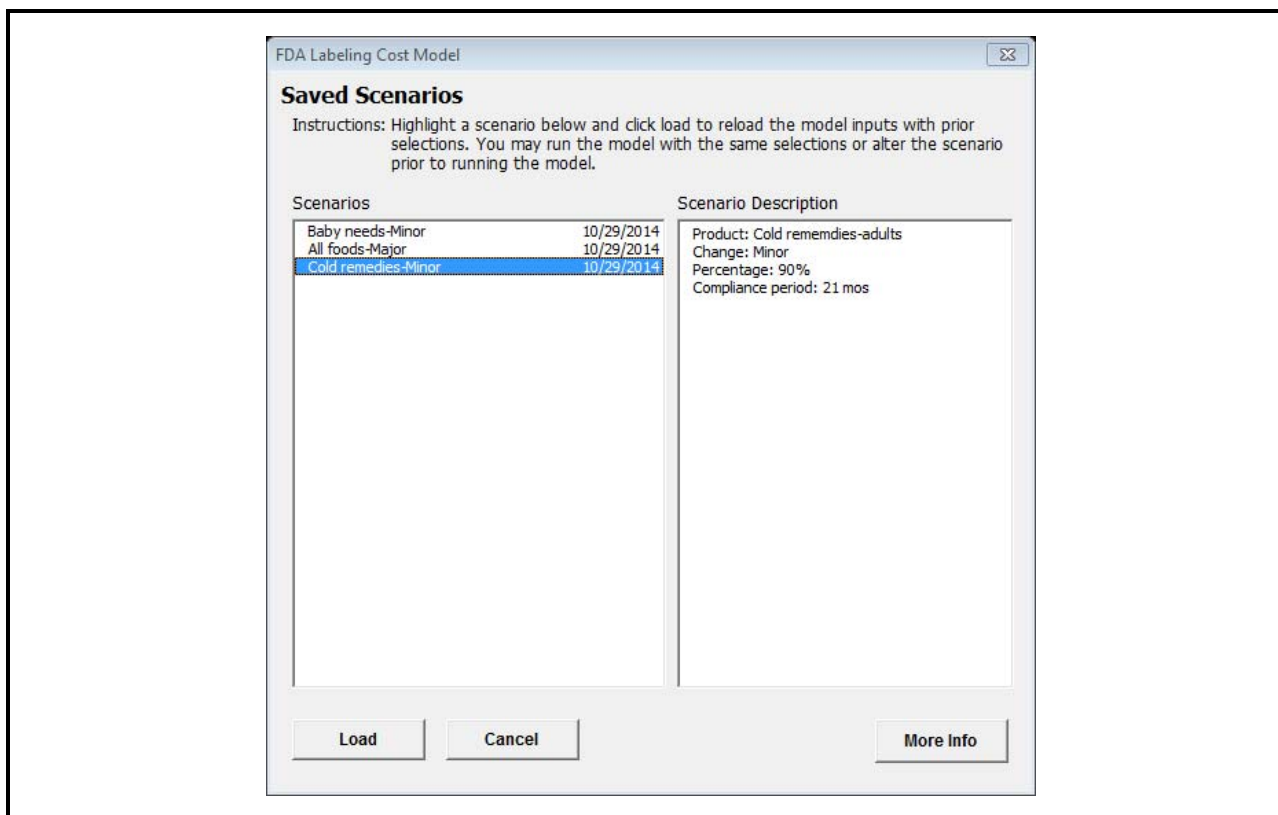
To run the model using the parameters selected in previous steps, select the **Calculate Costs** button on the Main Menu screen.

A screen will open asking you to "Save and Run Model" or "Run Model." By selecting "Save and Run Model" the parameters that have previously been chosen will be saved in an Excel Workbook named *Scenarios.xlsx* at the same location as the model on your computer. Otherwise, you may select "Run Model" and not retain the selected inputs.

Once the model run is complete, the output worksheet opens in a new Excel Workbook with the outputs described in Section 5.3.

Note that in future model runs, you can recall a saved scenario to rerun the model as is or make modifications to the input selections prior to rerunning the model. To do this, click the **Load Saved Scenario** button in the upper right of the Main Menu screen in the model. A screen will open with the saved scenarios as depicted in Figure 5-16. Highlight the chosen scenario and click **Load** to populate the inputs in the Main Menu screen.

Figure 5-16. Saved Scenarios Screen



### 5.3 VIEWING THE MODEL OUTPUTS

The results of the model will appear in four worksheets:

- **Summary**—presents an overview of selections by the user and a summary of costs. This worksheet allows you to view all input selections for review and to re-create the model if necessary (see Figures 5-17a and 5-17b). This worksheet contains the following information:
  - date of run
  - product type selected



- 3-digit NAICS
- selected type of change
- selected type of analytical tests, number of samples tested, and costs (if specified by user)
- selected type of market tests and costs (if specified by user)
- inclusion of recordkeeping costs
- selected compliance period
- assumed percentage of changes that cannot be coordinated with a scheduled labeling change
- inflation factor
- selected product categories and product subcategories and assumed package types
- summary of costs based on user selections
- **Detailed Costs**—presents detailed cost estimates for each selected product category and product subcategory (not shown because of the size of the table) and the number of UPCs, unique formulas, and units. This worksheet details a range of estimated overall costs for industry compliance for products that are and are not able to coordinate a regulatory labeling change with a scheduled labeling change. This worksheet also contains a range of estimated per-UPC cost breakdowns by the following criteria:
  - product categories
  - product subcategories
  - branded versus private-label products
  - type of cost (e.g., labor, materials, tests)
- **Aggregate Costs**—presents aggregated cost estimates for each selected product category and product subcategory (not shown due to size of the table), delineated by branded and private-label UPCs. This worksheet also contains the number of UPCs for products that are and are not able to coordinate a regulatory labeling change with a scheduled labeling change.
- **Package Inserts Costs**—presents detailed cost estimates for each selected product category and product subcategory, indicates whether the products already contain inserts, and provides the number of UPCs and recurring costs for including package inserts for products that do not already have them.

- **Peel-Back Label Costs**—presents detailed cost estimates for each selected product category and product subcategory and provides the number of UPCs and recurring costs for adding peel-back labels (also a proxy for the costs of increased package size).

Figure 5-17a. Model Output—Input Selections Summary (Upper Portion)

	A	B	C	D	E
1	<b>FDA Labeling Cost Model User Input Selections</b>				
2	Date of Run:	6/25/2015			
3	Product Type:	Cosmetics			
4	3-Digit NAICS:	325 - Chemical Manufacturing			
5					
6	<b>Selected Type of Change</b>				
7	Extensive				
8					
9	<b>Package Inserts Affected by Change?</b>				
10	No				
11					
12	<b>Add Peel-Back Labels?</b>				
13	Yes				
14					
15	<b>Selected Types of Analytical Tests</b>				
16	None Selected				
17					
18	<b>Specified Analytical Test Cost</b>				
19	None Specified				
20					
21	<b>Number of Samples Tested</b>				
22	2				
23					
24	<b>Selected Market Tests</b>				
25	Focus group				
26					
27	<b>Specified Market Test Cost</b>				
28	None Specified				
29					
30	<b>Include Recordkeeping Costs?</b>				
31	No				
32					
33	<b>Selected Compliance Period</b>				
34	24 months				
35					
36	<b>Assumed Percentage of Changes that Cannot be Coordinated with Planned Changes</b>				
37	Product Type	Branded Products	Private Label Products		
38	Cosmetics	67%	78%		
39					
40	<b>Inflation Factor</b>				
41	1				
42					
43	<b>Selected Product Categories and Product Sub-Categories and Assumed Package Types</b>				
44	Product Category	Product Sub-Category	% Affected	Assumed Package Type	
45	Baby needs	Baby care products - bath soap	95%	Plastic-label	
46	Baby needs	Baby care - oils & lotions	100%	Plastic-label	
47	Baby needs	Baby care - ointments	80%	Paperboard-carton	
	< >	Summary	Detailed Costs	Aggregate Costs	Peel-Back Label Costs
				Data	+

Additionally, the output contains a worksheet detailing the data included in the cost estimates. This is provided for user convenience, should a task require further analyses.

