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Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration

Contract No. GS-10F-0097L, Task Order 5

Revised Final Report

Prepared for

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RTI Project Number 0211460.005

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Contents

Section	Page
1 Introduction	1-1
1.1 Background on the Labeling Cost Model	1-2
1.2 Objective	1-3
1.3 Organization of this Report	1-4
2 Overview of Packaging Types, Label Types, and Printing Methods	2-1
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

3	Overview of Labeling Changes Conducted by Manufacturers	3-1
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
4	Model Structure, Data, Assumptions, and Calculations	4-1
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	4-4
4.2.1	Selection of a Baseline for Product Categories	4-5
4.2.2	Private-Label UPC Counts	4-5
4.2.3	Product Categories, Subcategories, and Adjustments to the UPC Counts and Unit Sales.....	4-7
4.3	Formulas for Calculating the Costs of Labeling Changes.....	4-32
4.3.1	Costs of Changing Product Labels	4-32
4.3.2	Adjustments for Short Compliance Periods.....	4-38
4.3.3	Adjustments for Inflation	4-40
4.4	Cost Calculation Data Included in the Model.....	4-40
4.4.1	Per-UPC Cost Calculation Data.....	4-40
4.4.2	Per-Formulation Cost Calculation Data.....	4-45
4.4.3	Per-Sales Unit Cost Calculation Data	4-47
4.4.4	Accounting for Uncertainty in the Cost Estimates	4-72
4.5	Assumptions and Limitations of the Methodology	4-73
5	Instructions for Using the Labeling Cost Model	5-1
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)	5-8
5.2.3	Type of Labeling Change Selection	5-10
5.2.4	Analytical and Market Testing Costs Selection	5-11
5.2.5	Recordkeeping Costs Selection	5-13
5.2.6	Compliance Period Selection.....	5-14
5.2.7	Inflation Factor Modification (optional)	5-16
5.2.8	Running the Model Using Input Values.....	5-17
5.3	Viewing the Model Outputs	5-17

References

R-1

Appendixes

A:	Industry Interview Materials	A-1
B:	Selection of Baseline Year in the Model.....	B-1
C:	Detailed Information on Nielsen Product Modules Included in Each Model Subcategory	C-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	5-3
5-2. Affected Products by Type Selection Screen—Drop-Down Menu for Product Type	5-5
5-3. Affected Products by Type Selection Screen—Selecting Entire List of Product Subcategories.....	5-5
5-4. Affected Products by NAICS Selection Screen—Selecting 3-Digit NAICS from a Drop-Down Menu.....	5-7
5-5. Affected Products by NAICS Selection Screen—Selecting and Adding 6-Digit NAICS and Product Subcategories	5-7

5-6.	Percentage of Affected Products Screen—Entering a Percentage to Apply to All Subcategories Previously Selected.....	5-9
5-7.	Percentage of Affected Products Screen—Entering a Percentage for Each Subcategory	5-9
5-8.	Type of Labeling Change—Selecting Type of Labeling Change and Whether Package Inserts Are Affected.....	5-10
5-9.	Selecting Analytical Tests	5-11
5-10.	Selecting Market Tests	5-13
5-11.	Selecting Recordkeeping Costs.....	5-14
5-12.	Compliance Period Selection Screen—Select Amount of Time Manufacturers Will Have to Comply with the Labeling Regulation	5-15
5-13.	Compliance Period Selection Screen—Modify the Percentages of Changes That Could Be Coordinated with a Scheduled Change	5-16
5-14.	Inflation Factor Modification.....	5-17
5-15a.	Model Output—Input Selections Summary.....	5-18
5-15b.	Model Output—Input Selections Summary.....	5-19

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 (ρ^B) and Private-Label (ρ^{PL}) UPCs that Cannot be Coordinated with a Planned Change	3-10
4-1. Types of Labeling Changes that May Be Required by Regulation.....	4-2
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 Unit Sales.....	4-9
4-4. Adjustments to UPCs, Formulas, and Sales Units to Account for Nonrepresentation in the Nielsen ScanTrack Data	4-31
4-5. Estimated Labor, Materials, and Recordkeeping Costs Associated with Labeling Changes (\$/UPC)	4-41
4-6. Labor Hours and Consultant Costs for Each Type of Change	4-42
4-7. Estimated Percentages of UPCs Printed Using Each Printing Method by Package-Label Type (Preliminary Estimates).....	4-44
4-8. Estimated Analytical Testing Costs in the Labeling Cost Model (\$/Formula)	4-46

4-9.	Estimated Market Testing Costs in the Labeling Cost Model (\$/Formula)	4-47
4-10.	Estimated Sticker and Application Costs on a Per-Sticker Basis (\$/Sales Unit)	4-48
4-11.	Assumed Remaining Percentages of Package-Label Inventory Based on Compliance Period	4-49
4-12.	Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit)	4-50

1

Introduction

This report was revised from the version delivered in March 2011 to (1) correct the calculations and codes for pet foods, (2) correct the total number of products stated in the text, and (3) make other minor editorial corrections. A corrected version of the model dated August 2012 was also provided.

In September 2009, the U.S. Food and Drug Administration (FDA) contracted with RTI International to provide support to economics staff in FDA's Center for Food Safety and Applied Nutrition (CFSAN) and FDA's Office of the Commissioner (OC) by providing a tool to estimate the costs of risk-reduction strategies that include product labeling changes.

The 2010 FDA Labeling Cost Model is programmed in Microsoft Excel 2003 with a Visual Basic interface that steps the user through the selection of the model inputs.¹ 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:

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

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.

¹ The model also operates in Excel 2007.

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. Labeling is part of FDA's risk-reduction strategy for heart disease, allergic reactions and other nutrition-related illness, and foodborne hazards. Recent legislation, such as the Food and Drug Administration Amendments Act of 2007 (FDAAA), has specified changes to and studies of the FDA consumer product labeling regulations. FDAAA, for example, requires a review of whether labeling requirements on indoor tanning devices are adequate to communicate the risks of skin cancer to users. FDAAA requires promulgation of a rule to revise the current regulations governing the use of a toll-free number on certain drug products to track and reduce the risks to children and other users. As a response to new risks from international supply chains in pet food, another FDAAA provision requires changes to pet food labels. Other regulations and guidance documents requiring or leading to labeling changes on FDA-regulated products are also likely to be promulgated in the coming years. For example, new approaches to the presentation of nutrition and health information could lead to substantive changes in food labels.

The CFSAN Economics staff and the OC Economics staff both 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.

FDA needed to expand the previous model beyond foods and dietary supplements to cosmetics, OTC medications, pet food, retail medical devices, and tobacco products and accessories. Furthermore, the cost and industry data required updating, and certain aspects of the methodology needed to be further refined based on the availability of new data.

1.2 OBJECTIVE

The objective of this task order was to develop 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 information on the costs of labeling changes from industry, Appendix B provides a discussion of the choice of 2008 as the baseline for the model based on the available data, and Appendix C provides the detailed Nielsen product modules that are included in each model subcategory.

2

Overview of Packaging Types, Label Types, and Printing Methods

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. Each 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. In general, the use of flexography is increasing relative to the other printing 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 inadvertently be removed 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).

The types of packages that are directly printed include cartons, flexible packaging, cans, rigid plastic containers, blister-packs, gable-top cartons, and aseptic boxes. 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%) (FPA, 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—blister pack				●		●	
Foil-backed paper—pouch	●		●	●		●	
Foil—bag			●				
Foil—top			●				
Foil—tube	●			●			
Gable-top carton			●				
Paper				●		●	
Paper backed—blister pack						●	
Paper—bag			●		●		
Paper—coated			●				
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—label	●	●	●	●		●	
Plastic—molded	●		●			●	
Plastic—sheet	●	●	●	●	●	●	
Plastic—tube	●		●	●			
Popcorn bag			●				
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 reviewed and adjusted by Packaging Technology and Integrated Solutions, Inc. (PTIS) based on their labeling and packaging knowledge.¹ 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.² 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.

Below, we describe the contents of principal display panels (PDP) and information panels (IPs) for products under each

¹ PTIS is a consulting firm with expertise in retail product packaging and printing, including how manufacturers choose packaging types and printing methods. They were hired as a subcontractor on this project to aid in packaging and printing distribution estimates used in the labeling cost model.

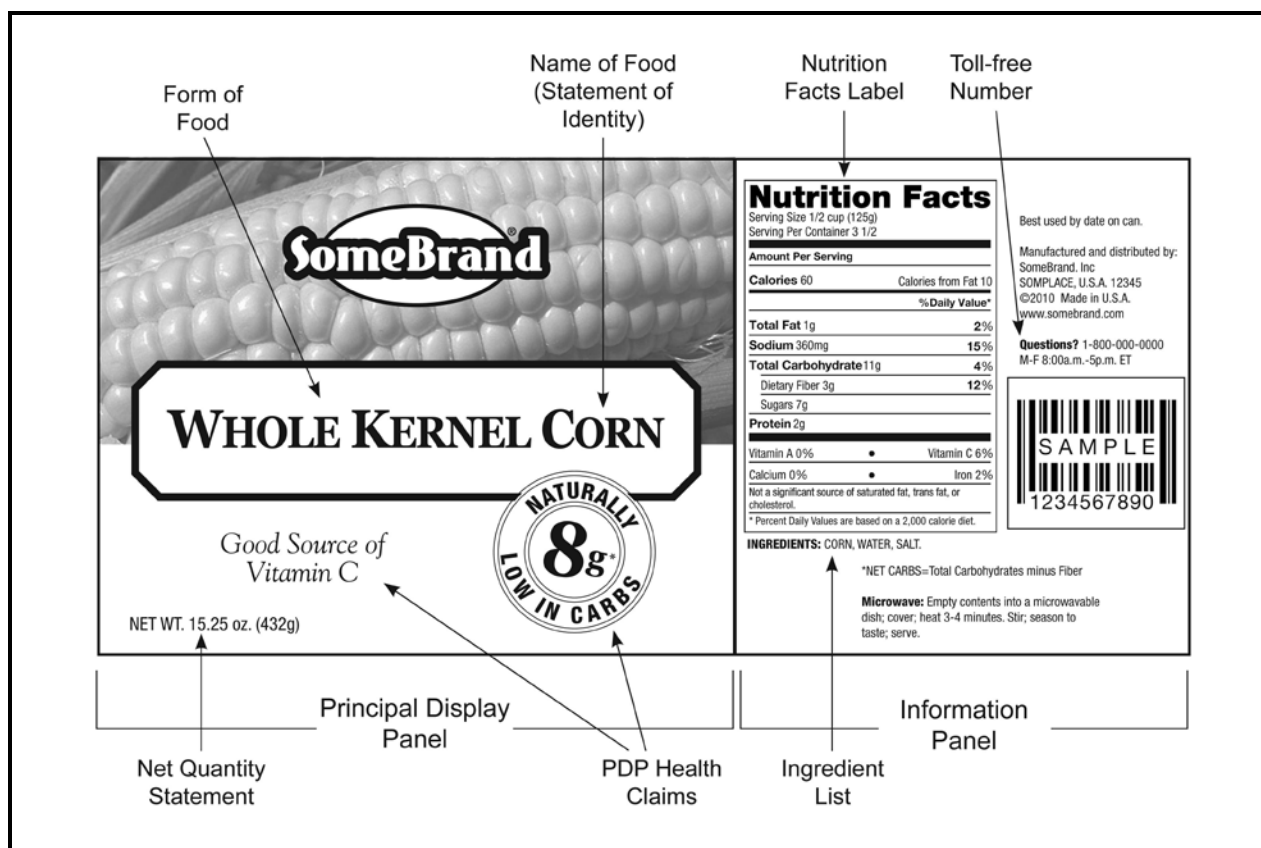
² Many manufacturers list ingredients using black ink; however, some manufacturers that we spoke with use colored inks, in which case, a change in ingredients would be considered a major change.

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.

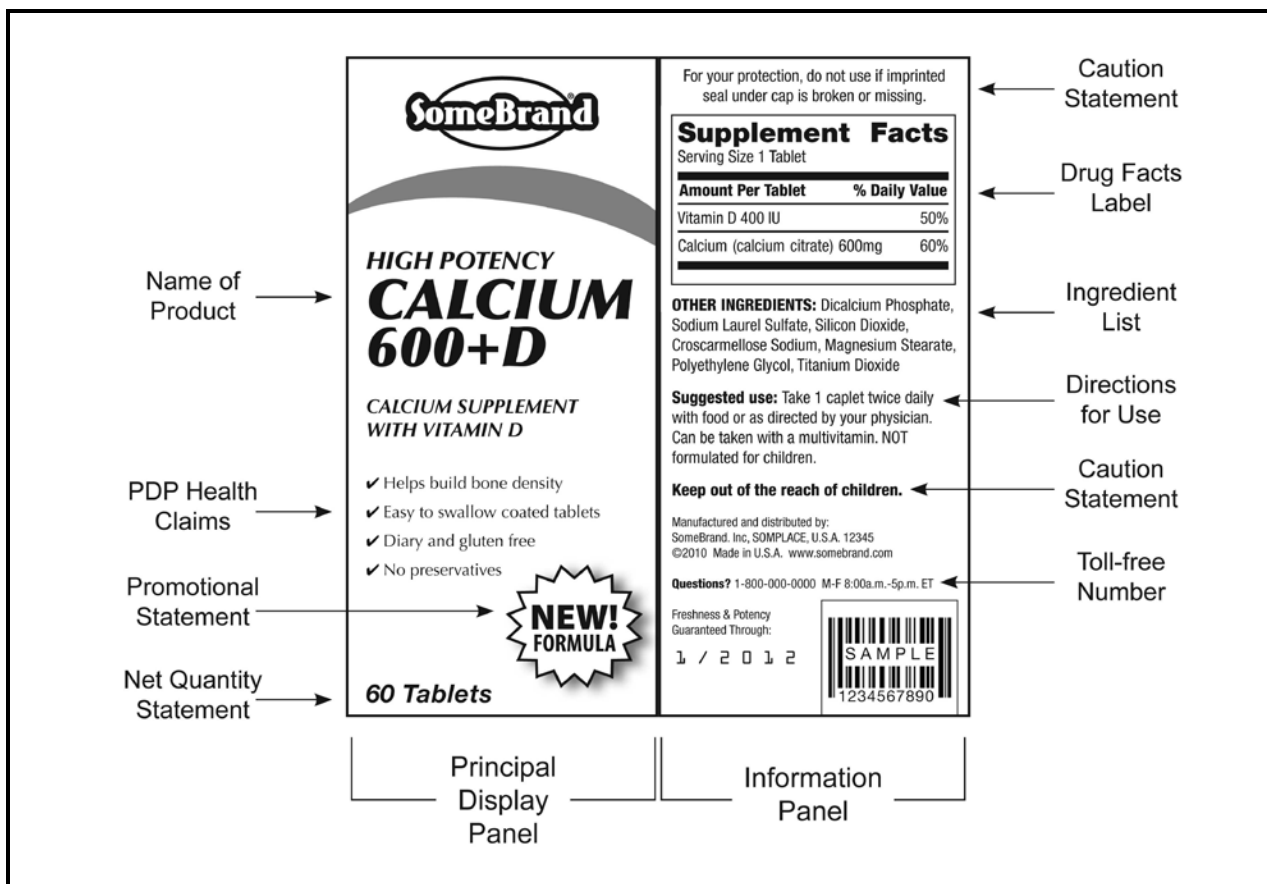
Figure 2-1. Example of Parts of Food Labels that May Change as a Result of a Regulation: Canned Corn