To print the results, click **File**, then select **Print** and then **Print Preview**. You may wish to select **Page Setup** and alter the format of the tables prior to printing.

To save the results, click **File**, then select **Save As...**, choose the file location and name for the output, and click **OK**.

Figure 5-17b. Model Output—Input Selections Summary (Lower Portion)

	A	B	C	D	E
35					
36	<b>Assumed Percentage of Changes that Cannot be Coordinated with Planned Changes</b>				
37	<i>Product Type</i>	<i>Branded Products</i>	<i>Private Label Products</i>		
38	Cosmetics	67%	78%		
39					
40	<b>Inflation Factor</b>				
41	1				
42					
43	<b>Selected Product Categories and Product Sub-Categories and Assumed Package Types</b>				
44	<i>Product Category</i>	<i>Product Sub-Category</i>	<i>% Affected</i>	<i>Assumed Package Type</i>	
45	Baby needs	Baby care products - bath soap	95%	Plastic-label	
46	Baby needs	Baby care - oils & lotions	100%	Plastic-label	
47	Baby needs	Baby care - ointments	80%	Paperboard-carton	
48	Baby needs	Baby care - powder	100%	Plastic-molded	
49					
50	<b>Summary of Costs</b>				
51					
52	<b>Number of UPCs</b>				
53		<b># UPCs</b>			
54	<b>Brand Type</b>	<b>Uncoordinated</b>	<b>Coordinated</b>	<b>Total</b>	
55	Branded	1,339	659	1,998	
56	Private	1,804	509	2,313	
57	Total	3,143	1,168	4,311	
58					
59	<b>Costs per Uncoordinated UPC</b>				
60		<b>Costs per Uncoordinated UPC</b>			
61	<b>Brand Type</b>	<b>5th Percentile</b>	<b>Mean</b>	<b>95th Percentile</b>	
62	Branded	\$12,797	\$20,905	\$32,407	
63	Private	\$12,344	\$20,004	\$30,854	
64	Total	\$12,537	\$20,388	\$31,516	
65					
66	<b>Costs per Coordinated UPC</b>				
67		<b>Costs per Coordinated UPC</b>			
68	<b>Brand Type</b>	<b>5th Percentile</b>	<b>Mean</b>	<b>95th Percentile</b>	
69	Branded	\$0	\$0	\$0	
70	Private	\$0	\$0	\$0	
71	Total	\$0	\$0	\$0	
72					
73	<b>Total Costs</b>				
74		<b>Total Costs</b>			
75	<b>Brand Type</b>	<b>5th Percentile</b>	<b>Mean</b>	<b>95th Percentile</b>	
76	Branded	\$17,131,635	\$27,985,595	\$43,383,962	
77	Private	\$22,268,891	\$36,088,385	\$55,661,837	
78	Total	\$39,400,526	\$64,073,980	\$99,045,799	
79					
80					
81					

# References

Brody, A.L. 2000. Offset on Plastic Yields High-Quality Short Runs. *Brand Packaging* (May/June). <<http://www.packaginginfo.com>>.

Bruno, M.H., ed. 1995. *Label Industry Facts & Guidelines*, 2nd edition. Arlington, VA: Label Printing Industries of America.

Demetrician, R. 1996. *Label and Package Graphic Design*. Plainview, NY: Jelmar Publishing Co., Inc.

Flexible Packaging Association. Summer 2009. "2009 State of the Flexible Packaging Industry Report Preview." Linthicum, MD: Flexible Packaging Association.

Food and Drug Administration. April 2006. Cosmetic Labeling & Label Claims Overview. <<http://www.fda.gov/Cosmetics/CosmeticLabelingLabelClaims/default.htm>>. As obtained on October 11, 2010.

Hawley, R. Printbid Tutorial: Pre-Press. <<http://www.printbid.com/styles/resources-tutorialprepress.htm>>. As obtained on September 22, 2000.

Malenke, C. April 2010. A Comparison of Folding Carton Substrates and Appropriate Applications. *Brand Packaging*. <[http://www.brandpackaging.com/Articles/Case\\_Studies/BNP\\_GUID\\_9-5-2006\\_A\\_1000000000000805552](http://www.brandpackaging.com/Articles/Case_Studies/BNP_GUID_9-5-2006_A_1000000000000805552)>. As obtained on October 11, 2010.

Muth, M.K., M.J. Ball, M.C. Coglaiti, and S.A. Karns. October 2012. *Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration*. Research Triangle Park, NC: RTI International.

- Mykytiuk, A. October 1999. Printing for Flexible Packaging. Flexible Packaging. <<http://www.packaginginfo.com>>.
- National Institutes of Health. (2013, June 17). NIH launches Dietary Supplement Label Database. <<http://www.nih.gov/news/health/jun2013/nlm-17.htm>>. As obtained on August 28, 2014.
- NPES—The Association for Suppliers of Printing, Publishing, and Converting Technologies. The Packaging Study, Executive Summary. <<http://www.npes.org/research/index.htm>>. As obtained on December 11, 2000.
- Reardon, C. June 2008. A Look at the North American Label Market Today. Paper, Film & Foil Converter. <[http://pffc-online.com/label\\_tape/look\\_north\\_american\\_0608/](http://pffc-online.com/label_tape/look_north_american_0608/)>. As obtained on October 11, 2010.
- Shulman, J.J., and N.R. Elred. 2007. *Trends in Package Printing*. Pittsburgh: PIA/GATF Press.
- Speirs, H.M. 1998. *Introduction to Printing and Finishing*. Surrey, UK: Pira International.
- Theodore, S. April 2005. Container Demand Spans all Categories. Beverage Industry. <[http://www.bevindustry.com/Archives\\_Davinci?article=1496](http://www.bevindustry.com/Archives_Davinci?article=1496)>. As obtained on October 11, 2010.
- U.S. Department of Agriculture. October 17, 2014. Food Expenditures. <[http://www.ers.usda.gov/data-products/food-expenditures.aspx#.U\\_83JFco\\_8](http://www.ers.usda.gov/data-products/food-expenditures.aspx#.U_83JFco_8)>.

# Appendix A: Industry Interview Materials

This appendix contains the following materials used for conducting industry interviews for the labeling costs model:

- Project overview and interview guide for obtaining feedback from manufacturers on costs of labeling changes
- Project overview and interview guide for obtaining feedback from vendors on costs of labeling changes

The more detailed interview guides used to obtain the original estimates are provided in Appendix A of Muth et al. (2012).

## **FDA Labeling Cost Model—2014 Update Project Overview and Interview Guide**

Under contract with the U.S. Food and Drug Administration (FDA), RTI International<sup>1</sup> is updating and expanding the model that FDA uses to estimate industry costs associated with labeling changes required by regulation. The updated model will provide FDA with more accurate and up-to-date estimates of the costs to comply with upcoming regulations that will require relabeling of all food products.

RTI is updating the model to include more recent store scanner data from Nielsen as well as revised cost information from several product manufacturers, many of which were contacted in the 2010 update. We are conducting industry interviews again to allow us to characterize the frequency of nonregulatory labeling changes and revise the typical costs of making labeling changes by category of cost. The model includes three types of labeling changes that may be required by regulation:

- Minor change—one-color changes that do not require a label redesign (for example, changes to an ingredient list or addition of a toll-free number)
- Major change—multiple color changes that require a label redesign (for example, adding a facts panel or modifying the front of the package)
- Extensive change—major format change that requires a change to the product packaging to accommodate labeling information (for example, addition of a peel-back label or increasing the package surface area)

All information collected during the interviews will be kept strictly confidential. No company-specific information will be shared outside of the RTI project team. All data will be combined into representative estimates for use in the labeling cost model and report for FDA.