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

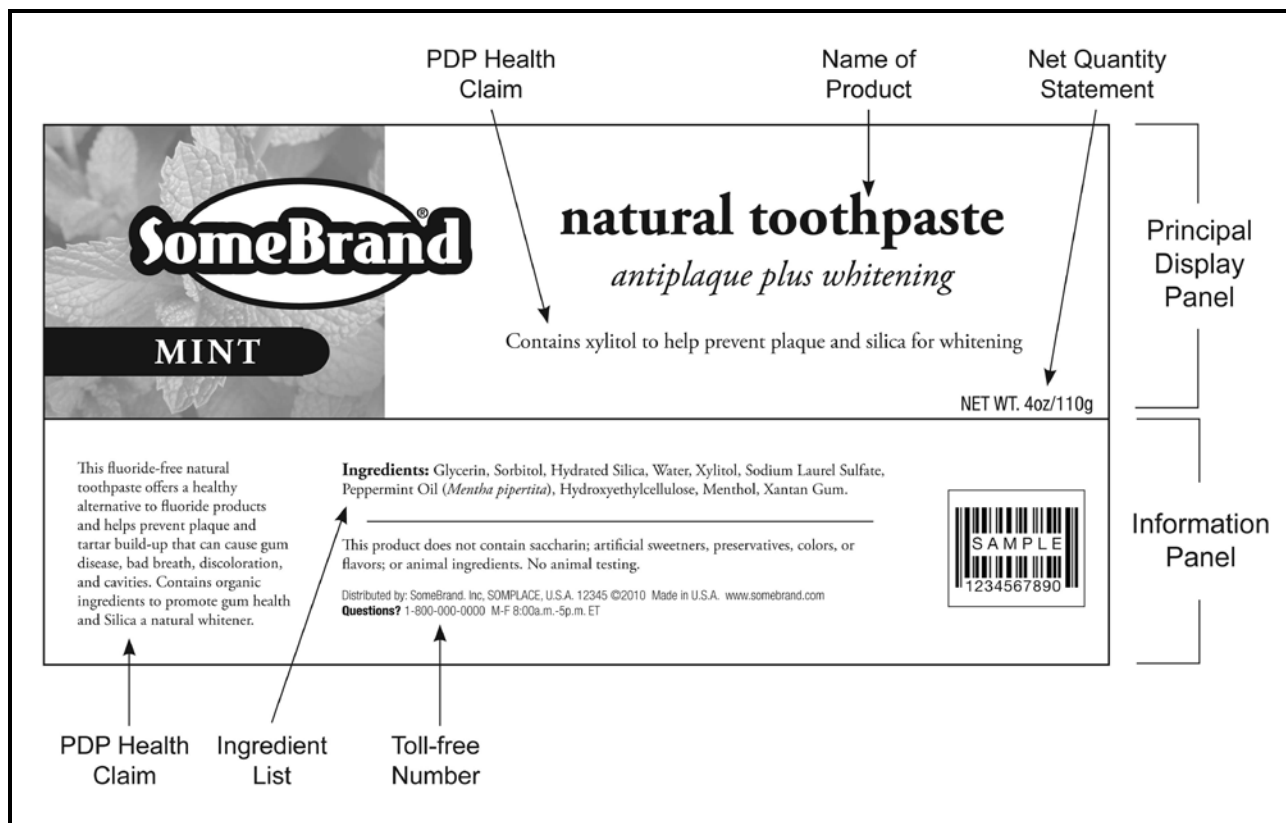


2.3.2 Cosmetics Label Contents

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

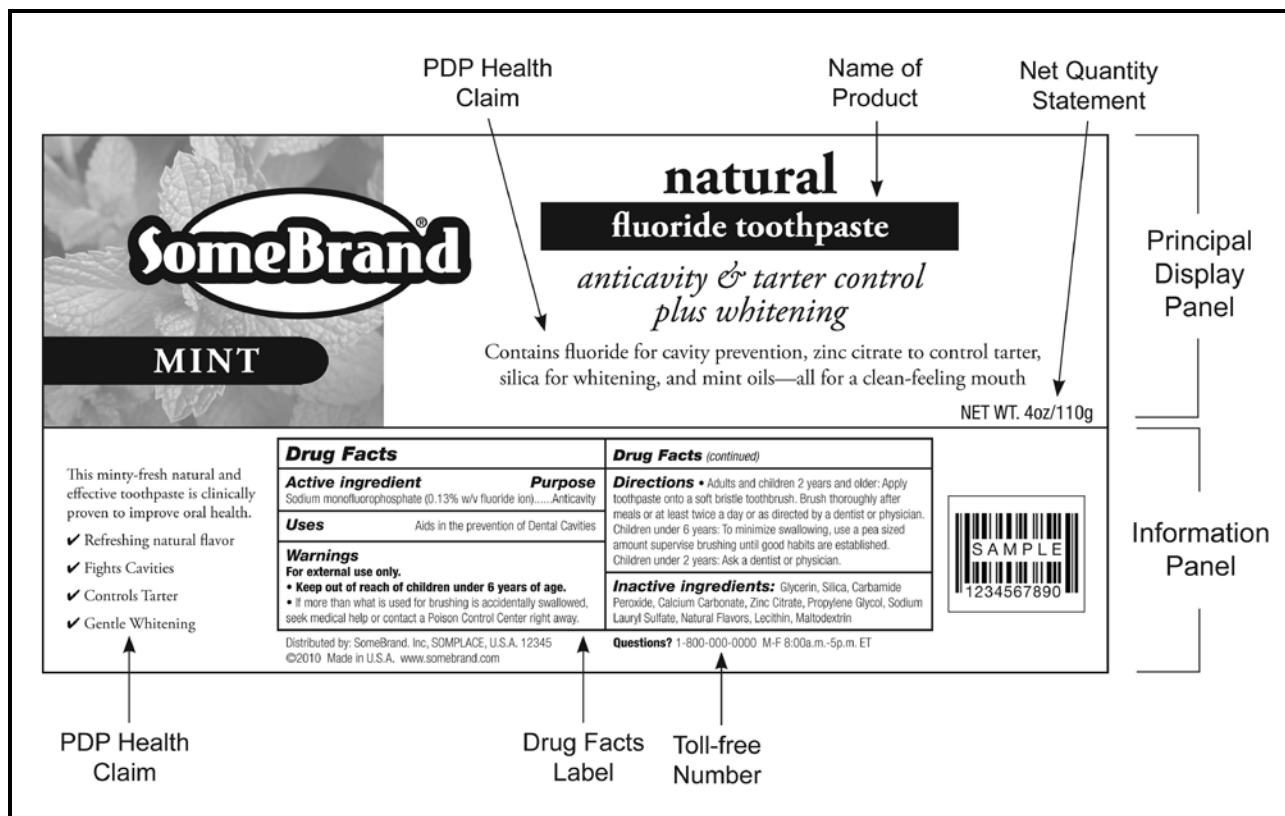


In the example cosmetic product in Figure 2-3, a labeling regulation may affect the following parts of the PDP: the name of the cosmetic, the health claim or marketing claim, or the net quantity statement. Other parts of the PDP such as the brand name or vignette are unlikely to be affected by a labeling 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

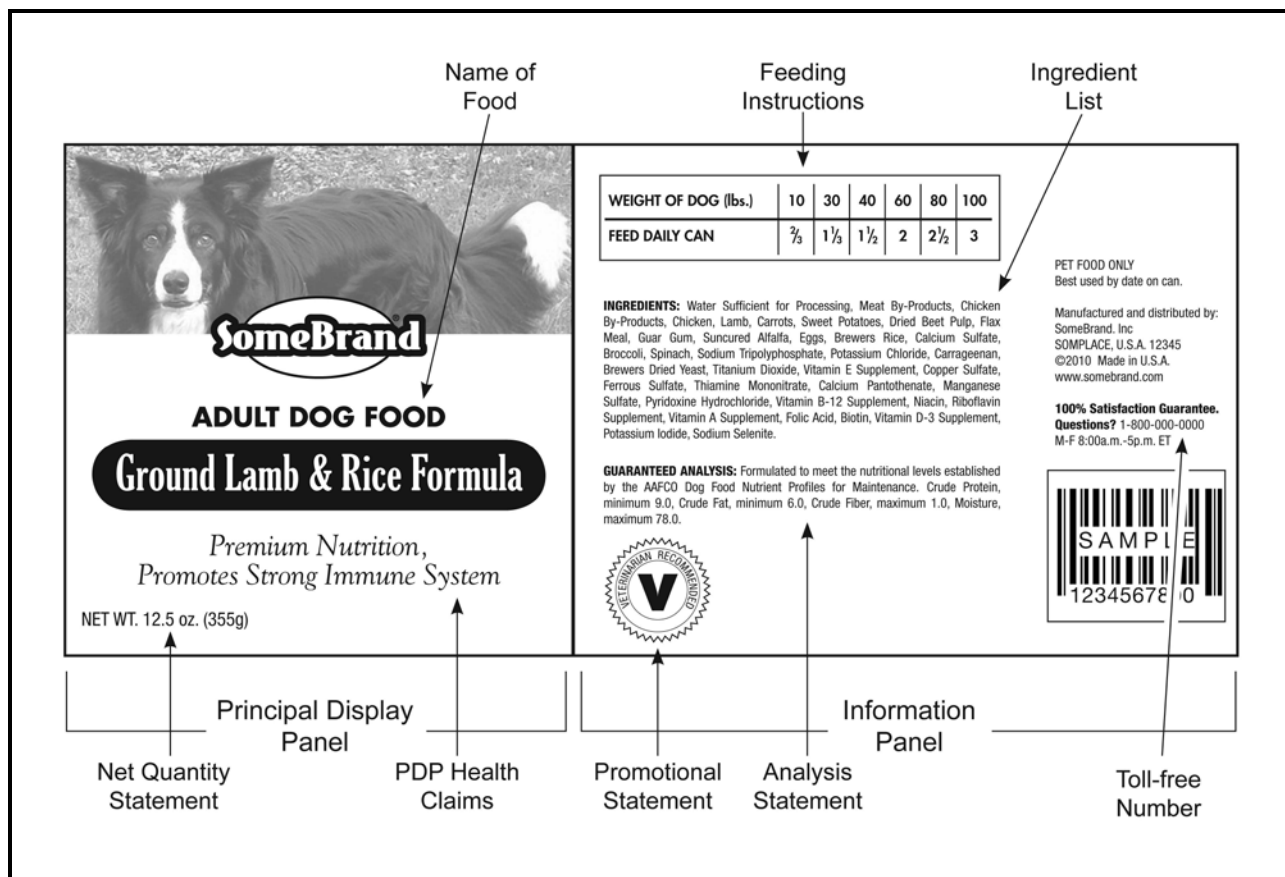
to guide states' legislative and regulatory entities. Although the model regulations are not inclusive of all states' regulations on animal foods and animal products, they do offer a starting point for manufacturers to plan for regulatory labeling of the products. It is the responsibility of each manufacturer 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.³ 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.

³ 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

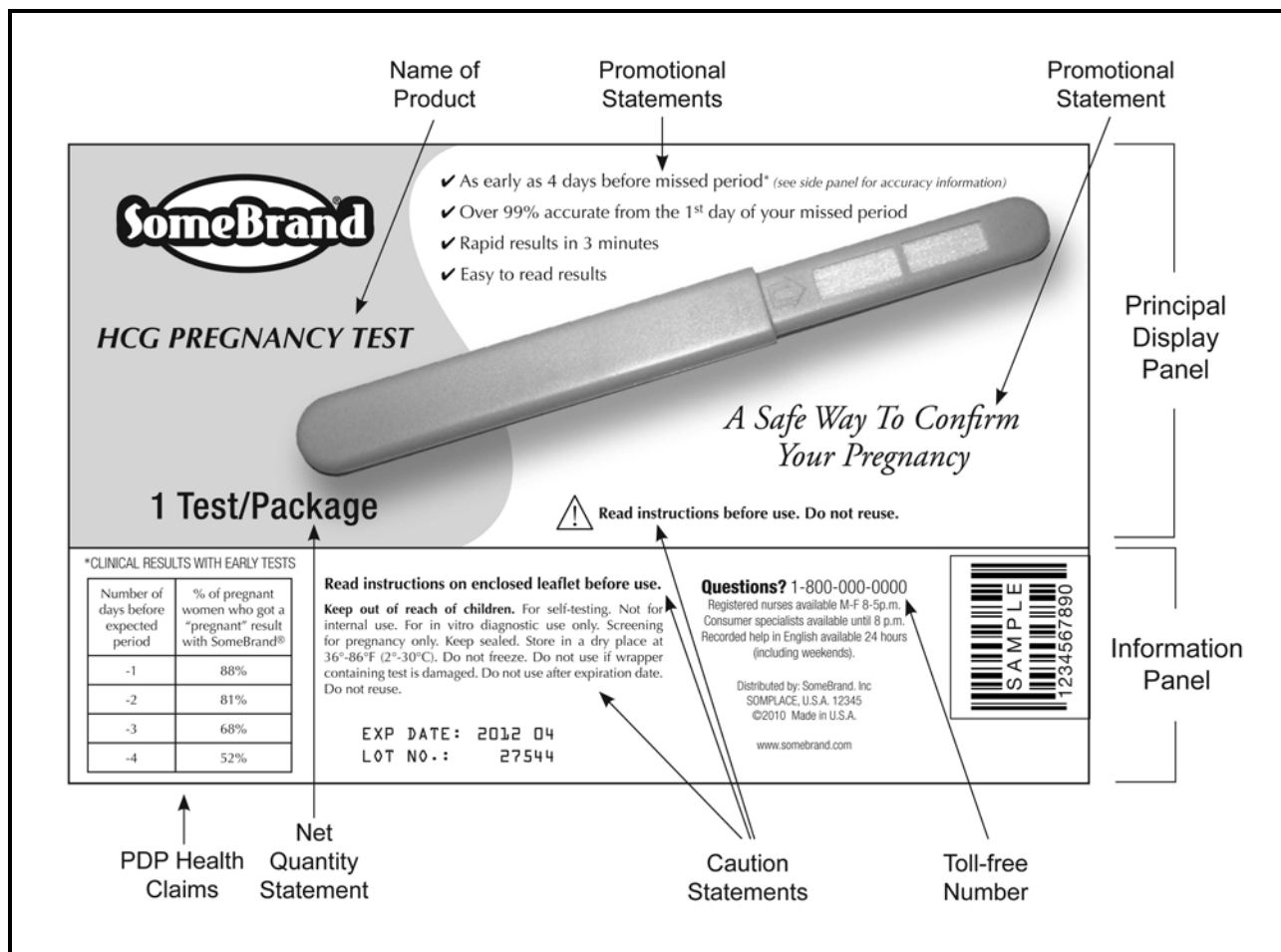
metabolized for the achievement of any of its primary intended purposes” (FDA, 2006).

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.

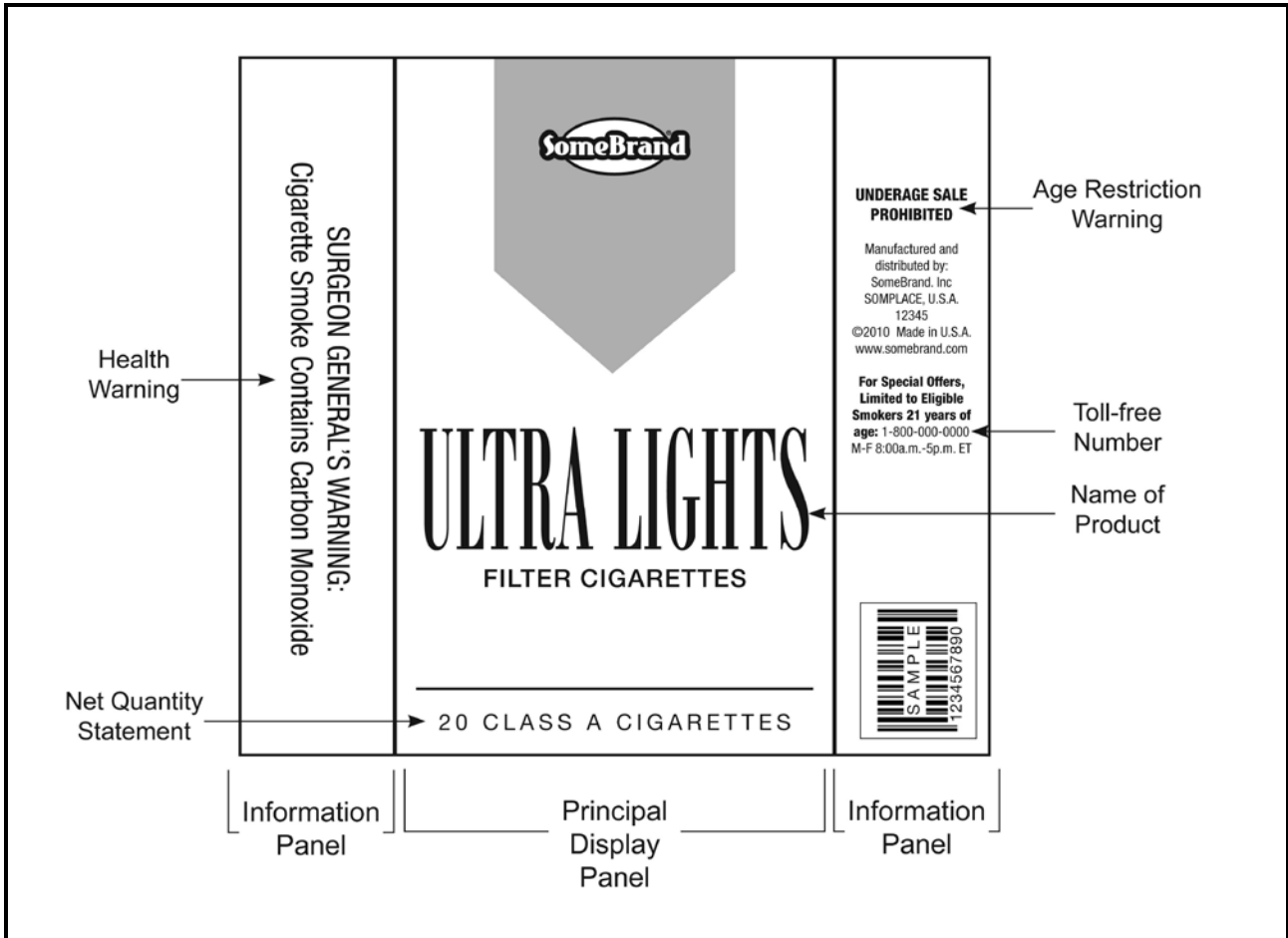
Figure 2-6. Example of Parts of Retail Medical Device Labels that May Change as a Result of a Regulation: Pregnancy Test



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

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.

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.

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.¹

¹ The costs are described in more detail in Section 4.

3.1 OVERVIEW OF THE LABEL CHANGE PROCESS

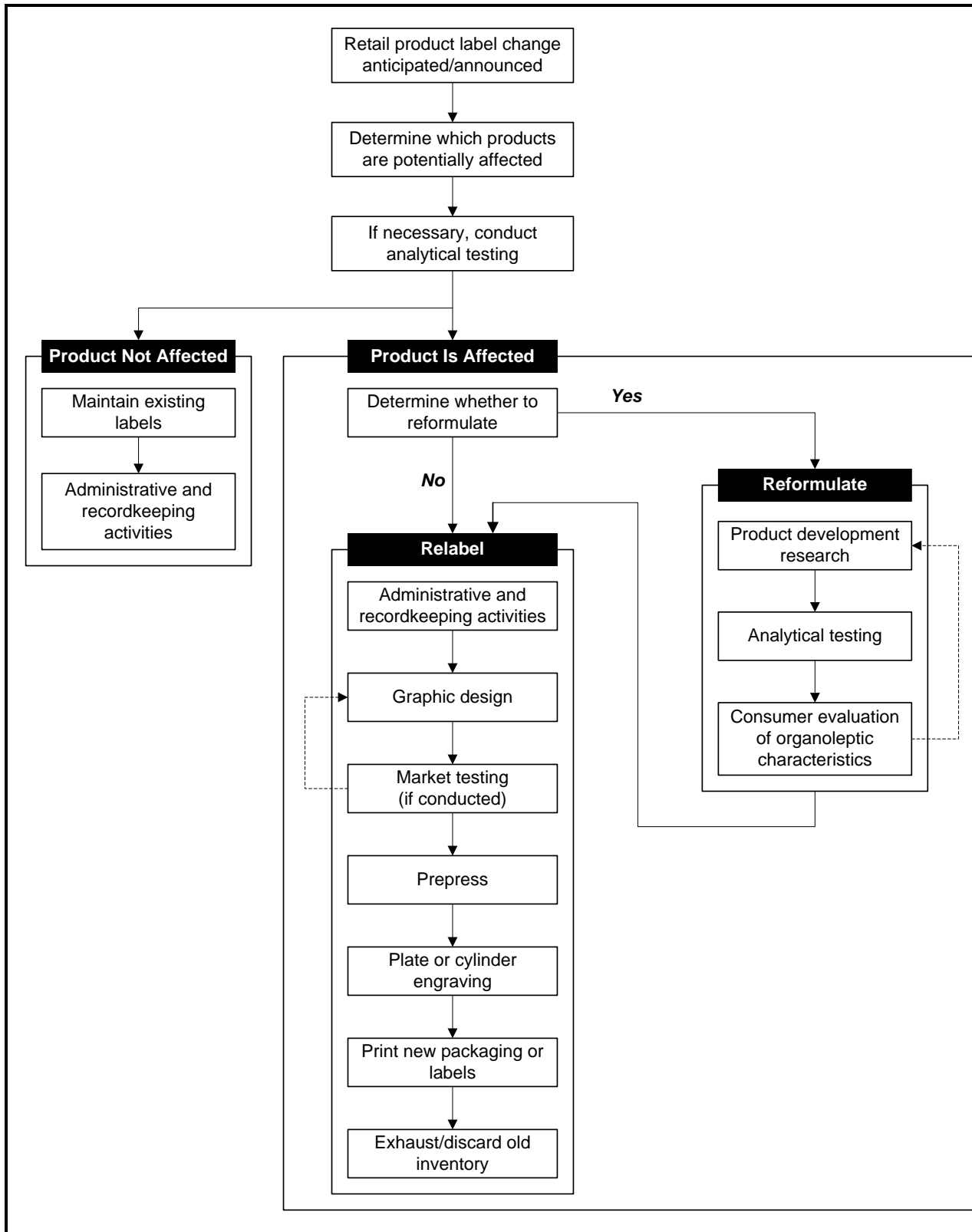
Figure 3-1 provides an overview of the process by which labeling information and graphics on consumer products included in the FDA Labeling Cost Model may be changed as a result of regulation. Once a product manufacturer has determined that a product might be affected, the manufacturer may conduct some 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; coordinating with the marketing, legal, and environmental departments to determine and implement the response; and working 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); 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 assume these activities are typically outsourced, but we account for the internal labor costs associated with coordinating with an outside vendor.

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. 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. We conducted discussions with a total of nine manufacturers—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 ρ^B represent the proportion of uncoordinated changes for branded products and ρ^{PL} the proportion of uncoordinated changes for private-label products.² These proportions are each a function of the number of months of compliance since longer compliance periods increase the proportion of changes that can be coordinated. The model includes default values for ρ^B and ρ^{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; therefore, the default values ρ^B and ρ^{PL} are set to 100% for $m = 3, 6, \text{ and } 9$.