Questions regarding this project can be directed to either of the following:

### **FDA Project Officer**

Dr. Bradley Brown  
U.S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740  
Voice: 240-402-1551  
[Bradley.Brown@fda.hhs.gov](mailto:Bradley.Brown@fda.hhs.gov)

### **RTI Technical Lead**

Dr. Kristen Capogrossi  
RTI International  
3040 E. Cornwallis Road  
Research Triangle Park, NC 27709  
Voice: 919-541-7330  
[kcapogrossi@rti.org](mailto:kcapogrossi@rti.org)

---

<sup>1</sup> RTI International is an independent nonprofit research organization based in Research Triangle Park, North Carolina. More information about RTI is available at [www.rti.org](http://www.rti.org).

## Industry Interview Guide on Food Product Labeling Costs and Practices

### *Costs of Changing Labels*

- The following tables show the estimated typical industry costs for updating a single food label based on the previous model estimates. Please review these estimates and provide feedback on whether you believe your company's costs would fall within these ranges.

### Estimated Printing Plate Costs Associated with Labeling Changes (\$/label)

	Minor Change			Major Change			Extensive Change		
	Low	Medium	High	Low	Medium	High	Low	Medium	High
Printing Plates—flexography	\$310	\$750	\$1,270	\$1,930	\$4,800	\$7,670	\$4,280	\$10,000	\$13,190
Printing Plates—offset	\$130	\$210	\$440	\$520	\$1,100	\$1,350	\$650	\$1,380	\$1,680
Printing Plates—gravure	\$1,080	\$1,500	\$1,830	\$5,910	\$6,150	\$9,690	\$7,390	\$7,690	\$12,110
Printing Plates—other miscellaneous materials	\$120	\$160	\$240	\$130	\$210	\$250	\$160	\$290	\$440

### Labor Hours and Consultant Costs for Each Type of Change (hours/label or \$/label)

	Minor Change			Major Change			Extensive Change		
	Low	Medium	High	Low	Medium	High	Low	Medium	High
Administrative—internal labor hours	3.5	12.0	20.0	9.0	24.4	40.0	12.5	40.8	60.0
Graphic design—internal labor hours	1.0	4.4	8.5	2.0	11.4	35.0	4.0	24.0	70.0
Graphic design—consultant labor costs (\$)	\$275	\$1,825	\$3,500	\$1,000	\$2,213	\$5,000	\$1,700	\$3,740	\$10,000
Prepress—internal labor hours	2.0	3.4	8.0	2.0	5.6	8.0	2.0	6.9	15.0
Prepress—consultant labor costs (\$)	\$350	\$538	\$900	\$1,000	\$1,725	\$2,750	\$1,500	\$2,025	\$2,750
Recordkeeping—internal labor hours	0.9	1.8	2.2	0.9	1.8	2.2	0.9	1.8	2.2

- How frequently does your company update product labeling as part of routine operations?
- What percentage of your company's product labels are changed in a typical year?



## **FDA Labeling Cost Model—2014 Update Project Overview and Interview Guide**

Under contract with the U.S. Food and Drug Administration (FDA), RTI International<sup>2</sup> is updating and expanding the model that FDA uses to estimate industry costs associated with labeling changes required by regulation. The updated model will provide FDA with more accurate and up-to-date estimates of the costs to comply with upcoming regulations that will require relabeling of all food products.

RTI is updating the model to include more recent store scanner data from Nielsen as well as revised cost information from several product manufacturers and vendors, many of which were contacted in the 2010 update. We are conducting industry interviews again to allow us to characterize the frequency of nonregulatory labeling changes and revise the typical costs of making labeling changes by category of cost. The model includes three types of labeling changes that may be required by regulation:

- Minor change—one-color changes that do not require a label redesign (for example, changes to an ingredient list or addition of a toll-free number)
- Major change—multiple color changes that require a label redesign (for example, adding a facts panel or modifying the front of the package)
- Extensive change—major format change that requires a change to the product packaging to accommodate labeling information (for example, addition of a peel-back label or increasing the package surface area)

All information collected during the interviews will be kept strictly confidential. No company-specific information will be shared outside of the RTI project team. All data will be combined into representative estimates for use in the labeling cost model and report for FDA.

Questions regarding this project can be directed to either of the following:

### **FDA Project Officer**

Dr. Bradley Brown  
U.S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740  
Voice: 240-402-1551  
[Bradley.Brown@fda.hhs.gov](mailto:Bradley.Brown@fda.hhs.gov)

### **RTI Technical Lead**

Dr. Kristen Capogrossi  
RTI International  
3040 E. Cornwallis Road  
Research Triangle Park, NC 27709  
Voice: 919-541-7330  
[kcapogrossi@rti.org](mailto:kcapogrossi@rti.org)

---

<sup>2</sup> RTI International is an independent nonprofit research organization based in Research Triangle Park, North Carolina. More information about RTI is available at [www.rti.org](http://www.rti.org).

### Industry Interview Guide on Food Product Labeling Costs and Practices

#### *Costs of Changing Labels*

The following tables show the estimated typical industry prices for updating a single food label based on the previous model estimates. Please review these estimates and provide feedback on whether you believe your company's prices would fall within these ranges.

#### Estimated Printing Plate Prices Associated with Labeling Changes (\$/label)

	Minor Change			Major Change			Extensive Change		
	Low	Medium	High	Low	Medium	High	Low	Medium	High
Printing Plates—flexography	\$310	\$750	\$1,270	\$1,930	\$4,800	\$7,670	\$4,280	\$10,000	\$13,190
Printing Plates—offset	\$130	\$210	\$440	\$520	\$1,100	\$1,350	\$650	\$1,380	\$1,680
Printing Plates—gravure	\$1,080	\$1,500	\$1,830	\$5,910	\$6,150	\$9,690	\$7,390	\$7,690	\$12,110
Printing Plates—other miscellaneous materials	\$120	\$160	\$240	\$130	\$210	\$250	\$160	\$290	\$440

#### Labor Hours and Consultant Prices for Each Type of Change (hours/label or \$/label)

	Minor Change			Major Change			Extensive Change		
	Low	Medium	High	Low	Medium	High	Low	Medium	High
Administrative—internal labor hours	3.5	12.0	20.0	9.0	24.4	40.0	12.5	40.8	60.0
Graphic design—internal labor hours	1.0	4.4	8.5	2.0	11.4	35.0	4.0	24.0	70.0
Graphic design—consultant labor prices (\$)	\$275	\$1,825	\$3,500	\$1,000	\$2,213	\$5,000	\$1,700	\$3,740	\$10,000
Prepress—internal labor hours	2.0	3.4	8.0	2.0	5.6	8.0	2.0	6.9	15.0
Prepress—consultant labor prices (\$)	\$350	\$538	\$900	\$1,000	\$1,725	\$2,750	\$1,500	\$2,025	\$2,750
Recordkeeping—internal labor hours	0.9	1.8	2.2	0.9	1.8	2.2	0.9	1.8	2.2



# **Appendix B: Detailed Information on Nielsen Product Modules Included in Each Model Subcategory**

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Cosmetics	Baby needs	Baby care—oils & lotions	Baby care products—lotions
			Baby care products—oil
		Baby care—ointments	Baby care products—ointments
		Baby care—powder	Baby care products—powder
		Baby care products—bath soap	Baby care products—bath
	Cosmetics—talc & dusting powder	Talcum & dusting powder	Talcum & dusting powder
	Deodorant (nonantiperspirant)	Deodorant—aerosol	Deodorant—aerosol <sup>a</sup>
		Deodorant—cologne type	Deodorant—cologne type
		Deodorant—roll-on	Deodorant—roll-on <sup>a</sup>
		Deodorant—stick/solid	Deodorant—stick/solid <sup>a</sup>
		Remaining deodorants	Remaining deodorants <sup>a</sup>
	Ethnic health & beauty	Ethnic health & beauty aids	Hair preparations—ethnic
		Ethnic home permanents	Home permanents—ethnic
	Facial/eye/lip makeup	Cosmetic kits	Cosmetic kits
		Cosmetics—remaining	Cosmetics—remaining
		Eye makeup	Cosmetics—eye shadows
			Cosmetics—eyebrow & eye liner
			Cosmetics—mascara

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Cosmetics (cont.)	Facial/eye/lip makeup (cont.)	Facial makeup	Cosmetics—concealers
			Cosmetics—blushers
			Cosmetics—face powder
			Cosmetics—foundation—cream and powder
			Cosmetics—foundation—liquid
		False eyelash and accessory	False eyelash and accessory
		Lip remedies	Lip remedies—remaining <sup>b</sup>
			Lip remedies—solid
		Lipstick	Cosmetics—lipsticks
	Feminine hygiene	Feminine deodorant sprays	Feminine hygiene—deodorant sprays
		Remaining feminine hygiene	Feminine hygiene—miscellaneous <sup>c</sup>
	Foot care	Foot preparations—remaining	Foot preparations—remaining
	Fragrances	Colognes and perfumes	Cologne & perfume—women’s
		Men’s aftershave/cologne/lotion	After shave cosmetics—men’s
			Cologne/lotion—men’s
	Gift sets & kits		Pre-shave cosmetics
		Children’s cologne & gift sets	Children’s cologne & gift sets
		Fragrance gift sets—women	Women’s gift sets & skin care packages
		Men’s aftershave/cologne/lotion	Men’s sets

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Cosmetics (cont.)	Hair care	Cream rinses & conditioners	Cream rinses & conditioners
		Hair coloring products	Hair coloring—costume
			Hair coloring—men's
			Hair coloring—women's
		Hair preparations	Hair preparations—other than men's
			Hair preparations—men's
		Hairspray	Hair spray—men's
			Hair spray—women's
		Home permanents	Home permanents
		Shampoo (nonmedicated)	Shampoo—aerosol/liquid/ lotion/powder <sup>d</sup>
			Shampoo—bars/ concentrates/and creams <sup>d</sup>
			Shampoo—combinations
	Nail care/manicure needs	Wave setting products	Wave setting products
		Manicure needs	False nail and nail decoration
			Manicuring needs
		Nail care	Cosmetics—nail polish
			Cosmetics—nail polish remover
	Oral hygiene	Breath fresheners	Breath fresheners
		Denture cleansers	Denture cleansers
		Tooth whiteners	Tooth whiteners

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Cosmetics (cont.)	Oral hygiene (cont.)	Toothpaste (nonfluoride)	Tooth cleaners <sup>e</sup>
	Personal soap/bath need	Bath additives—dry	Bath additives—dry
			Bath oil—dry
		Bath additives—liquid	Bath additives—liquid
			Bath oil—liquids
		Soap—bar (nondeodorant)	Soap—bar
		Soap—liquid	Soap—liquid
		Soap—specialty	Soap—specialty
		Shaving needs	Depilatories—men’s
			Depilatories—women’s
			Shave cream—other than women’s
		Shaving cream	Shave creams—women’s
	Skin care preparations	Face cream and lotions	Face cleansers & creams & lotions
			Hand & body lotions
			Hand cream
		Hand cream and body lotions (cont.)	Skin cream—all purpose
			Skin cream—special purpose
		Suntan preparations—lotions/oils/etc.	Sun exposure detector product topical
	Sunburn aids	Sunburn aids	Suntan preparations—lotions/oils/etc.
			Sunburn aids

(continued)



Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Dietary Supplements	Diet aids	Appetite suppressants	Dieting aids—appetite suppressant
		Diet aids—complete nutritional	Dieting aids—complete nutritional
	Mineral supplements	Minerals	Minerals
	Nutritional supplements	Complete nutritional products	Complete nutritional products
		Nutritional supplements	Nutritional supplements
	Protein supplements	Protein supplements	Protein supplements
	Vitamin supplements	Vitamins-B complex w/C	Vitamins-B complex w/C
		Vitamins—children—flavored chewable	Vitamins—children—flavored chewable
		Vitamins—multiple	Vitamins—multiple
		Vitamins—remaining	Vitamins—remaining
Foods	Vitamins/tonics—liquid	Vitamins/tonics—liquid & powder	Vitamins/tonics—liquid & powder
	Baked goods	Bagels/biscuits/buns/ muffins/rolls—fresh	Bakery—bagels—fresh
			Bakery—biscuits—fresh
			Bakery—buns—fresh
			Bakery—muffins—fresh
			Bakery—rolls—fresh
		Bagels/biscuits/buns/ muffins/rolls—frozen	Bakery—biscuits/rolls/ muffins—frozen
			Bakery—bagels—frozen
		Baked goods—remaining—fresh	Bakery—remaining—fresh
		Baked goods—remaining—frozen	Bakery—remaining—frozen

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Baked goods (cont.)	Bread—fresh	Bakery—bread—fresh
		Bread—frozen	Bakery—bread—frozen
		Breading products	Breading products
			Croutons
			Matzo meal/mixes
			Stuffing products
		Cakes/doughnuts/sweet rolls—fresh	Bakery—breakfast cakes/ sweet rolls—fresh
			Bakery—cakes—fresh
			Bakery—doughnuts—fresh
		Cakes/doughnuts/sweet rolls—frozen	Bakery—cobbler/dumplings/ strudel—frozen
			Bakery—dessert cakes—frozen
			Bakery—doughnuts—frozen
			Bakery—breakfast cakes & sweet rolls—frozen
		Cookies/cones	Cookies
			Ice cream cones & cups
		Crackers	Crackers—cheese
			Crackers—flaked soda
			Crackers—flavored snack
			Crackers—graham
			Crackers—oyster

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Baked goods (cont.)	Crackers (cont.)	Crackers—remaining Crackers—sprayed butter Crackers—sprayed flake Matzo Wafers & toast & bread sticks
		Mexican shells/tortillas	Mexican shells Mexican tortillas
	Baking ingredients	Baking mixes	Mixes—brownies Mixes—cake/layer—10 oz & under Mixes—cake/layer—over 10 oz. Mixes—cake/specialty—10 oz & under Mixes—cake/specialty—over 10 oz. Mixes—hushpuppy Mixes—pancake Mixes—bread Mixes—coffee cake Mixes—cookie Mixes—dessert—misc. Mixes—dumpling & kugel Mixes—frosting Mixes—gingerbread

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Baking ingredients (cont.)	Baking mixes (cont.)	Mixes—muffin
			Mixes—pie crust
			Mixes—rolls & biscuits
		Baking supplies	Baking chips—milk chocolate
			Baking chips other than chocolate
			Baking chocolate
			Baking powder
			Baking soda
			Cake decorations & icing
			Chocolate chips & morsels
			Cocoa
			Coconut
			Confectionery paste
			Corn/potato starch
			Food coloring
			Frosting ready-to-spread
			Fruit pectins
			Fruit protectors
			Fruit—glazed
			Graham cracker & dessert crumbs
			Pie & pastry shells—prepared

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Baking ingredients (cont.)	Baking supplies (cont.)	Yeast—dry
			Yeast—refrigerated
		Bread/cookie/dough products—frozen	Bakery—cookies RTE/cookie dough—frozen
			Dough products—bread—frozen
			Pizza crust—frozen
			Dough products—cookies & brownies—refrigerated
		Dough products—refrigerated	Dough products—biscuits—refrigerated
			Dough products—dinner rolls—refrigerated
			Dough products—remaining—refrigerated
			Dough products—sweet rolls—refrigerated
		Flour/corn meal	Corn meal
			Flour—all purpose—remaining
			Flour—single purpose
			Flour—all purpose—white wheat
	Beverages	Buttermilk—refrigerated	Dairy—buttermilk—refrigerated
		Carbonated beverages—low calorie	Soft drinks—low calorie all rem. carb.
			Soft drinks—low calorie cola diet
			Soft drinks—low calorie lemon/lime diet