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 assume

² The formulas in the model that incorporate ρ^B and ρ^{PL} are described in Section 4.3.

that ρ^B and ρ^{PL} vary by product type with products such as OTCs having higher ρ (a higher proportion of uncoordinated changes) and others, such as pet foods, having lower ρ (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 ρ^B and ρ^{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.³ 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.

³ 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 (ρ^B) and Private-Label (ρ^{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*

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 is affected by a labeling requirement.
- Select whether the labeling change is minor, major, or extensive based on the definitions provided in Table 4-1.

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"> ▪ Changes to the net quantity statement ▪ Minimal changes to a facts panel (e.g., nutrition facts, supplement facts, or drug facts) ▪ Minimal changes to an ingredient list ▪ Addition of a toll-free number ▪ Minimal changes to a claim, caution statement, or disclaimer on the back or side of a package (affecting one color)
Major change	Multiple color changes that require a label redesign	<ul style="list-style-type: none"> ▪ Changes to the name of the product ▪ Changes to the standard of identity or fanciful name for a food product ▪ Addition of a facts panel (e.g., nutrition facts, supplement facts, or drug facts) ▪ Substantial changes to an ingredient list ▪ Substantial changes to or elimination of a claim ▪ Addition of or substantial changes to a caution statement ▪ Addition of or substantial changes to a disclaimer
Extensive change	Major format change that requires a change to the product packaging to accommodate labeling information	<ul style="list-style-type: none"> ▪ Addition of a peel-back label ▪ Increases in the package surface area for labeling information

- 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 Labeling and Education Act [NLEA] panel, fatty acid profile, trans fatty acids, sugar profile, soluble fiber, vitamins, minerals, iodine, caffeine, allergens),
 - bioengineered ingredients (e.g., polymerase chain reaction [PCR] test, bioengineered enzyme-linked

- immunosorbent assay [ELISA] lab test, and ELISA strip test),
- dietary supplement ingredients (e.g., vitamins, minerals, amino acids, and botanicals),
- guaranteed analysis for pet foods,
- pathogens, and
- contaminants (e.g., melamine, mercury in cosmetics, and metals in cosmetics).
- 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 and
 - quantitative studies.
- 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.
- 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.¹
- Revise, if desired, the default estimates of the percentage of labeling changes that could be coordinated with a nonregulatory labeling change.

¹ 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.

- 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 package inserts to products that currently do not include package inserts

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 Selection of a Baseline for Product Categories

The time period represented in the Nielsen ScanTrack data provided by FDA is from approximately the last quarter of 2007 through the third quarter of 2009. In Appendix B, we show the trends in the raw numbers of branded UPCs by quarter and the raw numbers of unique private-label product/size combinations. In general, across all product types the number of branded UPCs and private-label products trends upward through the third or fourth quarter of 2008 and trends downward thereafter.

For the purposes of determining a baseline in the model, we selected 2008 because this is the most recent calendar year for which data are available and appears to be generally similar to the end of 2007 and the beginning of 2009. However, based on the data presented in Appendix B, using 2008 may provide a somewhat higher estimate of the number of branded UPCs than might be expected in a typical year; thus, the model may slightly overestimate the number of UPCs and, therefore, slightly overestimate the total costs of compliance with a labeling regulation.² The degree of overestimation could be calculated when later scanner data become available and the difference in the number of actual UPCs could be calculated.

4.2.2 Private-Label UPC Counts

In the ScanTrack data files, Nielsen provides aggregate sales information for private-label UPCs within each product module rather than for each individual private-label UPC. Thus, unlike

² Losses due to discarded inventory are based on the unit sales and thus are likewise affected by the year of the scanner data.

for branded products, it is not possible to discern which private-label UPCs are active. Nielsen provided a separate data file containing the number of private-label UPCs by product module, but the data represent all UPCs in use over 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.

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

FDA Type	% Active UPCs
Cosmetics	71.6
Dietary supplements	80.8
Foods	75.9
OTCs	71.6
Pet foods	75.5
Retail medical devices	71.6
Tobacco products	79.4

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

However, we note that in some cases manufacturers may reuse private-label UPCs, in which case this method may overadjust the number of private-label UPCs.³

We have also examined the rates of entry and exit of branded UPCs to determine whether these data might be used to adjust the total count of private-label UPCs. To calculate these rates, we compared the 52-week period from Week 37 in 2007 through Week 36 in 2008 (year 1) against the 52-week period from Week 37 in 2008 through Week 36 in 2009 (year 2). From year 1 to year 2, 19,849 branded UPCs were introduced out of

³ PLMA also said that retailers may have to change multiple labels for a single private-label product if they manufacture the same product in different regions of the country using different contract manufacturers. Thus, costs of making labeling changes to a single product may be incurred by a retailer for each region of the country in which the product is manufactured. However, it is unclear whether each of those identical products would have the same UPC, in which case the counts need to be adjusted, or whether each would have a unique UPC code, in which case the counts do not need to be adjusted.

a total of 238,096, resulting in an entry rate of 8.3%, and 18,601 branded UPCs were discontinued for an exit rate of 7.6%. If these years were representative, then the number of UPCs is generally trending up over time; however, given the available data, it is unknown whether this trend is representative. Furthermore, it is unknown whether trends in branded UPCs are similar to those of private-label UPCs. Thus, we relied on the method described above to adjust the private-label UPC counts.

4.2.3 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 model along with the counts of branded, private-label, and total UPCs, formulas, and sales units. The numbers of UPCs total 784,017 for branded products and 394,247 for private-label products. In addition to the adjustments to the private-label UPC counts noted in Section 4.2.2, we adjusted the numbers of UPCs, formulas, and sales units to account for sales in outlets not represented in the Nielsen ScanTrack data.

Based on our assessment, the following adjustments were needed:

- Sales of products in Wal-Mart are not represented in ScanTrack data because Wal-Mart does not participate in scanner data reporting. Across all product types, this affects the number of UPCs because Wal-Mart has unique UPCs for some products (e.g., for special sizing of brand name products) and its own private-label UPCs. It also affects the unit sales for branded and private-label UPCs. We applied adjustment factors based on limited data available from the Economic Research Service (ERS) that compare food sales data between Nielsen Homescan (representing all product sales for its panel of 125,000 households) and Nielsen ScanTrack to capture all sources of missing sales, including not only Wal-Mart but also warehouse and specialty stores. The adjustment factor for foods was applied to other product types that are sold in similar types of outlets.
- For cosmetics, the ScanTrack data do not include sales in department stores, which are a major source of sales for these products. Because the trade associations representing the cosmetics industry did not respond to our request for a teleconference, we do not have data on which to base an adjustment. Thus, we assumed the

same adjustment as for dietary supplements based on the assumption that cosmetics are sold at a similarly wide range of store types.

- For dietary supplements, the Natural Products Association estimates that about one-third of sales are represented in food stores, drug stores, and mass merchandisers. The other two-thirds of sales are in independent stores, through multilevel marketing, on the Internet, and through practitioners. Thus, we adjusted the number of UPCs and unit sales to reflect these estimates.
- For OTCs and retail medical devices, we applied the same proportionate adjustments as for foods to represent missing Wal-Mart, warehouse store, and specialty store sales based on ERS data.
- For pet foods, the PFI estimates there are a total of 15,000 to 17,000 UPCs for pet foods (excluding pet treats), including both branded and private-label products. Therefore, we proportionately adjusted the estimates of UPCs and unit sales based on the totals provided by PFI.
- For tobacco products and accessories, a large proportion of unit sales are underrepresented because about 85% of sales are through convenience stores not captured in the ScanTrack data based on Nielsen data obtained by tobacco control researchers at RTI. In addition, sales at specialty tobacco stores, on Indian reservations, and on the Internet are not represented. The proportion of UPCs not captured is likely much less than for other product types since similar products are sold in the different types of outlets; thus, we did not adjust the data.⁴

Table 4-4 shows the final adjustments to the original counts of UPCs, formulas, and sales units in the Nielsen ScanTrack data along with a brief explanation of each adjustment.

In Appendix Table C-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

⁴ The number of UPCs for tobacco may also be undercounted because some specialty products, such as handmade cigars, are not captured in the types of outlets tracked by scanner data or do not have UPCs.

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Cosmetics	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

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Cosmetics (continued)	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
	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

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Cosmetics (continued)	Nailcare/manicure needs	Manicure needs	325620—Toilet Preparation Manufacturing	5,320	133	3,705	93	98,909,620	1,635,117
	Nailcare/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
	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

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Dietary Supplements	Diet aids	Appetite suppressants	325412—Pharmaceutical Preparation Manufacturing	335	6	276	6	11,332,106	1,231
	Diet aids	Diet aids—complete nutritional	325412—Pharmaceutical Preparation Manufacturing	893	422	725	344	156,865,732	5,803,042
	Mineral supplements	Minerals	325412—Pharmaceutical Preparation Manufacturing	3,776	6,665	3,184	5,620	99,659,448	61,440,379
	Nutritional supplements	Complete nutritional products	325412—Pharmaceutical Preparation Manufacturing	921	1,039	481	543	175,978,881	20,202,765
	Nutritional supplements	Nutritional supplements	325412—Pharmaceutical Preparation Manufacturing	26,524	13,677	23,256	11,991	497,390,725	157,962,977
	Protein supplements	Protein supplements	325412—Pharmaceutical Preparation Manufacturing	1,414	214	1,085	164	14,689,130	780,689
	Vitamin supplements	Vitamins—B complex w/C	325412—Pharmaceutical Preparation Manufacturing	341	654	310	595	11,133,008	3,730,246
	Vitamin supplements	Vitamins—children-flavored chewable	325412—Pharmaceutical Preparation Manufacturing	651	1,150	558	986	39,666,915	7,389,337
	Vitamin supplements	Vitamins—multiple	325412—Pharmaceutical Preparation Manufacturing	2,920	4,926	2,393	4,036	123,302,184	59,554,460
	Vitamin supplements	Vitamins—remaining	325412—Pharmaceutical Preparation Manufacturing	5,915	11,904	4,994	10,050	141,708,285	77,314,760
	Vitamins/tonics—liquid	Vitamins/tonics—liquid & powder	325412—Pharmaceutical Preparation Manufacturing	939	81	753	65	12,376,552	1,786,412
Foods	Baked goods	Bagels/biscuits/buns/muffins/rolls—fresh	311812—Commercial Bakeries	6,614	8,130	5,646	6,930	1,436,617,879	1,013,961,495
	Baked goods	Bagels/biscuits/buns/muffins/rolls—frozen	311812—Commercial Bakeries	382	536	343	482	130,477,959	19,585,702
	Baked goods	Baked goods—remaining—fresh	311812—Commercial Bakeries	1,026	1,028	833	834	59,207,404	19,956,679
	Baked goods	Baked goods—remaining—frozen	311812—Commercial Bakeries	434	273	368	231	70,109,701	31,056,925
	Baked goods	Bread—fresh	311812—Commercial Bakeries	9,673	8,760	8,543	7,731	2,672,784,733	1,681,467,501
	Baked goods	Bread—frozen	311812—Commercial Bakeries	381	354	346	322	170,523,686	56,605,087

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Foods (continued)	Baked goods	Breading products	311812—Commercial Bakeries	1,701	1,222	1,743	1,032	397,749,659	87,669,378
	Baked goods	Cakes/doughnuts/sweet rolls—fresh	311812—Commercial Bakeries	10,027	15,238	7,776	11,816	1,408,750,370	298,080,173
	Baked goods	Cakes/doughnuts/sweet rolls—frozen	311813—Frozen Cakes, Pies, & Other Pastries Manufacturing	416	137	361	119	60,011,739	2,498,567
	Baked goods	Cookies/cones	311821—Cookie & Cracker Manufacturing	13,416	8,347	10,170	6,327	1,954,036,508	381,958,374
	Baked goods	Crackers	311821—Cookie & Cracker Manufacturing	3,892	2,723	3,133	2,190	1,599,395,132	234,310,742
	Baked goods	Mexican shells/tortillas	311830—Tortilla Manufacturing	2,733	739	2,115	573	777,441,025	133,156,856
	Baking ingredients	Baking mixes	311822—Flour Mixes & Dough Mfg from Purchased Flour	3,079	1,527	2,750	1,364	1,168,471,629	79,305,244
	Baking ingredients	Baking supplies	311340—Nonchocolate Confectionery Manufacturing	3,198	1,714	2,395	1,323	700,290,489	138,863,925
	Baking ingredients	Bread/cookie/dough products—frozen	311822—Flour Mixes & Dough Mfg from Purchased Flour	210	91	192	83	14,520,547	6,334,745
	Baking ingredients	Dough products—refrigerated	311822—Flour Mixes & Dough Mfg from Purchased Flour	843	2,113	640	1,604	735,541,695	264,397,994
	Baking ingredients	Flour/corn meal	311211—Flour Milling	1,427	686	1,043	501	249,747,725	81,785,847
	Beverages	Buttermilk—refrigerated	311511—Fluid Milk Manufacturing	535	241	374	168	56,674,747	32,580,138
	Beverages	Carbonated beverages—low calorie	312111—Soft Drink Manufacturing	2,177	1,561	850	609	3,097,749,728	222,542,489
	Beverages	Carbonated beverages—regular	312111—Soft Drink Manufacturing	7,347	5,789	3,601	2,838	5,976,561,888	967,035,294
	Beverages	Cocktail mixes	312111—Soft Drink Manufacturing	1,114	90	879	70	52,037,852	1,482,565
	Beverages	Coffee—ground	311920—Coffee & Tea Manufacturing	4,701	2,167	4,264	1,966	607,247,417	90,175,914

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Foods (continued)	Beverages	Coffee—liquid	311920—Coffee & Tea Manufacturing	456	24	350	18	133,938,419	3,502,260
	Beverages	Coffee—soluble	311920—Coffee & Tea Manufacturing	637	547	476	409	139,372,556	17,553,873
	Beverages	Coffee—whole bean	311920—Coffee & Tea Manufacturing	2,148	791	2,026	746	52,672,502	8,180,355
	Beverages	Creamers—liquid	311511—Fluid Milk Manufacturing	307	297	182	176	452,437,124	27,715,489
	Beverages	Fruit drinks—frozen	311411—Frozen Fruit, Juice, & Vegetable Manufacturing	188	664	178	629	89,401,568	52,653,731
	Beverages	Fruit drinks—refrigerated	312111—Soft Drink Manufacturing	981	354	756	273	421,566,925	25,265,359
	Beverages	Fruit drinks—shelf stable	312111—Soft Drink Manufacturing	5,967	3,772	4,143	2,618	3,116,639,245	238,758,969
	Beverages	Fruit juice—frozen	311411—Frozen Fruit, Juice, & Vegetable Manufacturing	171	914	154	825	140,328,945	95,694,789
	Beverages	Fruit juice—refrigerated	311421—Fruit & Vegetable Canning	2,089	1,389	1,317	875	1,179,747,968	214,258,498
	Beverages	Fruit juice—shelf stable	311421—Fruit & Vegetable Canning	3,608	3,345	2,408	2,233	1,037,570,724	308,852,380
	Beverages	Fruit punch bases/syrups	311930—Flavoring Syrup & Concentrate Manufacturing	351	18	297	15	10,394,090	701,795
	Beverages	Ice	312113—Ice Manufacturing	636	207	452	147	274,000,692	90,328,840
	Beverages	Milk—flavored—refrigerated	311511—Fluid Milk Manufacturing	1,548	514	1,089	361	242,484,820	99,818,835
	Beverages	Milk—refrigerated	311511—Fluid Milk Manufacturing	5,060	4,470	2,869	2,533	1,752,575,409	3,512,795,761
	Beverages	Milk—shelf stable	311514—Dry, Condensed, & Evaporated Dairy Product Mfg	307	412	221	297	235,524,878	157,894,209
	Beverages	Milk/creamers—powdered	311514—Dry, Condensed, & Evaporated Dairy Product Mfg	235	1,429	169	1,023	69,019,170	78,553,808
	Beverages	Milk/water—additives	311514—Dry, Condensed, & Evaporated Dairy Product Mfg	1,096	700	965	616	188,704,635	32,083,968

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Foods (continued)	Beverages	Noncarbonated beverages—mixes	311999—All Other Miscellaneous Food Manufacturing	1,015	1,345	704	934	975,089,917	85,395,286
	Beverages	Shakes/drinks—remaining—nonrefrigerated	312111—Soft Drink Manufacturing	668	143	377	81	107,728,855	8,633,087
	Beverages	Shakes/drinks/eggnog—refrigerated	311514—Dry, Condensed, & Evaporated Dairy Product Mfg	994	433	671	291	238,520,230	45,312,690
	Beverages	Tea—bags/packaged	311920—Coffee & Tea Manufacturing	2,824	1,004	2,524	897	235,458,339	35,551,541
	Beverages	Tea—herbal	311920—Coffee & Tea Manufacturing	2,016	179	1,856	165	84,001,679	2,549,581
	Beverages	Tea—instant	311920—Coffee & Tea Manufacturing	500	717	410	588	92,885,635	24,271,892
	Beverages	Tea—liquid	311920—Coffee & Tea Manufacturing	2,948	510	2,016	349	944,902,393	70,988,408
	Beverages	Vegetable juice—shelf stable	311421—Fruit & Vegetable Canning	812	633	560	437	316,026,140	54,336,080
	Beverages	Water—bottled	312112—Bottled Water Manufacturing	4,570	3,142	2,646	1,819	2,399,835,347	857,181,783
	Beverages	Water—bottled/caloric	312111—Soft Drink Manufacturing	731	337	406	188	230,727,665	106,773,884
	Beverages	Water—bottled/low calorie	312111—Soft Drink Manufacturing	428	893	319	665	52,236,387	179,289,235
	Beverages	Wine—nonalcoholic	312130—Wineries	372	49	279	36	42,767,525	3,715,145
	Breakfast foods	Breakfast bars/pastries/powders	311340—Nonchocolate Confectionery Manufacturing	2,545	2,461	2,051	1,714	1,219,162,160	146,737,595
	Breakfast foods	Breakfasts—frozen	311412—Frozen Specialty Food Manufacturing	1,047	518	843	417	256,273,926	35,844,565
	Breakfast foods	Cereal—hot	311230—Breakfast Cereal Manufacturing	890	1,726	717	1,390	352,054,485	155,955,370
	Breakfast foods	Cereal—ready to eat	311230—Breakfast Cereal Manufacturing	2,817	5,380	1,585	3,025	2,640,947,176	420,590,029
	Breakfast foods	Waffle/pancake/French toast—frozen	311412—Frozen Specialty Food Manufacturing	420	911	358	778	341,206,509	105,899,912