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Beverages (cont.)	Carbonated beverages—regular	Soft drinks—carbonated all rem. carb.
			Soft drinks—carbonated cola regular
			Soft drinks—carbonated lemon/lime regular
		Cocktail mixes	Cocktail mixes—dry
			Cocktail mixes—liquid
			Cocktail products—bitters & heads
		Coffee—ground	Ground coffee
		Coffee—liquid	Coffee—liquid
		Coffee—soluble	Coffee—soluble
			Coffee—soluble flavored
			Coffee substitutes
		Coffee—whole bean	Whole bean coffee
		Creamers—liquid	Creamers—liquid
		Fruit drinks—frozen	Fruit drinks—orange—frozen
			Fruit drinks & mixes—frozen
		Fruit drinks—refrigerated	Fruit drinks & juices—cranberry ref.
			Fruit drinks—other container ref.
			Vegetable juice and drink remaining ref.

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Beverages (cont.)	Fruit drinks—shelf stable	Fruit drinks & juices—cranberry shelf
			Fruit drinks—canned shelf
			Fruit drinks—other container shelf
		Fruit juice—frozen	Fruit juice—apple—frozen
			Fruit juice—grape—frozen
			Fruit juice—grapefruit—frozen
			Fruit juice—orange—frozen
			Fruit juice—remaining—frozen
			Fruit juice—unconcentrated—frozen
		Fruit juice—refrigerated	Cider ref.
			Fruit juice—apple ref.
			Fruit juice—grape ref.
			Fruit juice—grapefruit—other container ref.
			Fruit juice—lemon/lime ref.
			Fruit juice—orange—other container ref.
			Fruit juice—pineapple ref.
			Fruit juice—nectars ref.
			Fruit juice—remaining ref.

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Beverages (cont.)	Fruit juice—shelf stable	Cider shelf
			Fruit juice—apple shelf
			Fruit juice—grape shelf
			Fruit juice—grapefruit—other container shelf
			Fruit juice—lemon/lime shelf
			Fruit juice—orange—other container shelf
			Fruit juice—pineapple shelf
			Fruit juice—grapefruit—canned shelf
			Fruit juice—nectars shelf
			Fruit juice—orange—canned shelf
			Fruit juice—prune shelf
			Fruit juice—remaining shelf
			Fruit punch bases & syrups
		Fruit punch bases/syrups	
		Fruit punch bases/syrups total	
		Ice	Ice
		Milk—flavored—refrigerated	Dairy—flavored milk—refrigerated
		Milk—refrigerated	Dairy—milk—refrigerated

(continued)



Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Beverages (cont.)	Milk—shelf stable	Milk—canned
			Milk—shelf stable
		Milk/creamers—powdered	Creamers—powdered
			Milk—powdered
		Milk/water—additives	Milk/water additives—sweetened
		Noncarbonated beverages—mixes	Breakfast drinks—powdered
			Soft drinks—powdered
		Shakes/drinks—remaining—nonrefrigerated	Remaining drinks & shakes—nonrefrigerated
		Shakes/drinks/eggnog—refrigerated	Eggnog—fresh & canned
			Remaining drinks & shakes—refrigerated
		Tea—bags/packaged	Tea—bags
			Tea—packaged
		Tea—herbal	Tea—herbal—instant
			Tea—herbal bags
			Tea—herbal packaged
		Tea—instant	Tea—instant
			Tea—mixes
		Tea—liquid	Tea—liquid

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Beverages (cont.)	Vegetable juice—shelf stable	Vegetable juice—tomato shelf
			Vegetable juice and drink remaining shelf
		Water—bottled	Water—bottled sparkling/carbonated water
			Water—bottled still/noncarbonated water
		Water—bottled/caloric	Soft drinks—carbonated sparkling/carbonated
			Soft drinks—carbonated still/noncarbonated
		Water—bottled/low calorie	Soft drinks—low calorie sparkling/carbonated
			Soft drinks—low calorie still/noncarbonated
		Wine—nonalcoholic	Wine—nonalcoholic shlf
	Breakfast foods	Breakfast bars/pastries/ powders	Breakfast bars
			Granola & yogurt bars
			Instant breakfast—powdered
			Toaster pastries
		Breakfasts—frozen	Frozen/refrigerated breakfasts
		Cereal—hot	Cereal—hot
			Hominy grits

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Breakfast foods (cont.)	Cereal—ready to eat	Cereal—granola & natural types
			Cereal—ready to eat
			Wheat germ
	Candy & gum	Waffle/pancake/French toast—frozen	Frozen waffles & pancakes & French toast
		Candy—chocolate	Candy—chocolate
			Candy—chocolate—miniatures
			Candy—chocolate—special
		Candy—dietetic	Candy—dietetic—chocolate
			Candy—dietetic—nonchocolate
			Breath sweeteners
		Candy—nonchocolate	Candy—hard rolled
			Candy—kits
			Candy—lollipops
			Candy—nonchocolate
			Candy—nonchocolate—miniatures
			Marshmallows
		Gum—low calorie	Gum—bubble—sugar free
			Gum—chewing—sugar free
		Gum—regular	Gum—bubble
			Gum—chewing

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Condiments/dips/spreads	Condiments	Catsup
			Fish & seafood & cocktail sauce
			Mustard
		Dips—refrigerated	Dairy—dip—refrigerated & frozen
			Dip—canned
		Dips—shelf stable	Dip—mixes
			Extracts
		Extracts	Extracts
		Honey	Honey
		Jams/jellies	Jams
			Jelly
			Marmalade
			Preserves
		Jams/spreads—remaining	Butter—fruit & honey
			Fruit spreads
			Garlic spreads
		Marinades/tenderizers/MSG	Meat marinades & tenderizers
			Monosodium glutamate & flavor enhancers

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Condiments/dips/spreads (cont.)	Mayonnaise	Mayonnaise
			Salad dressing—"Miracle Whip" type
			Sandwich spreads—relish type
		Peanut butter	Peanut butter
			Pepper
			Pepper
		Pickles/olives/relishes	Capers
			Chilies
			Olives—black
			Olives—green
			Peppers
			Pickles—dill
			Pickles—sweet
			Pimentos—canned
			Relishes
			Salt—cooking/edible/ seasoned
		Salt	Salt—table
			Salt—canning/pickling/ curing
			Salt substitutes
		Salt—substitutes	Salt substitutes
			Horseradish
			Meat & sandwich spreads—refrigerated
		Sandwich spreads/ horseradish/sauerkraut—refrigerated	Sauerkraut—refrigerated

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Condiments/dips/spreads (cont.)	Seasoning—dry	Seasoning—dry
		Spices/seasonings—remaining	Cooking bags w/seasoning
			Home canning seasonings
			Seasoning—liquid & remaining
			Vegetables—onions—instant
			Garlic spreads—refrigerated
			Spreads—remaining
			Butter
			Cheese—cottage
			Cheese—farmers
	Dairy foods	Cheese—cottage/farmers/ ricotta	Cheese—ricotta
			Cheese—grated
			Cheese—shredded
		Cheese—grated/shredded	Cheese—natural—American cheddar
			Cheese—natural—American colby
			Cheese—natural—brick
			Cheese—natural—mozzarella
			Cheese—natural—remaining
			Cheese—natural—variety pack