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Foods (continued)	Candy & gum	Candy—chocolate	311320—Chocolate & Confectionery Mfg from Cacao Beans	16,085	1,809	11,070	1,245	4,483,836,077	57,473,462
	Candy & gum	Candy—dietetic	311340—Nonchocolate Confectionery Manufacturing	1,474	129	1,214	106	123,234,317	10,129,956
	Candy & gum	Candy—nonchocolate	311340—Nonchocolate Confectionery Manufacturing	21,843	5,412	16,643	4,124	2,208,511,666	302,951,291
	Candy & gum	Gum—low calorie	311340—Nonchocolate Confectionery Manufacturing	970	77	461	36	1,146,098,106	2,869,439
	Candy & gum	Gum—regular	311340—Nonchocolate Confectionery Manufacturing	1,483	99	1,025	69	268,619,987	5,468,679
	Condiments/dips/spreads	Condiments	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	1,960	2,261	1,684	1,943	401,771,132	159,873,042
	Condiments/dips/spreads	Dips—refrigerated	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	1,786	924	1,355	701	195,046,183	59,766,739
	Condiments/dips/spreads	Dips—shelf stable	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	893	281	813	256	176,649,544	13,230,407
	Condiments/dips/spreads	Extracts	311942—Spice & Extract Manufacturing	1,109	508	878	402	43,016,784	21,444,567
	Condiments/dips/spreads	Honey	311999—All Other Miscellaneous Food Manufacturing	1,635	624	1,305	498	35,121,894	44,270,282
	Condiments/dips/spreads	Jams/jellies	311421—Fruit & Vegetable Canning	2,778	2,516	2,456	2,220	216,216,843	95,139,064
	Condiments/dips/spreads	Jams/spreads—remaining	311421—Fruit & Vegetable Canning	1,065	346	938	304	58,109,304	9,876,139
	Condiments/dips/spreads	Marinades/tenderizers/MSG	311942—Spice & Extract Manufacturing	1,186	475	1,109	444	109,023,695	15,904,034
	Condiments/dips/spreads	Mayonnaise	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	587	871	399	591	473,677,198	77,673,520
	Condiments/dips/spreads	Peanut butter	311911—Roasted Nuts & Peanut Butter Manufacturing	542	1,431	403	1,065	370,827,215	116,415,884

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Foods (continued)	Condiments/dips/spreads	Pepper	311942—Spice & Extract Manufacturing	1,600	791	1,288	636	86,442,033	40,682,377
	Condiments/dips/spreads	Pickles/olives/relishes	311421—Fruit & Vegetable Canning	7,619	5,421	6,264	4,337	672,819,246	375,931,444
	Condiments/dips/spreads	Salt	311942—Spice & Extract Manufacturing	1,285	924	1,016	731	197,816,508	66,808,749
	Condiments/dips/spreads	Salt—substitutes	311942—Spice & Extract Manufacturing	22	3	18	3	2,742,044	63
	Condiments/dips/spreads	Sandwich spreads/horseradish/sauerkraut—refrigerated	311421—Fruit & Vegetable Canning	697	241	564	195	61,103,245	19,678,506
	Condiments/dips/spreads	Seasoning—dry	311942—Spice & Extract Manufacturing	14,209	3,234	12,281	2,794	467,910,029	93,926,349
	Condiments/dips/spreads	Spices/seasonings—remaining	311942—Spice & Extract Manufacturing	1,056	358	843	286	81,275,411	9,932,807
	Condiments/dips/spreads	Spreads—refrigerated	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	1,392	134	1,190	115	110,029,917	8,519,195
	Dairy foods	Butter	311512—Creamery Butter Manufacturing	650	584	557	501	340,757,852	370,387,248
	Dairy foods	Cheese—cottage/farmers/ricotta	311511—Fluid Milk Manufacturing	1,501	1,365	962	874	345,667,561	249,733,660
	Dairy foods	Cheese—grated/shredded	311513—Cheese Manufacturing	1,763	3,339	1,324	2,509	655,049,349	744,605,417
	Dairy foods	Cheese—natural	311513—Cheese Manufacturing	4,571	4,841	6,614	3,503	807,248,147	692,815,057
	Dairy foods	Cheese—processed	311513—Cheese Manufacturing	3,063	3,422	2,344	2,618	1,070,149,011	527,405,003
	Dairy foods	Cheese—specialty/imported	311513—Cheese Manufacturing	2,964	491	2,139	354	248,860,797	54,652,346
	Dairy foods	Cream—refrigerated	311511—Fluid Milk Manufacturing	829	553	487	325	206,269,777	205,045,484
	Dairy foods	Frozen novelties	311520—Ice Cream & Frozen Dessert Manufacturing	4,085	2,244	3,669	2,016	894,063,996	213,194,654

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Foods (continued)	Dairy foods	Ice cream	311520—Ice Cream & Frozen Dessert Manufacturing	7,552	6,961	6,537	6,024	1,118,307,429	482,015,181
	Dairy foods	Ice milk/sherbet/yogurt— frozen	311520—Ice Cream & Frozen Dessert Manufacturing	1,002	924	862	795	69,034,871	57,724,178
	Dairy foods	Ice pops—unfrozen	311520—Ice Cream & Frozen Dessert Manufacturing	186	85	141	64	63,027,682	7,132,468
	Dairy foods	Sour cream	311511—Fluid Milk Manufacturing	802	763	445	423	385,953,470	227,354,628
	Dairy foods	Whipping cream	311511—Fluid Milk Manufacturing	406	251	248	153	44,485,701	61,508,275
	Dairy foods	Yogurt—refrigerated	311511—Fluid Milk Manufacturing	3,340	4,200	2,689	3,381	3,947,492,599	916,804,792
	Dairy foods	Yogurt—shakes/drinks— refrigerated	311511—Fluid Milk Manufacturing	683	154	500	112	233,564,653	29,529,518
	Desserts	Cheesecake/pies—fresh	311812—Commercial Bakeries	2,885	3,273	1,887	2,141	173,452,087	64,344,231
	Desserts	Cheesecake/pies—frozen	311813—Frozen Cakes, Pies, & Other Pastries Manufacturing	714	127	571	102	124,257,221	2,950,111
	Desserts	Dessert—RTS single serving	311999—All Other Miscellaneous Food Manufacturing	643	1,358	559	1,180	543,645,509	123,715,452
	Desserts	Desserts/toppings—frozen	311813—Frozen Cakes, Pies, & Other Pastries Manufacturing	1,023	655	895	573	357,162,562	75,976,265
	Desserts	Gelatin/pudding—mixes— diet	311999—All Other Miscellaneous Food Manufacturing	116	441	83	314	145,996,463	21,811,314
	Desserts	Gelatin/pudding—mixes— sweetened	311999—All Other Miscellaneous Food Manufacturing	659	1,088	494	815	341,879,712	64,136,555
	Desserts	Pudding—refrigerated	311999—All Other Miscellaneous Food Manufacturing	518	407	405	318	192,154,381	14,463,018

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Foods (continued)	Desserts	Syrups/toppings—shelf stable	311999—All Other Miscellaneous Food Manufacturing	1,096	361	903	298	183,711,249	27,299,577
	Desserts	Toppings—refrigerated	311999—All Other Miscellaneous Food Manufacturing	204	353	162	279	88,452,164	67,723,179
	Dressings & sauces	Salad dressing—liquid	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	2,884	2,080	2,261	1,631	565,338,717	129,337,186
	Dressings & sauces	Salad dressing—reduced/low calorie	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	676	295	595	260	101,603,769	13,566,976
	Dressings & sauces	Salad dressing—refrigerated	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	897	130	630	91	85,886,468	1,348,985
	Dressings & sauces	Salad dressings/ toppings—dry	311942—Spice & Extract Manufacturing	281	175	249	155	110,799,258	13,275,094
	Dressings & sauces	Sauce—barbecue	311421—Fruit & Vegetable Canning	1,875	770	1,610	661	229,430,072	28,984,208
	Dressings & sauces	Sauce—Mexican	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	2,694	1,334	2,405	1,191	351,928,882	65,482,976
	Dressings & sauces	Sauce—spaghetti/ marinara	311421—Fruit & Vegetable Canning	2,152	1,565	1,994	1,449	707,202,798	90,328,794
	Dressings & sauces	Sauce/gravy—mixes	311942—Spice & Extract Manufacturing	1,821	1,035	1,639	931	456,078,699	139,809,683
	Dressings & sauces	Sauce/gravy/glaze	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	6,745	1,795	6,020	1,602	619,150,881	103,229,445
	Dressings & sauces	Vinegar/cooking wine	311941—Mayonnaise, Dressing, & Other Prepared Sauce Mfg	1,644	1,235	1,308	983	66,975,594	71,736,307
	Eggs	Eggs—fresh	311999—All Other Miscellaneous Food Manufacturing	2,106	1,646	1,641	1,282	534,428,229	1,641,084,974
	Entrees	Combination lunches	311911—Roasted Nuts & Peanut Butter Manufacturing	231	38	178	29	436,553,082	2,047,303

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Foods (continued)	Entrees	Entrees—frozen	311412—Frozen Specialty Food Manufacturing	8,466	2,430	7,557	2,169	3,865,195,706	180,442,655
	Entrees	Entrees—refrigerated	311991—Perishable Prepared Food Manufacturing	4,350	2,773	3,689	2,352	395,598,305	203,916,119
	Entrees	Prepared foods—canned/shelf stable	311999—All Other Miscellaneous Food Manufacturing	5,858	1,474	5,043	1,268	1,120,842,103	135,981,194
	Entrees	Sandwiches—refrigerated/frozen	311999—All Other Miscellaneous Food Manufacturing	1,789	1,319	1,611	1,187	602,757,257	54,910,387
	Fats & oils	Cooking sprays	311225—Fats & Oils Refining & Blending	168	536	136	434	93,537,013	47,978,162
	Fats & oils	Lard/shortening	311613—Rendering & Meat Byproduct Processing	154	225	76	111	50,539,079	10,580,744
	Fats & oils	Margarine/spreads	311225—Fats & Oils Refining & Blending	504	924	311	570	812,731,315	103,599,583
	Fats & oils	Oils—olive/salad/cooking	311225—Fats & Oils Refining & Blending	3,221	2,496	1,924	1,490	299,043,793	242,667,663
	Fruits & vegetables	Beans—canned	311421—Fruit & Vegetable Canning	1,666	1,749	1,263	1,324	589,099,809	292,993,917
	Fruits & vegetables	Beans/peas/lentils/barley—dry	311423—Dried & Dehydrated Food Manufacturing	2,031	1,820	1,527	1,368	105,533,606	133,662,815
	Fruits & vegetables	Fruit—canned	311421—Fruit & Vegetable Canning	2,694	6,360	2,449	5,110	766,731,416	548,902,641
	Fruits & vegetables	Fruit—dried	311423—Dried & Dehydrated Food Manufacturing	4,334	1,963	3,326	1,506	554,472,143	128,397,522
	Fruits & vegetables	Fruit—fresh	111339—Other Noncitrus Fruit Farming	4,521	540	2,723	326	1,747,396,108	83,856,307
	Fruits & vegetables	Fruit/fruit salad—refrigerated	311991—Perishable Prepared Food Manufacturing	2,065	917	1,187	528	214,337,571	28,689,083

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Foods (continued)	Fruits & vegetables	Fruits—frozen	311411—Frozen Fruit, Juice, & Vegetable Manufacturing	581	1,158	517	1,028	44,702,815	115,028,372
	Fruits & vegetables	Garlic/herbs—fresh	111219—Other Vegetable (except Potato) & Melon Farming	1,712	238	1,404	195	107,934,546	27,995,548
	Fruits & vegetables	Leafy greens—fresh	111219—Other Vegetable (except Potato) & Melon Farming	371	53	293	42	878,722,344	107,920,816
	Fruits & vegetables	Potatoes—canned	311421—Fruit & Vegetable Canning	200	602	154	463	61,345,794	61,532,080
	Fruits & vegetables	Potatoes—dehydrated	311423—Dried & Dehydrated Food Manufacturing	410	676	308	508	255,198,871	53,343,989
	Fruits & vegetables	Potatoes—fresh	111211—Potato Farming	1,418	137	886	85	518,734,479	283,208,041
	Fruits & vegetables	Potatoes—frozen	311411—Frozen Fruit, Juice, & Vegetable Manufacturing	1,082	1,952	907	1,634	532,347,633	201,697,563
	Fruits & vegetables	Tomatoes—canned	311421—Fruit & Vegetable Canning	1,763	2,919	1,428	2,365	956,214,629	724,936,919
	Fruits & vegetables	Vegetables—canned	311421—Fruit & Vegetable Canning	4,400	6,413	3,542	5,155	1,368,380,742	1,318,384,613
	Fruits & vegetables	Vegetables—fresh	111219—Other Vegetable (except Potato) & Melon Farming	6,870	1,350	5,195	1,021	2,092,230,819	615,055,343
	Fruits & vegetables	Vegetables—frozen	311411—Frozen Fruit, Juice, & Vegetable Manufacturing	2,380	7,421	1,985	6,182	788,411,739	788,549,926
	Fruits & vegetables	Vegetables—precut salad mix—fresh	311991—Perishable Prepared Food Manufacturing	787	431	1,159	318	1,232,074,754	156,927,645
	Infant foods	Baby food	311422—Specialty Canning	1,274	315	1,162	287	1,052,561,602	14,913,846
	Infant foods	Infant formulas	311514—Dry, Condensed, & Evaporated Dairy Product Mfg	309	267	392	169	323,535,708	6,449,871

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Foods (continued)	Infant foods	Juices—baby	311421—Fruit & Vegetable Canning	109	4	154	3	73,025,008	663,862
	Meat & poultry	Meat—frozen	311612—Meat Processed from Carcasses	875	322	710	262	68,855,399	24,397,383
	Meat & poultry	Meat/poultry—canned	311422—Specialty Canning	2,855	1,497	4,418	1,158	1,403,349,665	172,171,467
	Meat & poultry	Poultry—frozen	311615—Poultry Processing	423	300	344	244	100,937,952	85,046,228
	Pizza	Pizza—frozen	311412—Frozen Specialty Food Manufacturing	2,037	1,446	1,781	1,264	1,229,897,911	172,229,282
	Pizza	Pizza—refrigerated	311991—Perishable Prepared Food Manufacturing	367	188	304	155	20,463,015	8,215,690
	Seafood	Fish—frozen	311712—Fresh & Frozen Seafood Processing	1,687	853	1,429	722	145,166,487	45,660,524
	Seafood	Seafood—canned	311711—Seafood Canning	3,486	860	2,867	707	1,121,637,388	217,917,381
	Seafood	Seafood—refrigerated	311711—Seafood Canning	1,676	188	1,323	148	72,226,190	12,451,167
	Seafood	Seafood—remaining—frozen	311712—Fresh & Frozen Seafood Processing	942	123	827	108	16,196,972	8,165,493
	Seafood	Shrimp—frozen	311712—Fresh & Frozen Seafood Processing	2,478	1,189	1,547	742	68,173,388	98,231,956
	Side dishes & starches	Hors d'oeuvres/snacks—frozen	311412—Frozen Specialty Food Manufacturing	2,010	889	1,715	759	293,893,632	42,412,083
	Side dishes & starches	Pasta/noodles—dry	311823—Dry Pasta Manufacturing	6,588	4,596	5,753	4,014	1,222,721,014	427,482,489
	Side dishes & starches	Prepared foods—dry mixes	311823—Dry Pasta Manufacturing	2,395	2,514	2,122	2,227	1,832,677,480	283,179,635
	Side dishes & starches	Prepared foods—remaining—frozen/refrigerated	311412—Frozen Specialty Food Manufacturing	3,444	1,425	3,024	1,250	218,610,246	75,801,096
	Side dishes & starches	Ready-made salads	311991—Perishable Prepared Food Manufacturing	2,381	2,437	1,688	1,728	257,380,059	154,772,499
	Side dishes & starches	Rice—instant/packageged	311212—Rice Milling	1,597	1,291	1,085	876	234,798,780	110,437,251

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Foods (continued)	Side dishes & starches	Vegetables—formulated/breaded—frozen	311411—Frozen Fruit, Juice, & Vegetable Manufacturing	350	311	312	277	196,603,623	25,533,277
	Snack foods	Nuts—cans/jars	311911—Roasted Nuts & Peanut Butter Manufacturing	2,968	3,226	2,418	2,628	278,482,441	199,727,770
	Snack foods	Nuts—cello wrapped	311911—Roasted Nuts & Peanut Butter Manufacturing	5,961	1,575	4,770	1,260	377,992,523	94,324,675
	Snack foods	Nuts—unshelled	311911—Roasted Nuts & Peanut Butter Manufacturing	673	193	389	112	48,089,079	16,889,544
	Snack foods	Popcorn—unpopped	311999—All Other Miscellaneous Food Manufacturing	820	1,383	525	885	294,625,565	84,725,696
	Snack foods	Snacks—caramel corn/popped popcorn	311919—Other Snack Food Manufacturing	2,001	200	1,351	136	167,411,376	15,382,802
	Snack foods	Snacks—health bars & sticks	311919—Other Snack Food Manufacturing	1,781	38	2,237	24	378,628,520	5,075,893
	Snack foods	Snacks—meat	311612—Meat Processed from Carcasses	2,880	344	2,362	283	127,372,342	18,286,925
	Snack foods	Snacks—remaining	311919—Other Snack Food Manufacturing	4,529	699	3,658	564	653,465,215	35,796,880
	Snack foods	Snacks—salty	311919—Other Snack Food Manufacturing	12,778	4,466	8,658	3,021	4,694,056,410	448,880,900
	Snack foods	Snacks—trail mixes	311919—Other Snack Food Manufacturing	2,205	647	1,771	519	75,579,237	40,221,535
	Soups	Soup—canned	311421—Fruit & Vegetable Canning	2,391	4,159	2,037	3,543	2,772,283,858	567,178,256
	Soups	Soup—dry	311423—Dried & Dehydrated Food Manufacturing	3,181	584	2,757	505	1,623,223,339	49,301,211
	Sweeteners	Sugar	311311—Sugarcane Mills	704	1,134	568	914	322,183,375	413,187,837

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Food (continued)	Sweeteners	Sugar—substitutes	325199—All Other Basic Organic Chemical Manufacturing	322	346	213	228	112,254,519	16,423,644
	Sweeteners	Table syrups/molasses	311999—All Other Miscellaneous Food Manufacturing	1,421	1,232	1,008	874	175,759,927	81,755,279
OTCs	Acne remedies	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
	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

(continued)

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

FDA Type	Model Category	Model Subcategory (1)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
OTCs (continued)	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 Unit Sales (continued)

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
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

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
OTCs (continued)	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
	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
	Skin care preparations	Suntan preparations—sunscreens & sunblock	325620—Toilet Preparation Manufacturing	1,492	732	1,303	640	71,330,098	13,998,566
Pet Foods	Pet care	Flea products	325320—Pesticide & Other Agricultural Chemical Manufacturing	649	19	500	15	24,049,740	77,282
	Pet care	Pet incontinence product	325412—Pharmaceutical Preparation Manufacturing	193	21	113	13	10,980,033	1,563,219
	Pet care	Pet treatments external	325412—Pharmaceutical Preparation Manufacturing	993	11	968	11	10,332,437	121,208
	Pet care	Pet treatments internal	325412—Pharmaceutical Preparation Manufacturing	1,016	19	861	17	36,198,895	468,065
	Pet food	Cat food—dry	311111—Dog & Cat Food Manufacturing	1,271	970	569	435	369,684,538	47,022,543
	Pet food	Cat food—moist/wet	311111—Dog & Cat Food Manufacturing	1,739	3,310	1,380	2,627	2,556,778,151	328,791,767
	Pet food	Dog food—dry	311111—Dog & Cat Food Manufacturing	2,398	2,150	1,199	1,075	338,859,807	56,565,858
	Pet food	Dog food—moist/wet	311111—Dog & Cat Food Manufacturing	1,552	2,549	1,254	2,060	1,151,807,845	172,369,073
	Pet food	Domestic bird food	311119—Other Animal Food Manufacturing	800	29	645	23	14,993,265	1,132,148

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Pet Foods (continued)	Pet food	Other pet food	311119—Other Animal Food Manufacturing	1,516	50	1,155	38	25,185,145	694,042
	Pet food	Pet treats	311111—Dog & Cat Food Manufacturing	3,749	1,634	3,058	1,334	570,822,389	63,439,037
Retail Medical Devices	Adult incontinence	Adult incontinence	322121—Paper (except Newsprint) Mills	477	1,344	393	1,107	64,249,191	29,615,879
	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
	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	

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Retail Medical Devices (continued)	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
	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

(continued)

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

FDA Type	Model Category	Model Subcategory (i)	6-digit NAICS	No. of UPCs (2008)		No. of Formulas (2008)		No. of Sales Units (2008)	
				Branded	PL	Branded	PL	Branded	PL
				UPC ^B	UPC ^{PL}	FORM ^B	FORM ^{PL}	UNIT ^B	UNIT ^{PL}
Retail Medical Devices (continued)	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	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

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	3.1	3.1	Assumed similar adjustments as dietary supplements due to large number of outlets.
Dietary supplements	3.1	3.1	According to the Natural Products Association, 36 to 37% of sales are in independent stores; 32 to 33% are in mass merchandiser stores; and the remaining 30 to 32% are through multilevel marketing, Internet, and practitioner sales. The adjustment was calculated as (1/.325) assuming mass merchandisers are represented in the ScanTrack data, with the same factor assumed for UPCs, formulas, and sales units.
Foods	1.4	1.4	Adjustment based on ERS data on sales dollar volumes not represented in ScanTrack data.
OTCs	1.4	1.4	Assumed same adjustment as for foods since they are sold in similar stores.
Pet foods	2.1	2.1	The PFI estimates that the number of branded and private-label UPCs for pet food (excluding treats) is 15,000 to 17,000. ScanTrack data counts for cat and dog foods total 7,590. We scaled up the UPCs and formulas based on the proportion (16,000/7,590) and applied the same scaling factor to sales units.
Retail medical devices	1.4	1.4	Assumed same adjustment as for foods since they are sold in similar stores.
Tobacco products	0	6.7	Based on Nielsen scanner data, about 15% of tobacco sales are in grocery stores, drug 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.