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Dairy foods (cont.)	Cheese—natural (cont.)	Cheese—natural—muenster
			Cheese—natural—Swiss
		Cheese—processed	Cheese—processed—cream cheese
			Cheese—processed—loaves
			Cheese—processed—snack
			Cheese—processed slices—remaining
			Cheese—processed slices—American
		Cheese—specialty/imported	Cheese—specialty/imported
		Cream—refrigerated	Dairy—cream—refrigerated
		Frozen novelties	Frozen novelties
		Ice cream	Ice cream—bulk
		Ice milk/sherbet/yogurt—frozen	Ice milk and sherbet
			Yogurt—frozen
		Ice pops—unfrozen	Ice pops—unfrozen
		Sour cream	Dairy—potato topping—refrigerated
			Dairy—sour cream—refrigerated & canned
		Whipping cream	Whipping cream
		Yogurt—refrigerated	Yogurt—refrigerated
		Yogurt—shakes/drinks—refrigerated	Yogurt—refrigerated—shakes & drinks

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Desserts	Cheesecake/pies—fresh	Bakery—cheesecake—fresh
			Bakery—pies—fresh
		Cheesecake/pies—frozen	Bakery—pies—frozen
			Bakery—cheesecake—frozen
		Dessert—RTS single serving	Desserts—RTS single servings—canned
		Desserts/toppings—frozen	Frozen cream substitutes
			Frozen desserts
			Toppings—whipped—frozen
		Gelatin/pudding—mixes—diet	Gelatin—diet—mix
			Pudding—diet—mix
		Gelatin/pudding—mixes—sweetened	Gelatin—sweetened—mix
			Pudding—sweetened—mix
		Pudding—refrigerated	Pudding—refrigerated
		Syrups/toppings—shelf stable	Mixes—ice cream
			Pudding—plum—canned
			Pudding/pie filling—canned
			Syrup—chocolate

(continued)



Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Desserts (cont.)	Syrups/toppings—shelf stable (cont.)	Syrup—specialty
			Toppings—liquid & dry
			Toppings—mixes
	Dressings & sauces	Toppings—refrigerated	Toppings—refrigerated
		Salad dressing—liquid	Salad dressing—liquid
		Salad dressing—reduced/low calorie	Salad dressing—reduced/low calorie
		Salad dressing—refrigerated	Salad dressing—refrigerated
		Salad dressings/toppings—dry	Salad & potato toppings—dry
			Salad dressing mixes—dry
		Sauce—barbecue	Barbecue sauces
		Sauce—Mexican	Mexican sauce
		Sauce—spaghetti/marinara	Sauce mix—spaghetti
			Spaghetti/marinara sauce
		Sauce/gravy—mixes	Egg mixes—dry
			Gravy aids & beef extract
			Gravy mixes—packaged
			Sauce & seasoning mix—remaining
			Sauce & seasoning mix—remaining Mexican
			Sauce mix—cheese

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Dressings & sauces (cont.)	Sauce/gravy—mixes (cont.)	Sauce mix—meat loaf
			Sauce mix—taco
			Seasoning mix—chili
			Seasoning mix—sloppy joe
		Sauce/gravy/glaze	Chili sauce
			Cooking sauce
			Fondue sauce
			Glazes—fruit
			Glazes—meat
			Gravy—canned
			Hot dog sauce
			Hot sauce
			Meat sauce
			Mushroom sauce
			Oriental sauces
			Pizza sauce
			Sauces—dipping
			Sauces—miscellaneous—shelf stable
			Tabasco/pepper sauce
			Worcestershire sauce

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Dressings & sauces (cont.)	Vinegar/cooking wine	Cooking wine & sherry
			Vinegar
	Eggs	Eggs—fresh	Eggs—fresh
	Entrees	Combination lunches	Combination lunches
			Dinners—frozen
		Entrees—frozen	Entrees—Italian—1 food—frozen
			Entrees—Italian—2 food—frozen
			Entrees—meat—1 food—frozen
			Entrees—meat—2 food—frozen
			Entrees—Mexican—1 food—frozen
			Entrees—Mexican—2 food—frozen
			Entrees—multipack—frozen
			Entrees—Oriental—1 food—frozen
			Entrees—Oriental—2 food—frozen
			Entrees—poultry—1 food—frozen
			Entrees—poultry—2 food—frozen
			Entrees—remaining—1 food—frozen
			Entrees—remaining—2 food—frozen

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Entrees (cont.)	Entrees—frozen (cont.)	Entrees—seafood—1 food—frozen
			Entrees—seafood—2 food—frozen
			Meal starters—frozen
			Pot pies—frozen
		Entrees—refrigerated	Chili—refrigerated
			Entrees—refrigerated
			Meal starters—refrigerated
			Pasta—refrigerated
		Prepared foods—canned/ shelf stable	Bread—specialty—canned
			Dumplings—canned
			Entrees/side dishes—shelf stable
			Lasagna—canned
			Macaroni products—shelf stable
			Meal starters—shelf stable
			Mexican dinners—canned
			Mexican specialties—remaining
			Mexican—refried beans
			Oriental foods—chow mein—canned
			Oriental foods—misc.
			Pickled vegetables & fruit
			Potato salad—canned

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Entrees (cont.)	Prepared foods—canned/ shelf stable (cont.)	Ravioli—canned
			Rice—canned
			Spaghetti—canned
			Spreads—hors d’oeuvres
	Fats & oils	Sandwiches—refrigerated/ frozen	Sandwiches—refrigerated/frozen
		Cooking sprays	Cooking sprays
		Lard/shortening	Lard
			Shortening
		Margarine/spreads	Margarine and spreads
		Oils—olive/salad/cooking	Olive oil
	Fruits & vegetables	Beans—canned	Salad and cooking oil
			Vegetables—beans—chili—canned
			Vegetables—beans—garbanzo—canned
			Vegetables—beans—kidney/red—canned
			Vegetables—beans—lima—canned

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Fruits & vegetables (cont.)	Beans—canned (cont.)	Vegetables—beans—pinto—canned
			Vegetables—beans—remaining—canned
			Vegetables—beans—vegetarian—shelf stable
			Vegetables—beans—waxed—canned
			Vegetables—beans—white/northern/navy—can
		Beans/peas/lentils/barley—dry	Barley—dry
			Beans—dry
			Peas & lentils & corn—dry
			Tapioca—pure
			Canned fruit—apple sauce
		Fruit—canned	Canned fruit—apples
			Canned fruit—berries
			Canned fruit—figs
			Canned fruit—fruit mixes & salad fruit
			Canned fruit—grapes
			Canned fruit—oranges
			Canned fruit—peaches—freestone
			Canned fruit—pineapple
			Canned fruit—prunes

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Fruits & vegetables (cont.)	Fruit—canned (cont.)	Canned fruit—remaining
			Canned fruit—apricots
			Canned fruit—cherries
			Canned fruit—fruit cocktail
			Canned fruit—grapefruit
			Canned fruit—peaches—cling
			Canned fruit—pears
			Canned fruit—plums
			Cherries—maraschino
			Cranberries—shelf stable
			Mincemeat—canned
			Pie & pastry filling—canned
			Pumpkin—canned
		Fruit—dried	Dates
			Fruit—dried and snacks
			Prunes—dried
		Fruit—fresh	Raisins
			Fresh apples
			Fresh cranberries
			Fresh fruit—remaining

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Fruits & vegetables (cont.)	Fruit—fresh (cont.)	Fresh grapefruit
			Fresh kiwi
			Fresh oranges
			Fresh strawberries
		Fruit/fruit salad—refrigerated	Fruit salads—refrigerated
			Fruit—refrigerated
		Fruits—frozen	Frozen fruits
		Garlic/herbs—fresh	Fresh garlic
			Fresh herbs
		Leafy greens—fresh	Fresh lettuce
			Fresh spinach
		Potatoes—canned	Vegetables—potatoes—canned
			Vegetables—sweet potatoes & yams—canned
		Potatoes—dehydrated	Vegetables—potatoes—mashed—dehydrated
			Vegetables—potatoes—specialty—dehydrated
		Potatoes—fresh	Fresh potatoes
		Potatoes—frozen	Vegetables—potatoes—frozen/refrigerated