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 and annual costs of package inserts if the regulation requires adding a package insert

Within each cost category, the calculations are 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 are assumed to be one-time costs.

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, α_i and (2) assumed percentages of required changes that cannot be coordinated with a planned change, ρ^B and ρ^{PL} .

Let α_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 numbers of unique branded and private-label UPCs in product subcategory i in 2008. 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 numbers of unique formulations for branded and private-label products in product subcategory i in 2008. 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 numbers of units of branded and private-label products sold in product subcategory i in 2008.

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 ρ^B represent the proportion of uncoordinated changes for branded products and ρ^{PL} represent the proportion of uncoordinated changes for private-label products.¹ 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 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

¹ The estimation of ρ^B and ρ^{PL} is discussed in Section 3.

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

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

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

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

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

Note that the assumed values for ρ^B and ρ^{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, and
- $k = 3$ for rotogravure.

We assume 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 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 associated with graphic design and prepress activities (incurred by either the manufacturer's employees or outside vendors or consultants);
- $\sum_{k=1}^3 \beta_k \cdot PC_{jk}$ are the weighted average printing plate costs where β_k represents the proportion of UPCs printed using each printing method, k , and PC_{jk} represents the plate costs for each printing method (because the

number of plates affected varies by the type of change j , the plate costs also depend on the type of change);

- OMC_j are the other materials costs associated with graphic design and prepress activities; and
- RC_j are recordkeeping costs associated with changing label information (i.e., labor costs associated with updating records to reflect the change) 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

$$TC_UPC_{ij} = (AC_j + RC_j + LC_j + \sum_{k=1}^3 \beta_k \cdot PC_{jk} + OMC_j) \cdot X_i^A,$$

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

$$C_TC_UPC_{ij} = (C_AC_j + C_RC_j) \cdot (X_i - X_i^A).$$

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 samples, shipping samples, and laboratory fees and supplies; and
- 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

$$TC_FORM_i = (ATC + MTC) \cdot Y_i^A.$$

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

- PLC_i represents the per-sales unit value of printed packages or labels for product subcategory i based on the representative packaging or labeling method for the product category.²

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 since manufacturers are likely to have larger inventories on hand for materials with lower bulkiness. Furthermore, inventories tend to be higher for private-label UPCs since label designs are less frequently updated and manufacturers can, therefore, order a relatively larger quantity of materials with each order.

Note that we assume 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

$$ALLCOSTS_{ij} = C_TC_UPC_{ij}.$$

² 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.

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 will be 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

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

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 assume 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 multiply TC_UPC_{ij} and TC_FORM_i by an escalation factor. Based on information provided by manufacturers during the industry interviews, we assume an escalation factor of 40% for compliance periods of 15 months or less.

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, 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 γ_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-months 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 2010, 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 2010. 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 labor, materials, and recordkeeping costs associated with labeling changes. 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 4-6 shows the underlying assumed number of hours per activity (which was multiplied by an estimated hourly rate of \$45) and outside consultant costs prior to application of the 90% probability range.³ Labor costs are associated with administrative activities, recordkeeping activities, graphic design, and prepress. Materials costs are associated with

³ The hourly rate of \$45 was obtained using the 2009 average labor rate including benefits for “professional and technical services” from the Bureau of Labor Statistics and applying a 2% inflation factor to convert the estimate to 2010 dollars.

Table 4-5. Estimated Labor, Materials, and Recordkeeping Costs Associated with Labeling Changes (\$/UPC)

	Minor Change (j=1)			Major Change (j=2)			Extensive Change (j=3)			Package Insert Change (j=4)			Package Insert Added (j=5)		
	Low	Mid-point	High	Low	Mid-point	High	Low	Mid-point	High	Low	Mid-point	High	Low	Mid-point	High
	Uncoordinated changes:														
Labor—administrative costs (AC _j)	280	540	780	620	1,100	1,580	930	1,840	2,400	280	540	780	620	1,090	1,570
Labor—nonadministrative (LC _j)	1,460	2,780	5,040	3,150	4,700	8,320	5,020	7,160	14,090	1,370	2,710	4,310	3,130	4,630	8,240
Materials—flexography (PC _{j1})	310	750	1,270	1,930	4,800	7,670	4,280	10,000	13,190	310	750	1,270	1,930	4,800	7,670
Materials—offset (PC _{j2})	130	210	440	520	1,100	1,350	650	1,380	1,680	130	210	440	520	1,100	1,350
Materials—gravure (PC _{j3})	1,080	1,500	1,830	5,910	6,150	9,690	7,390	7,690	12,110	1,080	1,500	1,830	5,910	6,150	9,690
Materials—other (OMC _j)	120	160	240	130	210	250	160	290	440	120	160	240	130	210	250
Recordkeeping (RC _j)	50	80	90	50	80	90	50	80	90	50	80	90	50	80	90
Coordinated changes:															
Labor—administrative costs (U_AC _j)	140	270	390	310	550	790	N/A	N/A	N/A	140	270	390	N/A	N/A	N/A
Recordkeeping (U_RC _j)	30	40	50	30	40	50	N/A	N/A	N/A	30	40	50	N/A	N/A	N/A

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.

Table 4-6. Labor Hours and Consultant Costs for Each Type of Change

	Minor Change (j=1)			Major Change (j=2)			Extensive Change (j=3)			Package Insert Change (j=4)			Package Insert Added (j=5)		
	Low	Mid-point	High	Low	Mid-point	High	Low	Mid-point	High	Low	Mid-point	High	Low	Mid-point	High
	Administrative—internal labor hours	3.5	12.0	20.0	9.0	24.4	40.0	12.5	40.8	60.0	3.5	12.0	20.0	9.0	24.4
Graphic design—internal labor hours	1.0	4.4	8.5	2.0	11.4	35.0	4.0	24.0	70.0	1.0	4.4	8.5	2.0	11.4	35.0
Graphic design—consultant labor costs (\$)	275	1,825	3,500	1,000	2,213	5,000	1,700	3,740	10,000	275	1,825	3,500	1,000	2,213	5,000
Prepress—internal labor hours	2.0	3.4	8.0	2.0	5.6	8.0	2.0	6.9	15.0	1.0	3.4	5.0	2.0	4.0	6.0
Prepress—consultant labor costs (\$)	350	538	900	1,000	1,725	2,750	1,500	2,025	2,750	350	538	900	1,000	1,725	2,750
Recordkeeping—internal labor hours	0.9	1.8	2.2	0.9	1.8	2.2	0.9	1.8	2.2	0.9	1.8	2.2	0.9	1.8	2.2

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.

In developing these estimates, we assumed the following:

- Materials costs for an extensive change (specifically, printing plates and other miscellaneous materials) are assumed to be 25% more than for a major change for offset and gravure. Separate estimates for flexography 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 4-7 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 subsequently reviewed and, in some cases, modified by PTIS based on its understanding of current industry practices.

Table 4-7. Estimated Percentages of UPCs Printed Using Each Printing Method by Package-Label Type (Preliminary Estimates)

Package-Label Type	Bulkiness	Percent		
		Flexography (β_1)	Offset (β_2)	Gravure (β_3)
Aluminum can	High	0%	100%	0%
Aseptic carton	High	0%	100%	0%
Foam carton	High	100%	0%	0%
Foil-backed paper	Medium	29%	51%	20%
Foil-backed paper—blister pack	Medium	29%	51%	20%
Foil-backed paper—pouch	Medium	78%	2%	20%
Foil—bag	Medium	78%	2%	20%
Foil—top	Low	78%	2%	20%
Foil—tube	High	78%	2%	20%
Gable top carton	High	29%	51%	20%
Paper	Medium	29%	51%	20%
Paper backed—blister pack	Medium	0%	100%	0%
Paper—bag	Medium	80%	20%	0%
Paper—coated	Medium	29%	51%	20%
Paper—label	Low	20%	78%	2%
Paper—pouch	Medium	2%	78%	20%
Paperboard—carton	Medium	20%	78%	2%
Paperboard—cigarette carton	Medium	0%	0%	100%
Paperboard—molded	High	100%	0%	0%
Paperboard—sheet	Medium	20%	78%	2%
Paperboard—sleeve	Medium	29%	51%	20%
Paperboard—tube	High	33%	33%	34%
Plastic bag—clear	Medium	98%	2%	0%
Plastic bag—opaque	Medium	78%	2%	20%
Plastic bag—resealable	Medium	78%	2%	20%
Plastic—label	Low	33%	33%	34%

(continued)

Table 4-7. Estimated Percentages of UPCs Printed Using Each Printing Method by Package-Label Type (Preliminary Estimates) (continued)

Package-Label Type	Bulkiness	Percent		
		Flexography (β_1)	Offset (β_2)	Gravure (β)
Plastic—molded	High	20%	60%	20%
Plastic—sheet	Medium	78%	2%	20%
Plastic—tube	High	0%	100%	0%
Popcorn—bag	Medium	10%	90%	0%
Steel can	High	0%	100%	0%
Package inserts	Low	50%	50%	0%

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. Table 4-8 shows estimated analytical testing costs for a list of common tests, and Table 4-9 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. Estimated analytical testing costs were based on published prices from testing laboratories,¹ and estimated market testing costs were based on information provided by industry participants. For both types of tests, users have the option of including additional testing costs other than the specific selections in the model.

¹ Analytical test costs were obtained from Industrial Laboratories Company, The National Food Lab, Midwest Laboratories, Microbac Laboratories, Inc., Eurofins Strasburger & Siegel, Eurofins Central Analytical Laboratories, Eurofins GeneScan, Eurofins (Iowa), Genetic ID, and EMSL Analytical, Inc.

Table 4-8. Estimated Analytical Testing Costs in the Labeling Cost Model (\$/Formula)

Type of Test	Low	Midpoint	High
	ATC_LO	ATC_MID	ATC_HI
Cosmetics—microbes and contaminants	69	99	129
Dietary supplements—vitamins	88	125	204
Dietary supplements—minerals	37	42	67
Dietary supplements—amino acids	179	235	249
Dietary supplements—botanicals	107	220	333
Dietary supplements—other ingredients	181	182	184
Food—NLEA panel	638	650	845
Food—fat composition	159	165	180
Food—trans fatty acids	161	162	164
Food—sugar profile	87	90	105
Food—total fiber	125	153	201
Food—soluble or insoluble fiber	103	110	117
Food—vitamins	120	146	158
Food—minerals	33	32	91
Food—iodine	47	52	58
Food—proximate analysis	63	70	77
Food—pathogens	22	34	52
Food—caffeine	96	130	131
Food—allergens	90	104	118
Food—bioengineered ingredients (ELISA)	67	70	73
Food—bioengineered ingredients and foods (PCR)	199	240	281
OTCs—microbes and contaminants	79	88	96
Pet foods—proximate assay	66	110	196
Pet foods—microbiology	22	38	54
Pet foods—inorganic assay	46	101	156
Pet foods—vitamin assay	96	175	254
Pet foods—amino acid assay	193	232	270
Pet foods—contaminants	74	125	176

Note: The total test costs included in the model assume two tests: \$25.30 for 1 hour of labor to prepare the samples, and \$60.55 for overnight shipment to the testing lab.

Table 4-9. Estimated Market Testing Costs in the Labeling Cost Model (\$/Formula)

Type of Test	Low	Midpoint	High
	ATC_LO	ATC_MID	ATC_HI
Focus groups	7,300	10,000	12,700
Quantitative tests	12,500	18,000	95,600

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 at a rate of \$25.30 based on the Bureau of Labor Statistics (BLS) rate for “goods producing, production, transportation, and material moving” laborers.
- Testing the samples requires shipping one 2-pound package overnight by FedEx at a cost of \$60.55.

Thus, the total cost per sample is two times the cost per test shown in Table 4-8 plus \$85.85.

In developing the focus group test costs, we assumed the following:

- The cost per focus group is \$6,000, and three products are included in each focus group (resulting in a cost for each product of \$2,000).
- The minimum cost estimate is based on three focus groups, the midpoint cost estimate is based on five focus groups, and the maximum cost estimate is based on seven focus groups.

Quantitative market testing cost estimates were developed by aggregating across different types of tests conducted by manufacturers.

4.4.3 Per-Sales Unit Cost Calculation Data

Per-sales unit costs include the costs of applying stickers and discarding inventory for short compliance periods and the annual costs of including package inserts for products that do not currently have them. Table 4-10 shows the low, midpoint, and high estimates of the costs of printing and applying the

Table 4-10. Estimated Sticker and Application Costs on a Per-Sticker Basis (\$/Sales Unit)

Type of Test	Low	Midpoint	High
	SC_LO	SC_MID	SC_HI
Sticker cost	0.005	0.042	0.150
Application cost	0.027	0.040	0.081
Total	0.032	0.082	0.231

stickers. For application costs, we assumed \$8.05 per hour labor costs and 300 (minimum cost), 200 (midpoint), and 100 (maximum costs) pieces per hour. 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 4-11. Table 4-12 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 4-7.

Table 4-11. 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 ^a	10%	150%	0%	10%	0%	0%
6 ^a	10%	150%	0%	10%	0%	0%
9 ^a	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%
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						

^a For 3-, 6-, and 9-month compliance periods, a portion of products are 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 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			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	Steel can	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	0.015	0.020	0.025					No
	Deodorant (nonantiperspirant)	Remaining deodorants	Paper—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

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Cosmetics (continued)	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
	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	Plastic—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	Steel can	0.180	0.200	0.220					No

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Cosmetics (continued)	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
	Nailcare/manicure needs	Manicure needs	Paperboard—carton	0.025	0.035	0.045					No
	Nailcare/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
	Oral hygiene	Denture cleansers	Paperboard—carton	0.025	0.030	0.035	Foil-backed paper—pouch	0.400	0.600	0.800	No
	Oral hygiene	Tooth whiteners	Paperboard—carton	0.020	0.025	0.030	Plastic—sheet	0.560	0.840	1.120	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

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Cosmetics (continued)	Shaving needs	Shaving cream	Steel can	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	Paperboard—carton	0.100	0.110	0.120	Aluminum can	0.420	0.540	0.660	No
	Mineral supplements	Minerals	Paper—label	0.010	0.012	0.014					No
	Nutritional supplements	Complete nutritional products	Plastic—sheet	0.065	0.070	0.075	Paper—label	0.270	0.300	0.330	No
	Nutritional supplements	Nutritional supplements	Paper—label	0.010	0.012	0.014					No
	Protein supplements	Protein supplements	Plastic—sheet	0.065	0.070	0.075	Plastic—label	0.180	0.200	0.220	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

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
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	0.150	0.175	0.200					No
	Baked goods	Baked goods—remaining—fresh	Paper—label	0.015	0.018	0.020					No
	Baked goods	Baked goods—remaining—frozen	Paperboard—carton	0.065	0.070	0.075					No
	Baked goods	Bread—fresh	Plastic bag—clear	0.040	0.045	0.050					No
	Baked goods	Bread—frozen	Paperboard—carton	0.070	0.075	0.080					No
	Baked goods	Breading products	Paperboard—carton	0.055	0.060	0.065					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	0.060	0.065	0.070					No
	Baked goods	Cookies/cones	Plastic bag—opaque	0.045	0.053	0.060					No
	Baked goods	Crackers	Paperboard—carton	0.065	0.070	0.075					No
	Baked goods	Mexican shells/tortillas	Plastic bag—clear	0.040	0.045	0.050					No
	Baking ingredients	Baking mixes	Paperboard—carton	0.040	0.045	0.050					No
	Baking ingredients	Baking supplies	Plastic bag—opaque	0.020	0.025	0.030					No

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (continued)	Baking ingredients	Bread/cookie/dough products—frozen	Plastic bag—clear	0.060	0.065	0.070					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	0.120	0.130	0.140					No
	Beverages	Carbonated beverages—low calorie	Paperboard—carton	0.075	0.080	0.085	Aluminum can	0.840	1.080	1.320	No
	Beverages	Carbonated beverages—regular	Plastic—label	0.025	0.030	0.035					No
	Beverages	Cocktail mixes	Paper—label	0.018	0.021	0.024					No
	Beverages	Coffee—ground	Paper—coated	0.055	0.063	0.070					No
	Beverages	Coffee—liquid	Plastic—label	0.025	0.030	0.035					No
	Beverages	Coffee—soluble	Paper—label	0.005	0.007	0.009					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	0.065	0.075					No
	Beverages	Fruit drinks—refrigerated	Gable top carton	0.140	0.150	0.160					No
	Beverages	Fruit drinks—shelf stable	Plastic—label	0.020	0.025	0.030					No
	Beverages	Fruit juice—frozen	Paper—label	0.055	0.065	0.075					No
	Beverages	Fruit juice—refrigerated	Gable top carton	0.140	0.150	0.160					No
	Beverages	Fruit juice—shelf stable	Paper—label	0.010	0.012	0.014					No
	Beverages	Fruit punch bases/syrups	Plastic—tube	0.110	0.130	0.150					No

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (continued)	Beverages	Ice	Plastic bag—clear	0.055	0.060	0.065					No
	Beverages	Milk—flavored—refrigerated	Plastic—label	0.045	0.050	0.055					No
	Beverages	Milk—refrigerated	Paper—label	0.005	0.007	0.009					No
	Beverages	Milk—shelf stable	Paper—label	0.005	0.007	0.009					No
	Beverages	Milk/creamers—powdered	Paper—label	0.075	0.085	0.095					No
	Beverages	Milk/water—additives	Paperboard—carton	0.055	0.060	0.065	Foil-backed paper	0.250	0.300	0.350	No
	Beverages	Noncarbonated beverages—mixes	Foil-backed paper—pouch	0.025	0.030	0.035					No
	Beverages	Shakes/drinks—remaining—nonrefrigerated	Aseptic carton	0.080	0.100	0.120					No
	Beverages	Shakes/drinks/eggnog—refrigerated	Gable top carton	0.140	0.150	0.160					No
	Beverages	Tea—bags/packaged	Paperboard—carton	0.050	0.055	0.060					No
	Beverages	Tea—herbal	Paperboard—carton	0.045	0.050	0.055					No
	Beverages	Tea—instant	Paperboard—carton	0.030	0.035	0.040	Foil-bag	0.060	0.090	0.120	No
	Beverages	Tea—liquid	Paper—label	0.010	0.012	0.014					No
	Beverages	Vegetable juice—shelf stable	Paper—label	0.016	0.018	0.020					No

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (continued)	Beverages	Water—bottled	Plastic—label	0.015	0.020	0.025					No
	Beverages	Water—bottled/caloric	Plastic—label	0.020	0.025	0.030					No
	Beverages	Water—bottled/low calorie	Plastic—label	0.015	0.020	0.025					No
	Beverages	Wine—nonalcoholic	Paper—label	0.012	0.014	0.016					No
	Breakfast foods	Breakfast bars/pastries/powders	Paperboard—carton	0.055	0.060	0.065	Plastic—sheet	0.060	0.072	0.090	No
	Breakfast foods	Breakfasts—frozen	Gable top carton	0.100	0.110	0.120					No
	Breakfast foods	Cereal—hot	Paperboard—carton	0.055	0.060	0.065	Paper—pouch	0.100	0.150	0.200	No
	Breakfast foods	Cereal—ready to eat	Paperboard—carton	0.100	0.110	0.120					No
	Breakfast foods	Waffle/pancake/French toast—frozen	Paperboard—carton	0.050	0.055	0.060					No
	Candy & gum	Candy—chocolate	Plastic—sheet	0.020	0.025	0.030					No
	Candy & gum	Candy—dietetic	Plastic bag—opaque	0.040	0.050	0.060					No
	Candy & gum	Candy—nonchocolate	Foil—bag	0.070	0.080	0.090					No
	Candy & gum	Gum—low calorie	Paperboard—carton	0.020	0.025	0.030					No
	Candy & gum	Gum—regular	Paperboard—carton	0.020	0.025	0.030					No
	Condiments/dips/spreads	Condiments	Paper—label	0.004	0.007	0.010					No
	Condiments/dips/spreads	Dips—refrigerated	Plastic—molded	0.060	0.070	0.080					No
	Condiments/dips/spreads	Dips—shelf stable	Paper—label	0.004	0.006	0.008					No

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (continued)	Condiments/dips/ spreads	Extracts	Paperboard— carton	0.025	0.030	0.035	Paper—label	0.002	0.003	0.004	No
	Condiments/dips/ spreads	Honey	Paper—label	0.018	0.021	0.024					No
	Condiments/dips/ spreads	Jams/jellies	Paper—label	0.006	0.008	0.010					No
	Condiments/dips/ spreads	Jams/spreads—remaining	Paper—label	0.013	0.016	0.019					No
	Condiments/dips/ spreads	Marinades/tenderizers/MSG	Paper—label	0.007	0.010	0.013					No
	Condiments/dips/ spreads	Mayonnaise	Paper—label	0.006	0.008	0.010					No
	Condiments/dips/ spreads	Peanut butter	Paper—label	0.004	0.006	0.008					No
	Condiments/dips/ spreads	Pepper	Paper—label	0.004	0.006	0.008					No
	Condiments/dips/ spreads	Pickles/olives/relishes	Paper—label	0.003	0.005	0.007					No
	Condiments/dips/ spreads	Salt	Paper—label	0.010	0.012	0.014					No
	Condiments/dips/ spreads	Salt—substitutes	Paper—label	0.004	0.006	0.008					No
	Condiments/dips/ spreads	Sandwich spreads/ horseradish/sauerkraut— refrigerated	Plastic bag— resealable	0.070	0.080	0.090					No
	Condiments/dips/ spreads	Seasoning—dry	Paper—label	0.004	0.006	0.008					No
	Condiments/dips/ spreads	Spices/seasonings— remaining	Paper—label	0.002	0.004	0.006					No

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (continued)	Condiments/dips/spreads	Spreads—refrigerated	Paper—label	0.004	0.006	0.008					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	Foil—top	0.005	0.008	0.010	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	Plastic—sheet	0.030	0.040	0.050					No
	Dairy foods	Cheese—specialty/imported	Plastic bag—resealable	0.070	0.080	0.090					No
	Dairy foods	Cream—refrigerated	Gable top carton	0.120	0.130	0.140					No
	Dairy foods	Frozen novelties	Paperboard—carton	0.050	0.055	0.060					No
	Dairy foods	Ice cream	Paperboard—molded	0.085	0.090	0.095					No
	Dairy foods	Ice milk/sherbet/yogurt—frozen	Paperboard—molded	0.085	0.090	0.095					No
	Dairy foods	Ice pops—unfrozen	Plastic bag—clear	0.030	0.040	0.050	Plastic—sheet	0.005	0.008	0.010	No
	Dairy foods	Sour cream	Plastic—molded	0.060	0.070	0.080					No
	Dairy foods	Whipping cream	Gable top carton	0.100	0.110	0.120					No
	Dairy foods	Yogurt—refrigerated	Plastic—molded	0.020	0.030	0.040	Foil—top	0.005	0.008	0.010	No
	Dairy foods	Yogurt—shakes/drinks—refrigerated	Paperboard—sleeve	0.045	0.050	0.055	Plastic—label	0.120	0.150	0.180	No
	Desserts	Cheesecake/pies—fresh	Paper—coated	0.020	0.025	0.030					No

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (continued)	Desserts	Cheesecake/pies—frozen	Paperboard— carton	0.065	0.070	0.075					No
	Desserts	Dessert—RTS single serving	Paperboard— sleeve	0.030	0.035	0.040	Foil—top	0.020	0.032	0.040	No
	Desserts	Desserts/toppings—frozen	Paper—label	0.012	0.014	0.016					No
	Desserts	Gelatin/pudding—mixes— diet	Paperboard— carton	0.025	0.030	0.035					No
	Desserts	Gelatin/pudding—mixes— sweetened	Paperboard— carton	0.025	0.030	0.035					No
	Desserts	Pudding—refrigerated	Paperboard— sleeve	0.040	0.045	0.050	Foil—top	0.030	0.048	0.060	No
	Desserts	Syrups/toppings—shelf stable	Paper—label	0.018	0.021	0.024					No
	Desserts	Toppings—refrigerated	Steel can	0.220	0.240	0.260					No
	Dressings & sauces	Salad dressing—liquid	Paper—label	0.007	0.010	0.013					No
	Dressings & sauces	Salad dressing— reduced/low calorie	Paper—label	0.007	0.010	0.013					No
	Dressings & sauces	Salad dressing— refrigerated	Plastic—label	0.015	0.020	0.025					No
	Dressings & sauces	Salad dressings/toppings— dry	Foil-backed paper—pouch	0.030	0.035	0.040					No
	Dressings & sauces	Sauce—barbecue	Paper—label	0.012	0.015	0.018					No
	Dressings & sauces	Sauce—Mexican	Paper—label	0.005	0.007	0.009					No
	Dressings & sauces	Sauce—spaghetti/marinara	Paper—label	0.006	0.008	0.010					No
	Dressings & sauces	Sauce/gravy—mixes	Foil-backed paper—pouch	0.030	0.035	0.040					No

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (continued)	Dressings & sauces	Sauce/gravy/glaze	Paper—label	0.005	0.007	0.009					No
	Dressings & sauces	Vinegar/cooking wine	Paper—label	0.006	0.008	0.010					No
	Eggs	Eggs—fresh	Foam carton	0.020	0.030	0.040					No
	Entrees	Combination lunches	Paperboard—carton	0.055	0.060	0.065					No
	Entrees	Entrees—frozen	Paperboard—carton	0.035	0.040	0.045					No
	Entrees	Entrees—refrigerated	Paperboard—sleeve	0.045	0.050	0.055					No
	Entrees	Prepared foods—canned/shelf stable	Paper—label	0.005	0.007	0.009					No
	Entrees	Sandwiches—refrigerated/frozen	Paperboard—carton	0.050	0.055	0.060					No
	Fats & oils	Cooking sprays	Steel can	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	0.035	0.040	0.045					No
	Fats & oils	Oils—olive/salad/cooking	Paper—label	0.008	0.011	0.014					No
	Fruits & vegetables	Beans—canned	Paper—label	0.005	0.007	0.009					No
	Fruits & vegetables	Beans/peas/lentils/barley—dry	Plastic bag—clear	0.010	0.015	0.020					No
	Fruits & vegetables	Fruit—canned	Paper—label	0.006	0.008	0.010					No
	Fruits & vegetables	Fruit—dried	Plastic bag—resealable	0.090	0.110	0.130					No
	Fruits & vegetables	Fruit—fresh	Paper—label	0.007	0.009	0.011					No
	Fruits & vegetables	Fruit/fruit salad—refrigerated	Plastic—label	0.010	0.015	0.020					No

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (continued)	Fruits & vegetables	Fruits—frozen	Plastic bag—resealable	0.070	0.080	0.090					No
	Fruits & vegetables	Garlic/herbs—fresh	Paperboard—sleeve	0.040	0.045	0.050					No
	Fruits & vegetables	Leafy greens—fresh	Plastic bag—clear	0.020	0.025	0.030					No
	Fruits & vegetables	Potatoes—canned	Paper—label	0.005	0.007	0.009					No
	Fruits & vegetables	Potatoes—dehydrated	Paperboard—carton	0.045	0.050	0.055					No
	Fruits & vegetables	Potatoes—fresh	Plastic bag—clear	0.050	0.055	0.060					No
	Fruits & vegetables	Potatoes—frozen	Plastic bag—opaque	0.040	0.048	0.055					No
	Fruits & vegetables	Tomatoes—canned	Paper—label	0.004	0.006	0.008					No
	Fruits & vegetables	Vegetables—canned	Paper—label	0.005	0.007	0.009					No
	Fruits & vegetables	Vegetables—fresh	Plastic bag—clear	0.010	0.015	0.020					No
	Fruits & vegetables	Vegetables—frozen	Plastic bag—opaque	0.025	0.038	0.050					No
	Fruits & vegetables	Vegetables—precut salad mix—fresh	Plastic bag—clear	0.030	0.035	0.040					No
	Infant foods	Baby food	Paper—label	0.002	0.004	0.006					No
	Infant foods	Infant formulas	Paper—label	0.006	0.008	0.010					No
	Infant foods	Juices—baby	Paperboard—sleeve	0.035	0.040	0.045	Paper—label	0.002	0.004	0.005	No
	Meat & poultry	Meat—frozen	Paperboard—carton	0.045	0.050	0.055					No
	Meat & poultry	Meat/poultry—canned	Paper—label	0.005	0.007	0.009					No
Meat & poultry	Poultry—frozen	Plastic bag—resealable	0.120	0.140	0.160					No	

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (continued)	Pizza	Pizza—frozen	Paperboard—carton	0.050	0.055	0.060					No
	Pizza	Pizza—refrigerated	Paper—label	0.006	0.008	0.010					No
	Seafood	Fish—frozen	Plastic bag—resealable	0.110	0.130	0.150					No
	Seafood	Seafood—canned	Paper—label	0.002	0.004	0.006					No
	Seafood	Seafood—refrigerated	Plastic bag—resealable	0.100	0.120	0.140					No
	Seafood	Seafood—remaining—frozen	Paperboard—carton	0.045	0.050	0.055					No
	Seafood	Shrimp—frozen	Paperboard—carton	0.070	0.075	0.080					No
	Side dishes & starches	Hors d'oeuvres/snacks—frozen	Plastic bag—opaque	0.030	0.040	0.050					No
	Side dishes & starches	Pasta/noodles—dry	Paperboard—carton	0.045	0.050	0.055					No
	Side dishes & starches	Prepared foods—dry mixes	Paperboard—carton	0.030	0.035	0.040					No
	Side dishes & starches	Prepared foods—remaining—frozen/refrigerated	Paperboard—carton	0.400	0.425	0.450					No
	Side dishes & starches	Ready-made salads	Paperboard—sleeve	0.040	0.045	0.050	Foil—top	0.030	0.048	0.060	No
	Side dishes & starches	Rice—instant/packaged	Paperboard—carton	0.070	0.075	0.080					No
	Side dishes & starches	Vegetables—formulated/breaded—frozen	Paperboard—carton	0.040	0.045	0.050					No
	Snack foods	Nuts—cans/jars	Paper—label	0.006	0.008	0.010					No

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
Foods (continued)	Snack foods	Nuts—cello wrapped	Plastic bag—clear	0.035	0.040	0.045					No
	Snack foods	Nuts—unshelled	Plastic bag—clear	0.040	0.045	0.050					No
	Snack foods	Popcorn—unpopped	Paperboard—carton	0.050	0.055	0.060	Popcorn bag	0.180	0.240	0.300	No
	Snack foods	Snacks—caramel corn/popped popcorn	Plastic bag—opaque	0.040	0.045	0.050					No
	Snack foods	Snacks—health bars & sticks	Foil—bag	0.015	0.018	0.020					No
	Snack foods	Snacks—meat	Plastic—sheet	0.005	0.008	0.010					No
	Snack foods	Snacks—remaining	Plastic bag—opaque	0.040	0.045	0.050					No
	Snack foods	Snacks—salty	Plastic bag—opaque	0.050	0.060	0.070					No
	Snack foods	Snacks—trail mixes	Plastic bag—resealable	0.090	0.110	0.130					No
	Soups	Soup—canned	Paper—label	0.004	0.006	0.008					No
	Soups	Soup—dry	Plastic bag—opaque	0.015	0.020	0.025					No
	Sweeteners	Sugar	Paper—bag	0.050	0.055	0.060					No
	Sweeteners	Sugar—substitutes	Paperboard—carton	0.045	0.050	0.055	Paper—pouch	0.400	0.600	0.800	No
Sweeteners	Table syrups/molasses	Paper—label	0.022	0.025	0.028					No	
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	0.020	0.040	0.060	Yes

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
OTCs (continued)	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—opaque	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	0.020	0.040	0.060	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	0.040	0.060	0.080	Yes
	Deodorant (antiperspirant)	Deodorant—aerosol (OTC)	Steel can	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)	Paper—label	0.012	0.015	0.018					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

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
OTCs (continued)	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	0.200	0.300	0.400	No
	First aid	First aid—germicidal antiseptics	Paperboard—carton	0.040	0.045	0.050	Foil-backed paper—pouch	1.000	1.500	2.000	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	0.300	0.360	0.420	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	Paperboard—carton	0.015	0.020	0.025	Plastic—tube	0.100	0.120	0.140	No
	Oral hygiene	Oral rinse and antiseptic	Paper—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

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
OTCs (continued)	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	0.020	0.040	0.060	No
	Preparations/remedies	Antigas products	Paperboard—carton	0.015	0.020	0.025	Foil-backed paper—blister pack	0.020	0.040	0.060	No
	Preparations/remedies	Antisleep products	Paperboard—carton	0.030	0.035	0.040	Paper—label	0.008	0.010	0.012	Yes
	Preparations/remedies	Antismoking products	Paperboard—carton	0.035	0.040	0.045	Foil-backed paper—blister pack	0.140	0.280	0.420	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	0.060	0.090	0.120	Yes
	Preparations/remedies	Diarrhea remedies	Paperboard—carton	0.020	0.025	0.030	Foil-backed paper—blister pack	0.020	0.040	0.060	Yes
	Preparations/remedies	Diuretic remedies	Paperboard—carton	0.025	0.030	0.035	Foil-backed paper—blister pack	0.040	0.060	0.080	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	Steel can	0.120	0.140	0.160					No

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
OTCs (continued)	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	0.020	0.040	0.060	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
	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

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			Package Insert Yes/No
				Low	Mid	High		Low	Mid	High	
				PLC1_LO	PLC1_MID	PLC1_HI		PLC2_LO	PLC2_MID	PLC2_HI	
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	Paper—bag	0.300	0.325	0.350					No
	Pet food	Dog food—moist/wet	Paper—label	0.005	0.007	0.009					No
	Pet food	Domestic bird food	Paper—label	0.018	0.021	0.024					No
	Pet food	Other pet food	Paper—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—sheet	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	0.300	0.450	0.600	Yes
	Enemas—ready to use	Enemas—ready to use	Paperboard—carton	0.025	0.030	0.035	Plastic—label	0.020	0.026	0.032	Yes
	Family planning	Contraceptives—female	Paperboard—carton	0.015	0.020	0.025	Foil-back paper – blister pack	0.040	0.060	0.080	Yes

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			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 (continued)	Family planning	Contraceptives—male	Paperboard—carton	0.015	0.020	0.025	Foil-backed paper—pouch	0.120	0.240	0.360	Yes
	Family planning	Family planning test kits	Paperboard—carton	0.020	0.025	0.030	Foil-backed paper—pouch	0.060	0.080	0.100	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					Yes
	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	0.060	0.080	0.100	Yes
	First aid	First aid—thermometers	Paperboard—sheet	0.015	0.020	0.025					No
	Foot care	Foot comfort products	Steel can	0.120	0.140	0.160					No
	Foot care	Foot preparations—remaining (medical device)	Paperboard—sheet	0.010	0.015	0.020					No

(continued)

Table 4-12. Per-Package Label Costs for the Labeling Cost Model (\$/Sales Unit) (continued)

FDA Type	Model Category	Model Subcategory (i)	Primary Package Label	Primary Cost per Unit (2010)			Secondary Package Label	Secondary Cost per Unit (2010)			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 (continued)	Insulin syringes	Insulin syringes	Paperboard—carton	0.040	0.045	0.050	Paper	0.100	0.200	0.300	Yes
	Medical accessory—remaining	Medical accessory—remaining	Paperboard—carton	0.040	0.050	0.060					No
	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					No
	Oral hygiene	Oral care combinations—medical device	Paperboard—sheet	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	Plastic—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	0.040	0.060	0.080	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

4.4.4 Accounting for Uncertainty in the Cost Estimates

The per-UPC and per-formulation costs in the model represent 90% probability ranges of estimated industry costs. In the previous FDA Labeling Cost Model, the low and high cost estimates were developed by assigning the lowest of the low estimates provided by industry as the “low” estimate and assigning the highest of the high estimates provided by industry as the “high” estimate. This method likely overstated the difference between the typical low and high estimates of labeling cost changes. Thus, in the updated model, we applied a method in which the low and high estimates are interpreted as bounds of 90% probability ranges.