(continued)



Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Fruits & vegetables (cont.)	Tomatoes—canned	Tomato paste
			Tomato puree
			Tomato sauce
			Tomatoes—remaining—canned
			Tomatoes—stewed
			Tomatoes—whole—canned
		Vegetables—canned	Bean sprouts—canned
			Cocktail onions
			Grape leaves—canned
			Mushrooms—shelf stable
			Oriental canned vegetables
			Salad—jelled aspic
			Vegetables—red cabbage—canned
			Vegetables—artichokes—canned
			Vegetables—asparagus—shelf stable
			Vegetables—beans—green—canned
			Vegetables—beets—shelf stable
			Vegetables—carrots—shelf stable
			Vegetables—corn on the cob—canned
			Vegetables—corn—cream style—canned

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Fruits & vegetables (cont.)	Vegetables—canned (cont.)	Vegetables—corn—whole kernel—canned
			Vegetables—greens—canned
			Vegetables—hominy—canned
			Vegetables—mixed—canned
			Vegetables—okra—canned
			Vegetables—onions—canned
			Vegetables—peas & carrots—canned
			Vegetables—peas—canned
			Vegetables—peas—remaining—canned
			Vegetables—remaining—canned
			Vegetables—sauerkraut—shelf stable
			Vegetables—spinach—canned
			Vegetables—squash & rutabagas—canned
			Vegetables—succotash—canned
		Vegetables—fresh	Fresh carrots
			Fresh cauliflower
			Fresh celery
			Fresh mushrooms
			Fresh onions
			Fresh radishes

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Fruits & vegetables (cont.)	Vegetables—fresh (cont.)	Fresh sprouts
			Fresh tomatoes
			Fresh vegetables—remaining
		Vegetables—frozen	Vegetables—broccoli—frozen
			Vegetables—carrots—frozen
			Vegetables—corn—frozen
			Vegetables—corn on the cob—frozen
			Vegetables—lima beans—frozen
			Vegetables—mixed—frozen
			Vegetables—peas—frozen
			Vegetables—remaining—frozen
			Vegetables—green beans—frozen
		Vegetables—precut salad mix—fresh	Precut fresh salad mix
	Infant foods	Baby food	Baby cereal & biscuits
			Baby food—junior
			Baby food—strained
			Baby milk and milk flavoring
		Infant formulas	Baby milk and milk flavoring
		Juices—baby	Baby juice
	Meat & poultry	Cracklins—refrigerated	Cracklins—refrigerated

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Meat & poultry (cont.)	Meat—frozen	Frozen meat—ground beef
			Frozen meat—pork
			Frozen meat—remaining
			Frozen meat—sandwich steak
			Frozen meat—veal
		Meat/poultry—canned	Frozen meat—beef steak
			Barbecued beef & pork—canned
			Chicken—shelf stable
			Chili—shelf stable
			Corned beef—canned
			Corned beef hash—canned
			Deviled ham—canned
			Dried beef—shelf stable
			Meat products—imitation & additives
			Meat products—misc.—canned
			Pickled pork products
			Potted meat—canned
			Roast beef—canned
			Roast beef hash—canned
			Sandwich spreads—meat

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Meat & poultry (cont.)	Meat/poultry—canned (cont.)	Sausage—canned
			Scrapple & mush
			Spiced lunch meat—canned
			Stew—beef—shelf stable
			Stew—chicken—shelf stable
			Stew—remaining—shelf stable
			Turkey—canned
			Vegetables—beans with meat—shelf stable
			Vienna sausage—canned
		Poultry—frozen	Frozen poultry
	Pizza	Pizza—frozen	Pizza—frozen
		Pizza—refrigerated	Pizza—refrigerated
	Seafood	Fish—frozen	Seafood—fish—breaded—frozen
			Seafood—fish—unbreaded—frozen
		Seafood—canned	Anchovy paste
			Clam juice shelf stable
			Seafood—anchovies
			Seafood—oysters—canned
			Seafood—remaining—canned

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Seafood (cont.)	Seafood—canned (cont.)	Seafood—salmon—canned
			Seafood—sardines—canned
			Seafood—shrimp—canned
			Seafood—clams—canned
			Seafood—crab—canned
			Seafood—tuna—shelf stable
		Seafood—refrigerated	Seafood—refrigerated
		Seafood—remaining—frozen	Seafood—crab—unbreaded—frozen
			Seafood—remaining—breaded—frozen
			Seafood—remaining—unbreaded—frozen
		Shrimp—frozen	Seafood—shrimp—breaded—frozen
			Seafood—shrimp—unbreaded—frozen
	Side dishes & starches	Hors d'oeuvres/snacks—frozen	Frozen/refrigerated hors d'oeuvres & snacks
		Pasta/noodles—dry	Oriental noodles
			Pasta—macaroni
			Pasta—noodles & dumplings
			Pasta—spaghetti
		Prepared foods—dry mixes	Dry dinners—pasta
			Dry dinners—remaining

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Side dishes & starches (cont.)	Prepared foods—dry mixes (cont.)	Dry dinners—rice
			Mexican dinners—dry/kit
			Mixes—ethnic specialties
			Oriental foods—ramen noodles
			Pizza pie and crust mixes
			Rice—mixes
		Prepared foods—remaining— frozen/refrigerated	Corn dogs—frozen/ refrigerated
			Pasta—plain—frozen
			Sauces & gravies—frozen/ refrigerated
			Soup—frozen—refrigerated
			Taco filling—frozen/ refrigerated
			Gelatin salads—refrigerated
		Ready-made salads	Remaining—ready-made salads
		Rice—instant/packaged	Rice—instant
			Rice—packaged and bulk
		Vegetables—formulated/ breaded— frozen	Vegetables—breaded—frozen
			Vegetables—mushrooms—breaded— frozen
			Vegetables—onions—breaded—frozen
			Vegetables—in sauce—frozen

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Snack foods	Nuts—cans/jars	Nuts—cans
			Nuts—jars
		Nuts—cello wrapped	Nuts—bags
		Nuts—unshelled	Nuts—unshelled
		Popcorn—unpopped	Popcorn—unpopped
		Snacks—caramel corn/ popped popcorn	Popcorn—popped
			Snacks—caramel corn
		Snacks—health bars & sticks	Snacks—health bars & sticks
		Snacks—meat	Snacks—meat
		Snacks—remaining	Snacks—remaining
		Snacks—salty	Crackers—sandwich & snack packs
			Rice cakes
			Snacks—corn chips
			Snacks—pork rinds
			Snacks—potato chips
			Snacks—potato sticks
			Snacks—pretzel
			Snacks—puffed cheese
			Snacks—tortilla chips

(continued)



Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Foods (cont.)	Snack foods (cont.)	Snacks—salty (cont.)	Snacks—variety packs
		Snacks—trail mixes	Trail mixes
	Soups	Soup—canned	Soup—canned
		Soup—dry	Bouillon
			Instant meals
			Soup mixes—dry & bases
			Stew mixes—dry
	Sweeteners	Sugar	Sugar—brown
			Sugar—remaining
			Sugar—granulated
			Sugar—powdered
			Sugar substitutes
			Molasses
			Syrup—berry/fruit type
			Syrup—sorghum & sugar
			Syrup—table

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
OTCs	Acne remedies	Acne remedies	Acne remedies
	Cough and cold remedies	Cold remedies—adult	Cold remedies—adult
		Cold remedies—children	Cold remedies—children
		Cough and cold throat sprays	Cough and cold throat sprays
		Cough drops lozenges	Cough drops
			Throat lozenges
		Cough syrups and tablets	Cough syrups & tablets
		Nasal products	Nasal product internal
		Sinus remedies	Sinus remedies
	Deodorant (antiperspirant)	Deodorant—aerosol	Deodorant—aerosol <sup>a</sup>
		Deodorant—roll-on	Deodorant—roll-on <sup>a</sup>
		Deodorant—stick/solid	Deodorant—stick/solid <sup>a</sup>
		Remaining deodorants	Remaining deodorants <sup>a</sup>
	Eye care	Contact lens solution	Contact lens solution
		Eye care—remaining	Eye care—remaining
		Eye drops & lotions	Eye drops & lotions