In collecting the cost data for labeling changes, we asked industry participants to provide low, most likely, and high estimates. We then combined the individual estimates into aggregate low, most likely, and high estimates. For each of the types of costs, the aggregation procedures were as follows:

- Per-UPC costs—the low value was calculated as the minimum of the midpoints, the midpoint value as the mean of the midpoints, and the high value as the maximum of the midpoints.
- Per-formulation costs (analytical tests and market tests)—after excluding outliers, the low value was assigned the minimum value, the midpoint value was assigned the mean, and the high value was assigned the maximum.¹
- Per-unit costs—procedures varied by type as follows:
 - Sticker costs—the low value was assigned the minimum value, the midpoint value was assigned the mean, and the high value was assigned the maximum.
 - Sticker application costs—hourly labor rate was divided by the low, medium, and high estimates of the number of units per hour.
 - Printed package costs and label costs—low, midpoint, and high values were assigned as provided by PTIS.

For per-UPC and per-formulation costs, we generated 90% probability ranges assuming a triangular distribution using the @RISK software. In most cases, the distributions are not

¹ Per-formulation costs were aggregated differently than per-UPC costs because we had fewer data points to work with.

symmetrical; generally, the midpoint is closer to the minimum value than the maximum value. The values for per-unit costs were not recalculated based on 90% probability ranges because the ranges were generally small and rounding the 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 in 2008 calculated from the scanner data are assumed to be representative of a typical year but given the state of the economy at that time, these estimates may not be typical.
- 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 due to 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).

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

The model was programmed in Microsoft Excel 2007 and saved as the Microsoft Excel 2003 version. If FDA upgrades in the future, RTI can provide the model in the 2007 version.

The FDA Labeling Cost Model is a stand-alone program and thus can be run on any computer with Microsoft Excel 2003. 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. Other user inputs, such as including analytical testing costs, market testing costs, and recordkeeping costs, are optional. 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)
- **Analytical Costs:** Contains cost estimates for analytical tests used by manufacturers of products in the Labeling Cost Model
- **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

The output worksheets are as follows:

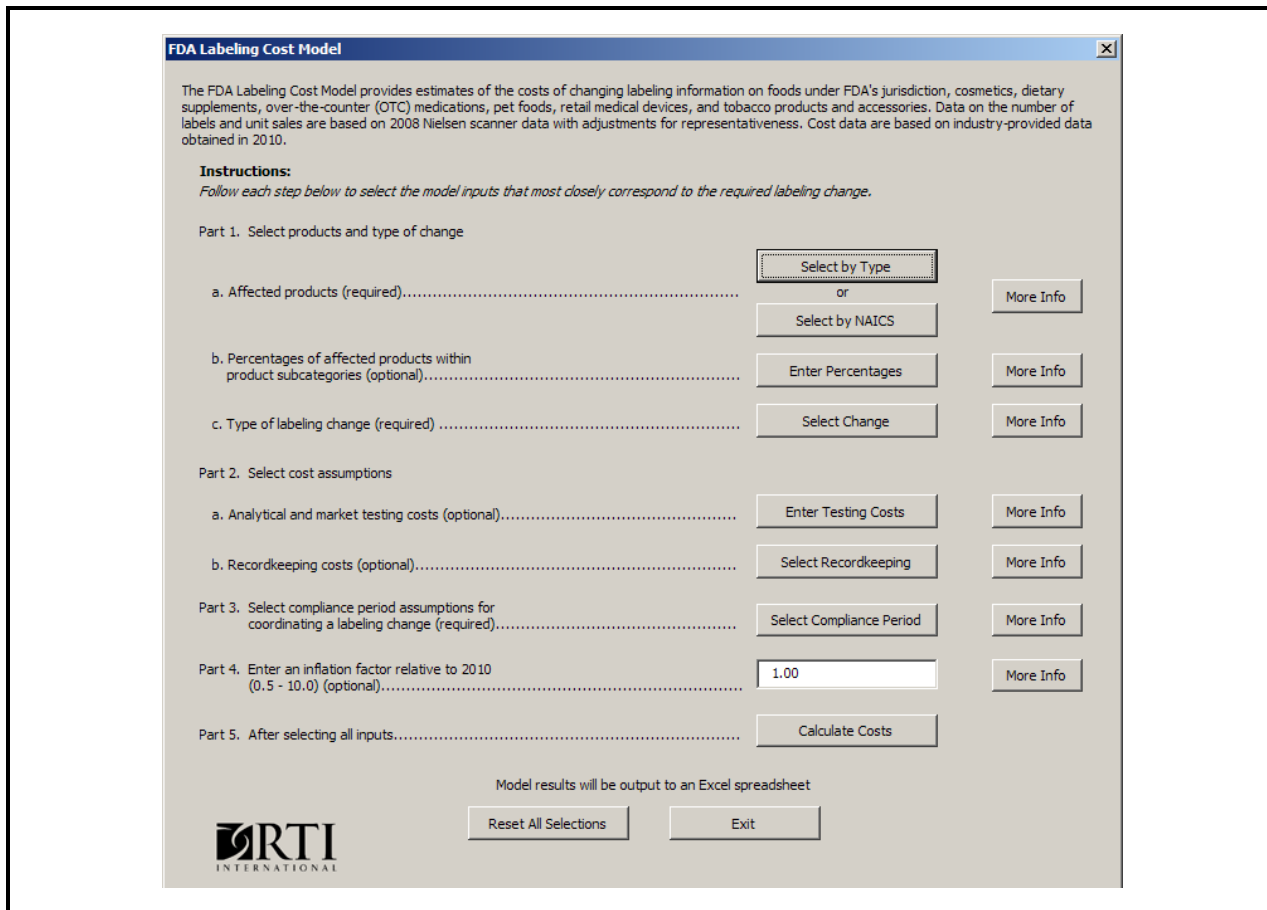
- **Summary:** Provides a summary of the user inputs for the model run
- **Detailed Costs:** Provides cost breakdowns for each selected subcategory detailed by private-label versus branded products including the following:
 - Numbers of UPCs, formulas, and sales units delineated by whether the change could be coordinated with a planned change
 - Low, midpoint, and high cost estimates for each type of cost incurred per coordinated and uncoordinated UPC

- **Aggregate Costs:** Provides low, midpoint, and high cost estimates for each type of cost incurred for each subcategory selected in the model inputs
- **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 2010.xls**. If a warning about macros appears, click **Enable Macros**. The file will open to the Main Menu selection screen (see Figure 5-1).

Figure 5-1. Main Menu Selection Screen



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 may be used to obtain additional instructions or information for each of the model inputs.

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 3- or 6-digit 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

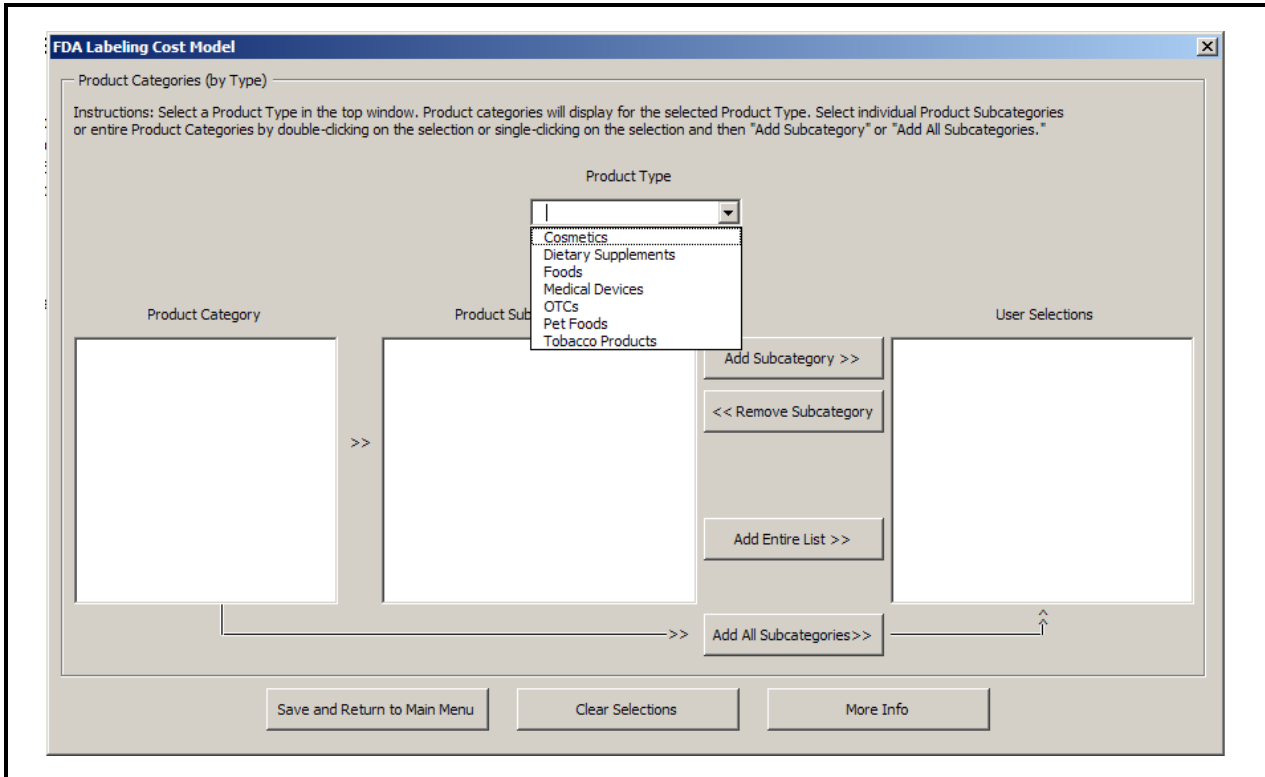
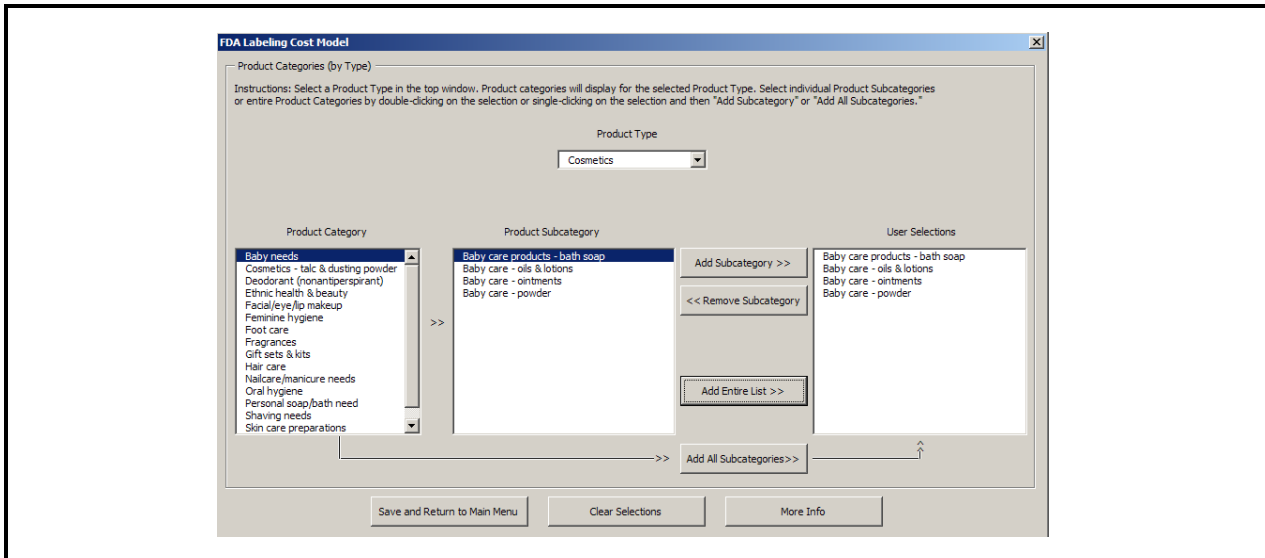


Figure 5-3. Affected Products by Type Selection Screen—Selecting Entire List of Product Subcategories



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

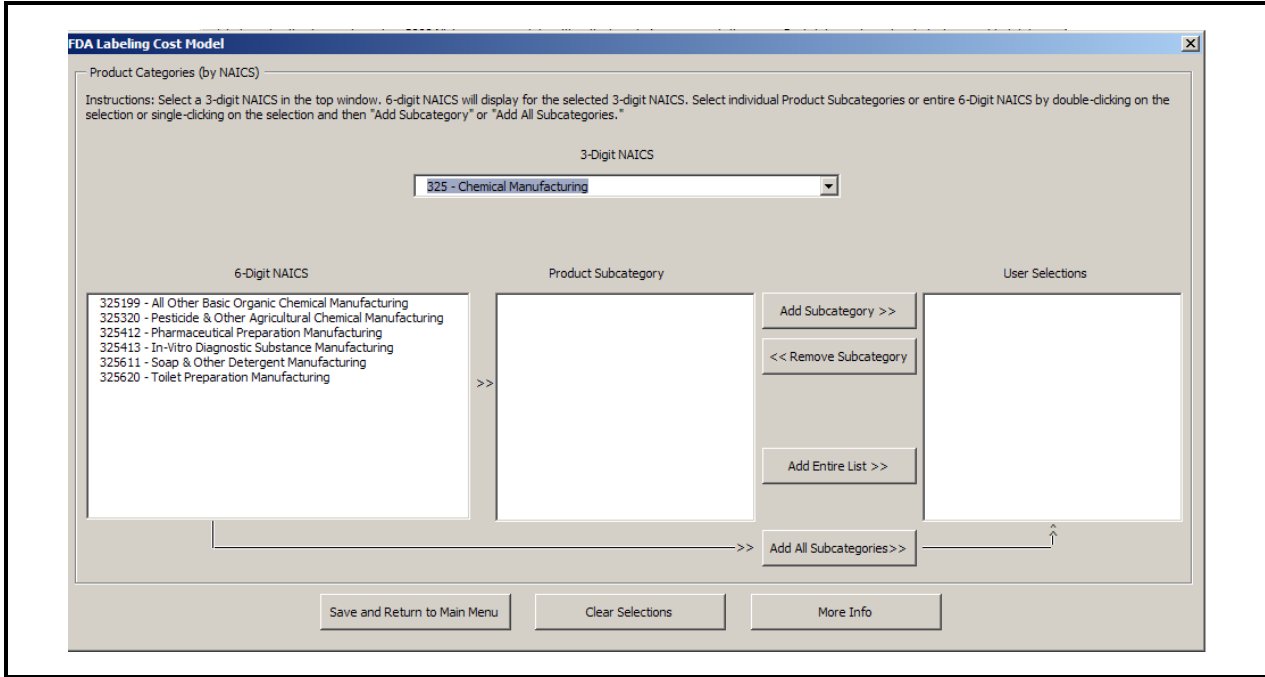
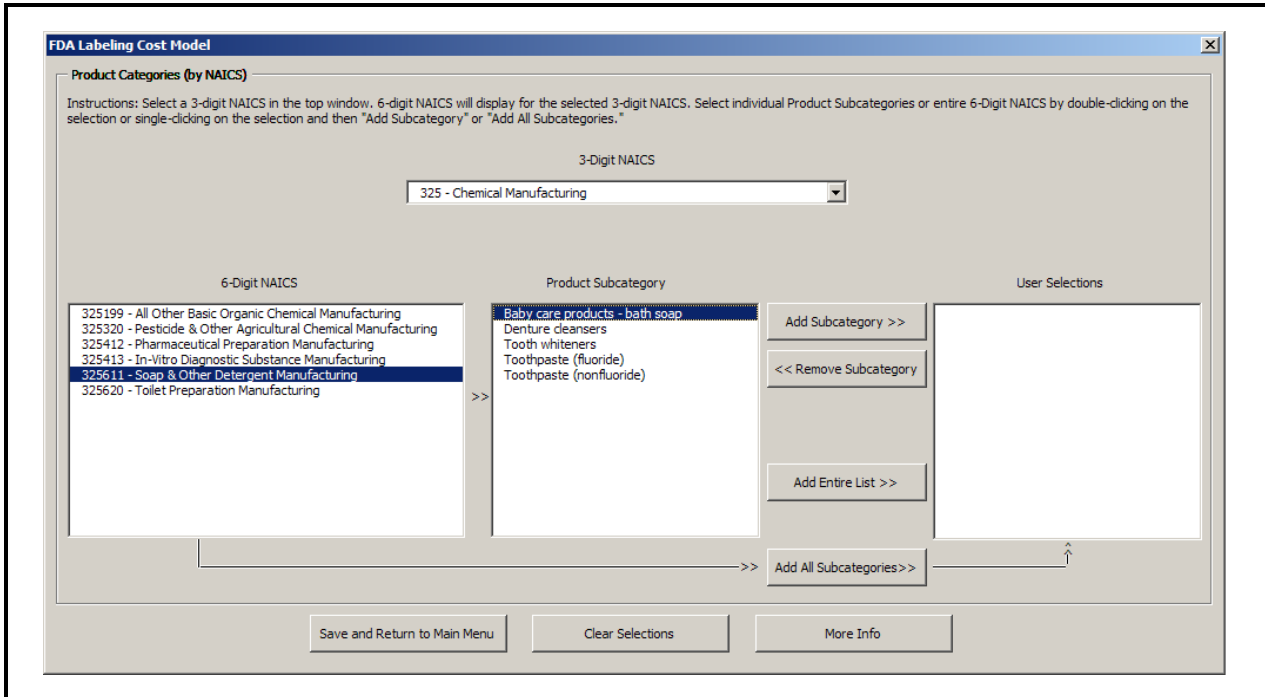


Figure 5-5. Affected Products by NAICS Selection Screen—Selecting and Adding 6-Digit NAICS and Product Subcategories