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
OTCs (cont.)	Feminine hygiene	Remaining feminine hygiene	Feminine hygiene—miscellaneous <sup>c</sup>
			Feminine hygiene—towelettes
	First aid	Adhesive bandages (medicated)	Adhesive bandages <sup>f</sup>
		First aid—germicidal antiseptics	Germicidal antiseptics
		First aid—hydrocortisones	First aid—hydrocortisones
		First aid—treatments	First aid—treatments
	Hair care	Hair growth products	Hair growth product
		Shampoo (medicated)	Shampoo—aerosol/liquid/ lotion/powder <sup>d</sup>
			Shampoo—bars/ concentrates/and creams <sup>d</sup>
	Oral hygiene	Denture adhesives	Denture adhesives
		Oral care combinations—OTC	Oral care combinations treatments and PR <sup>g</sup>
		Oral rinse and antiseptic	Oral rinse and antiseptic
		Toothpaste (fluoride)	Tooth cleaners

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
OTCs (cont.)	Pain remedies	Pain remedies	Pain remedies—alkalizing effervescent
			Pain remedies—arthritis
			Pain remedies—back & leg
			Pain remedies—headache
			Pain remedies—premenstrual
			Pain remedies—children's
			Pain remedies—children's liquid
			Pain remedies—urinary tract
			Tranquilizers/calmatives
			Hand cleaners and hand sanitizers
	Personal soap/bath need Preparations/remedies	Hand cleaners and hand sanitizers	Analgesic & chest rubs
			Analgesic & chest rubs
			Antacids
			Antacids
			Antigas products
			Antigas products
			Antisleep products
			Antisleep products
			Antismoking products
			Antismoking product
			Bronchial remedies
			Bronchial remedies
			Dairy digestive aids
			Dairy digestive aids
			Diarrhea remedies
			Diarrhea remedies
			Diuretic remedies
			Diuretic remedies

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
OTCs (cont.)	Preparations/remedies (cont.)	Ear drops	Ear drops
		Foot preparations—athlete's foot	Foot preparations—athlete's foot
		Ipecac product	Ipecac product
		Jock itch products	Jock itch products
		Laxatives	Laxatives
		Lip remedies—cold sore/fever blister	Lip remedies—remaining <sup>b</sup>
		Medicated products	Medicated products
		Motion sickness preventatives	Motion sickness preventatives
		Petroleum jelly	Petroleum jelly
		Psoriasis & eczema treatments	Psoriasis & eczema treatments
		Rectal medication	Rectal medication
		Sleeping aids	Sleeping aids
		Tooth & gum analgesics	Tooth & gum analgesics
		Vaporizing products	Vaporizing products
	Skin care preparations	Skin bleaching/toning products	Skin bleaching/toning products
		Suntan preparations—sunscreens & sunblock	Suntan preparations—sunscreens & sunblock

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Pet Foods	Pet care	Flea products	Pet care—flea & tick products
			Pet care—flea collars
			Pet incontinence product
		Pet treatments external	Pet treatments external
		Pet treatments internal	Pet treatments internal
	Pet food	Cat food—dry	Cat food—dry type
		Cat food—moist/wet	Cat food—moist type
			Cat food—wet type
			Dog food—dry type
		Dog food—moist/wet	Dog food—moist type
			Dog food—wet type
			Pet care—domestic bird food
		Other pet food	Pet care—pet food
		Pet treats	Dog & cat treats

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Retail Medical Devices	Adult incontinence	Adult incontinence	Adult—incontinence
	Baby needs	Baby and nursing accessories	Baby pacifier/teether & bottle/nipple brushes
			Nursing accessories
			Baby bottles & nipples
	Breathing aids external	Breathing aids external	Breathing aids external
	Enemas—ready to use	Enemas—ready to use	Enemas—ready to use
	Family planning	Contraceptives—female	Contraceptives—female
		Contraceptives—male	Contraceptives—male
		Family planning test kits	Ovulation and fertility test kits
	Feminine hygiene		Pregnancy test kits
		Douches	Feminine hygiene—douches
		Remaining feminine hygiene	Feminine hygiene—miscellaneous <sup>c</sup>
		Sanitary belts/panties/ napkins	Sanitary belts and panties
			Sanitary napkins
		Tampons	Tampons

(continued)

Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Retail Medical Devices (cont.)	First aid	Adhesive bandages—liquid—powder—PA	Adhesive bandages—liquid—powder—PA
		Adhesive bandages (nonmedicated)	Adhesive bandages <sup>f</sup>
		First aid—gauze & tape	Adhesive tape
			First aid—gauze—rolls
			First aid—gauze pads
		First aid—ice and heat pack	First aid—ice and heat pack
		First aid—thermometers	First aid—thermometers
		Foot comforts products	Foot comforts products
		Foot preparations—remaining	Insoles
	Foot care		
	Insulin syringes	Insulin syringes	Insulin syringes
	Medical wrap and brace	Medical wrap and brace	Medical wrap and brace
	Oral hygiene	Dental accessories	Dental accessories
		Dental floss	Dental floss
		Oral care combinations—medical device	Oral care combinations treatments and PR <sup>g</sup>
		Oral hygiene appliance and accessory	Oral hygiene appliance and accessory
		Oral hygiene brushes	Oral hygiene brushes

(continued)



Table B-1. Detailed Nielsen Product Modules by Model Category and Subcategory (continued)

FDA Type	Model Category	Model Subcategory	Product Module in Nielsen Data
Retail Medical Devices (cont.)	Test kits	Blood pressure kit and accessory	Blood pressure kit and accessory
		Blood urine stool test products	Blood urine stool test products
	Medical accessory—remaining	Medical accessory—remaining	Medical accessory—remaining
Tobacco Products	Tobacco & accessories	Cigarette and cigar paper	Cigarette and cigar paper
		Cigarettes	Cigarettes
		Cigars	Cigars
		Tobacco—chewing	Tobacco—chewing
		Tobacco—smoking	Tobacco—smoking

<sup>a</sup> The Deodorant-Aerosol, Deodorant—Roll-on, Deodorant-Stick/Solid, and Remaining Deodorants product modules were split into cosmetics and OTCs because deodorant without antiperspirant is classified as a cosmetic, and deodorant with antiperspirant is classified as an OTC.

<sup>b</sup> The Lip Remedies—Remaining product module was split into OTCs and cosmetics because medicated Lip Remedies are classified as OTCs, and nonmedicated lip remedies are classified as cosmetics.

<sup>c</sup> The Feminine Hygiene—Miscellaneous product module was split into cosmetics, OTCs, and medical devices because nonmedicated products applied to the human body are classified as cosmetics, medicated products applied to the human body are classified as OTCs, and application devices are classified as medical devices.

<sup>d</sup> The Shampoo-Aerosol/Liquid/Lotion/Powder and Shampoo-Bars/Concentrates/and Creams product modules were split into OTCs and cosmetics because medicated shampoo products are classified as OTCs, and nonmedicated shampoo products are classified as cosmetics.

<sup>e</sup> The Tooth Cleaners product module was split into OTCs and cosmetics because toothpaste containing fluoride is classified as an OTC, and toothpaste without fluoride is classified as a cosmetic.

<sup>f</sup> The Adhesive Bandages product module was split into OTCs and medical devices because medicated bandages are classified as OTCs, and nonmedicated bandages are classified as medical devices.

<sup>g</sup> The Oral Care Combinations Treatments and PR product module was split into OTCs and medical devices because oral care products containing fluoride are classified as OTCs, and oral care products that are toothbrushes are classified as medical devices.