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

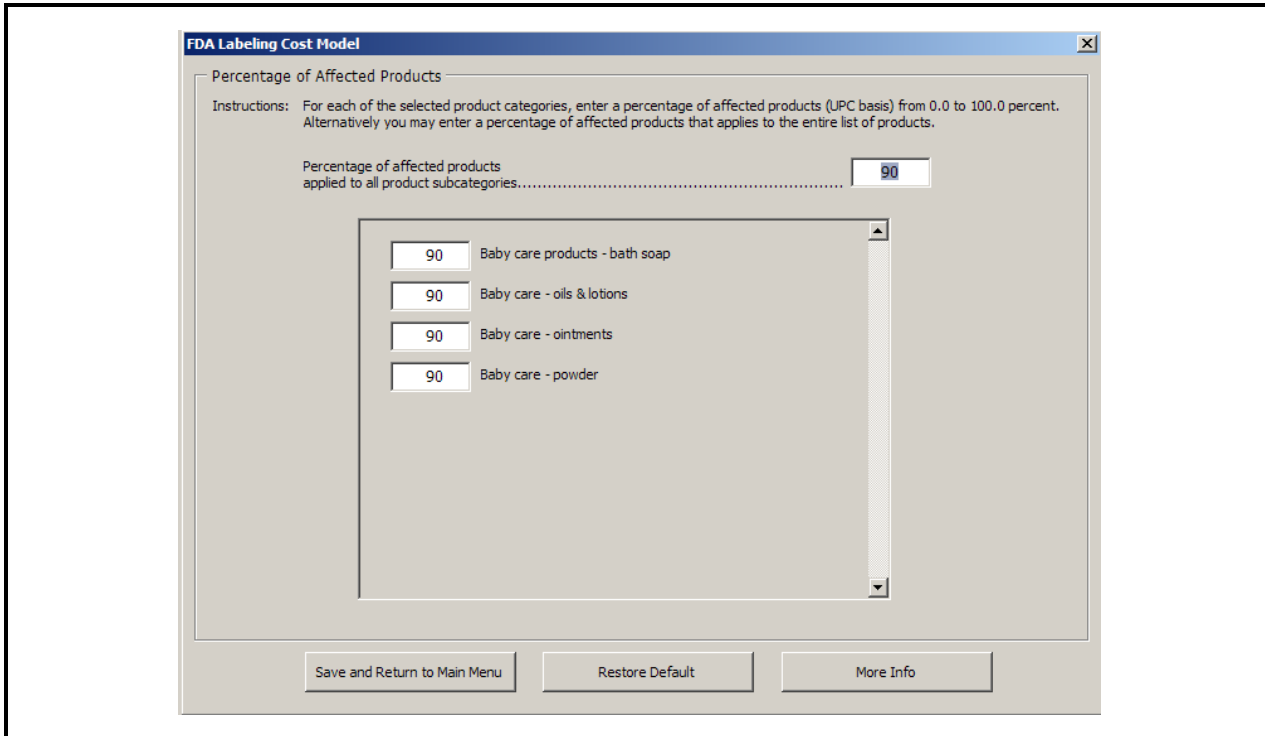
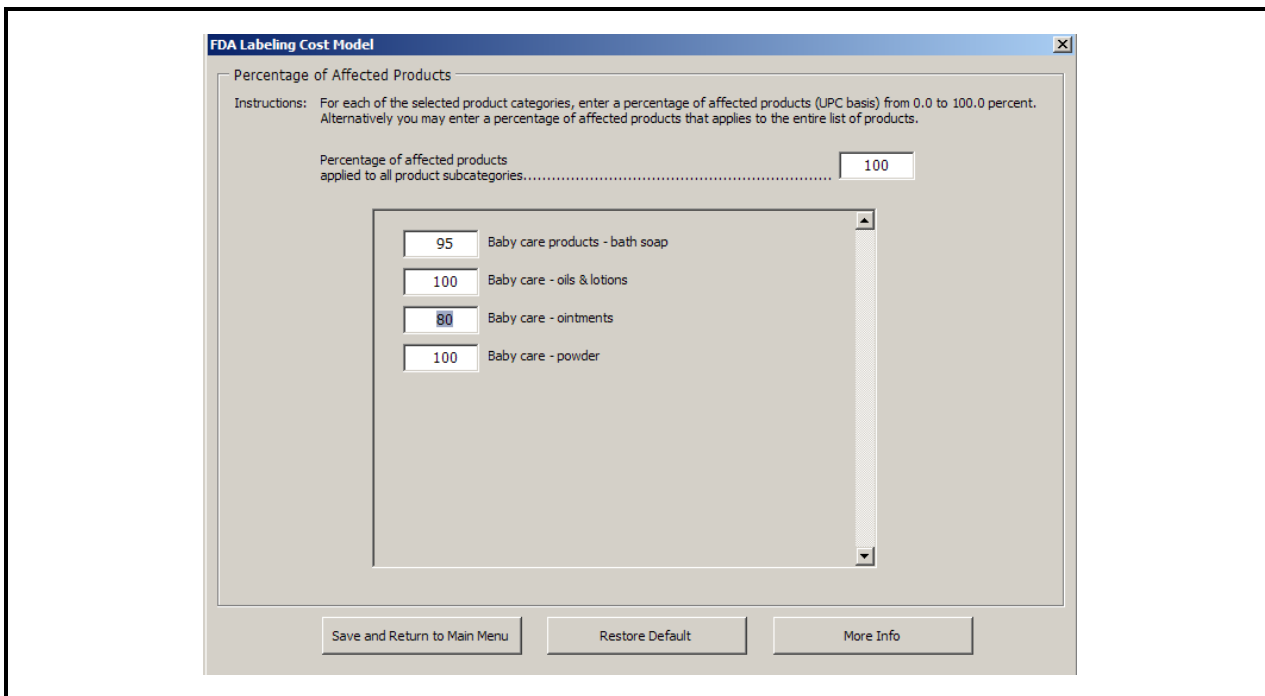


Figure 5-7. Percentage of Affected Products Screen—Entering a Percentage for Each Subcategory



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). 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

The screenshot shows a window titled "FDA Labeling Cost Model" with a close button (X) in the top right corner. The main content area is titled "Type of Labeling Change" and contains the following elements:

- 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:** A button labeled "Examples".
- Selections:** Three radio button options:
 - 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
- 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

At the bottom of the window, there are three buttons: "Save and Return to Menu", "Clear Selections", 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.

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

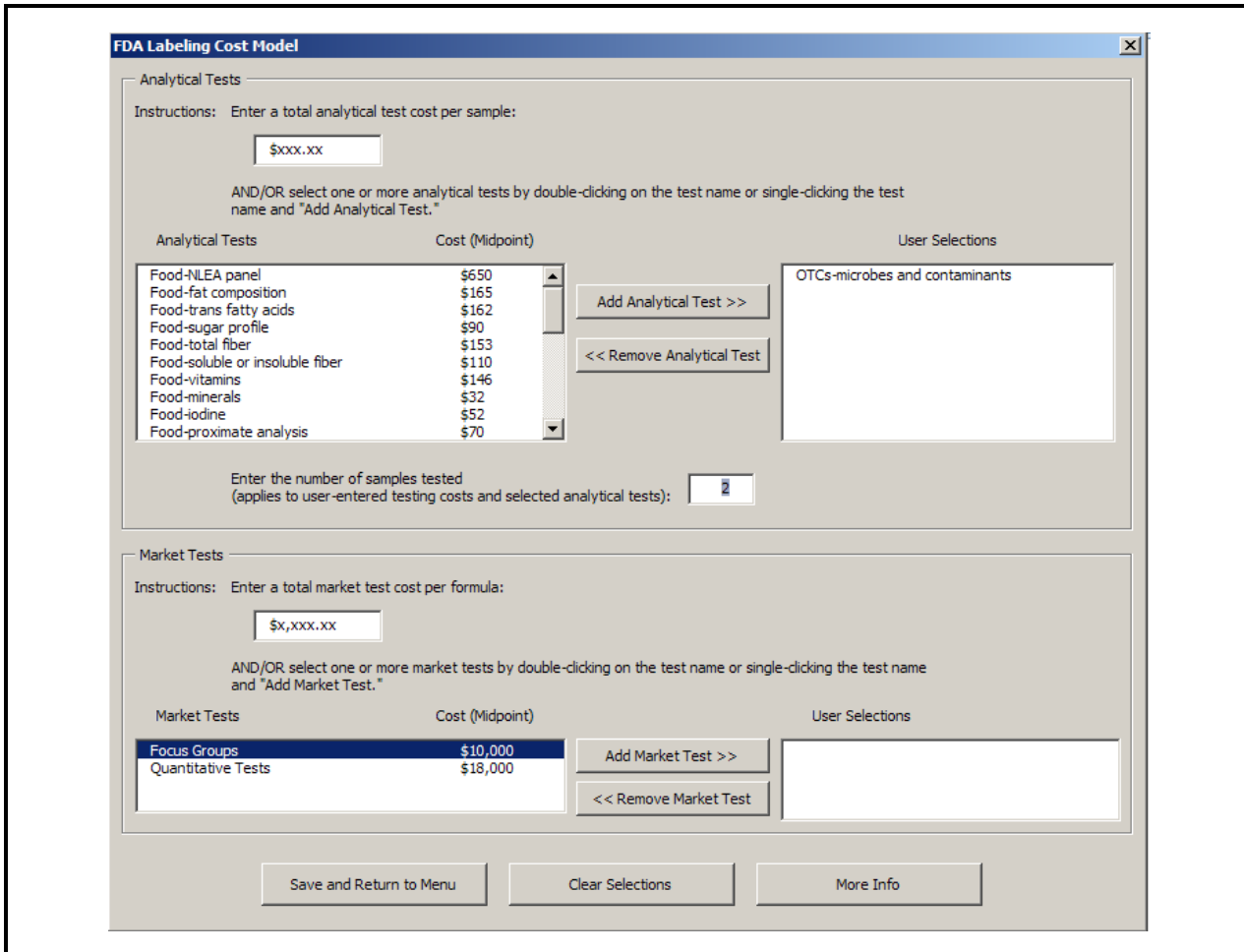
5.2.4 Analytical and Market Testing Costs Selection

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 5-9).

Figure 5-9. Selecting Analytical Tests



- 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. (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.

- 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.
 - 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 5-10).

Note that you may enter a market test cost, select focus groups or quantitative tests, or both.

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

Figure 5-10. Selecting Market Tests

FDA Labeling Cost Model

Analytical Tests

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	Cost (Midpoint)	User Selections
Food-NLEA panel	\$650	OTCs-microbes and contaminants
Food-fat composition	\$165	
Food-trans fatty acids	\$162	
Food-sugar profile	\$90	
Food-total fiber	\$153	
Food-soluble or insoluble fiber	\$110	
Food-vitamins	\$146	
Food-minerals	\$32	
Food-iodine	\$52	
Food-proximate analysis	\$70	

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

Market Tests

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	Cost (Midpoint)	User Selections
Focus Groups	\$10,000	Focus Groups
Quantitative Tests	\$18,000	

Buttons: Save and Return to Menu, Clear Selections, More Info

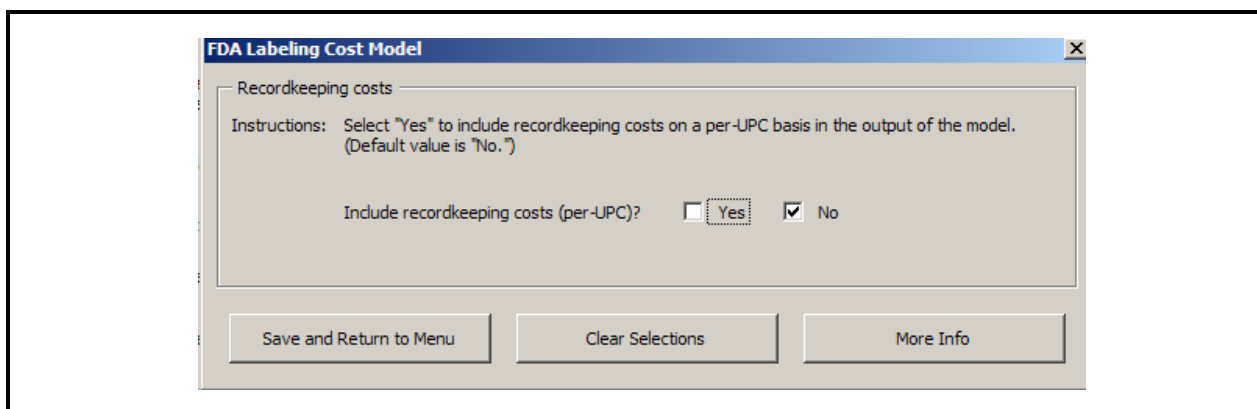
5.2.5 Recordkeeping Costs Selection

Step 5 (optional).

Indicate whether to include recordkeeping costs in the cost calculations (default is no).

Labeling regulations typically cause manufacturers to spend additional time on recordkeeping activities. To include these costs in the model, click **Select Recordkeeping** from the Main Menu screen. A dialogue box will open asking you whether to include recordkeeping costs for UPCs (see Figure 5-11). (Note: By default, the model will not include recordkeeping costs unless "Yes" is selected from this dialogue box.)

Figure 5-11. Selecting Recordkeeping Costs



After you have indicated whether to include recordkeeping costs in the model, click **Save and Return to Main Menu**.

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 5-12).

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 5-13). 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 Main Menu**.

Figure 5-12. Compliance Period Selection Screen—Select Amount of Time Manufacturers Will Have to Comply with the Labeling Regulation

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: [Dropdown menu showing 6 months, 9 months, 12 months, 15 months, 18 months, 21 months, 24 months, 27 months]

Percentages of label [Input field] [Input field] [Input field] [Input field] [Input field] [Input field] [Input field] [Input field]

Rate Label UPCs (%): [Input field] [Input field] [Input field] [Input field] [Input field] [Input field] [Input field] [Input field]

Cosmetics

Dietary Supplements

Foods

Medical Devices

OTCs

Pet Food

Tobacco Products

Save and Return to Menu Clear Selections More Info

Figure 5-13. Compliance Period Selection Screen—Modify the Percentages of Changes That Could 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:

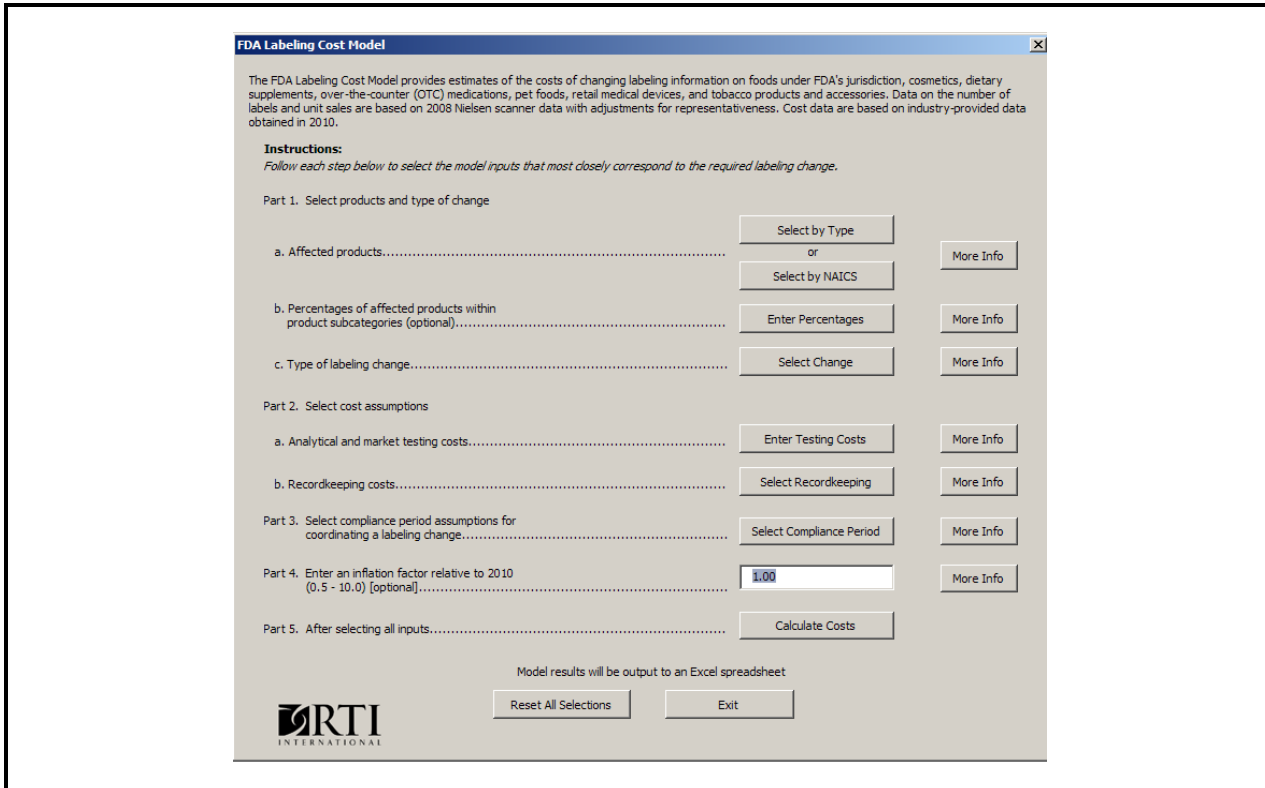
	Branded UPCs (%)	Private Label UPCs (%)
Cosmetics	<input type="text" value="44"/>	<input type="text" value="62"/>
Dietary Supplements	<input type="text" value="62"/>	<input type="text" value="71"/>
Foods	<input type="text" value="0"/>	<input type="text" value="55"/>
Medical Devices	<input type="text" value="62"/>	<input type="text" value="71"/>
OTCs	<input type="text" value="62"/>	<input type="text" value="71"/>
Pet Food	<input type="text" value="0"/>	<input type="text" value="29"/>
Tobacco Products	<input type="text" value="62"/>	<input type="text" value="71"/>

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 2010. If the costs are being estimated in a year beyond 2010, an inflation factor is necessary to more accurately reflect the present value of cost estimates. To obtain this factor, go to the Bureau of Labor Statistics' Web site (found at: http://www.bls.gov/data/inflation_calculator.htm) and use the CPI Inflation Calculator to calculate the inflation factor since 2010. The default inflation factor is 1.0 (see Figure 5-14). 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 2010 or to allow for the possibility of deflation.

Figure 5-14. Inflation Factor Modification



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

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 5-15a and 5-15b). 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

Figure 5-15a. Model Output—Input Selections Summary

	A	B	C	D
1	FDA Labeling Cost Model User Input Selections			
2	Date of Run:	2/21/2011		
3	Product Type:	Cosmetics		
4	3-Digit NAICS:	325 - Chemical Manufacturing		
5				
6	Selected Type of Change			
7	Major			
8				
9	Package Inserts Affected by Change?			
10	Yes			
11				
12	Add Package Inserts?			
13	Yes			
14				
15	Selected Types of Analytical Tests			
16	Cosmetics-microbes and contaminants			
17				
18	Specified Analytical Test Cost			
19	None Specified			
20				
21	Number of Samples Tested			
22	5			
23				
24	Selected Market Tests			
25	Focus Groups			
26				
27	Specified Market Test Cost			
28	None Specified			
29				
30	Include Recordkeeping Costs?			
31	No			
32				
33	Selected Compliance Period			
34	21 months			
35				
36	Assumed Percentage of Changes that Cannot be Coordinated with Planned Changes			
37	<i>Product Type</i>	<i>Branded Products</i>	<i>Private Label Products</i>	
38	Cosmetics	100%	100%	
39				
40	Inflation Factor			
41	1			
42				
43	Selected Product Categories and Product Sub-Categories and Assumed Package Types			
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	100%	Plastic-label
46	Baby needs	Baby care - oils & lotions	100%	Plastic-label
47	Baby needs	Baby care - ointments	100%	Paperboard-carton
48	Baby needs	Baby care - powder	100%	Plastic-molded
49	Ethnic health & beauty	Ethnic health & beauty aids	100%	Paper-label
50	Ethnic health & beauty	Ethnic home permanents	100%	Paperboard-carton
51	Personal soap/bath need	Bath additives - dry	100%	Paperboard-carton
52	Personal soap/bath need	Bath additives - liquid	100%	Paper-label
53	Personal soap/bath need	Soap - bar (nondeodorant)	100%	Plastic-sheet
54	Personal soap/bath need	Soap - liquid	100%	Plastic-label
55	Personal soap/bath need	Soap - specialty	100%	Plastic-label
56				

Figure 5-15b. Model Output—Input Selections Summary (Continued)

A	B	C	D
Selected Product Categories and Product Sub-Categories and Assumed Package Types			
<i>Product Category</i>	<i>Product Sub-Category</i>	<i>% Affected</i>	<i>Assumed Package Type</i>
Baby needs	Baby care products - bath soap	100%	Plastic-label
Baby needs	Baby care - oils & lotions	100%	Plastic-label
Baby needs	Baby care - ointments	100%	Paperboard-carton
Baby needs	Baby care - powder	100%	Plastic-molded
Ethnic health & beauty	Ethnic health & beauty aids	100%	Paper-label
Ethnic health & beauty	Ethnic home permanents	100%	Paperboard-carton
Personal soap/bath need	Bath additives - dry	100%	Paperboard-carton
Personal soap/bath need	Bath additives - liquid	100%	Paper-label
Personal soap/bath need	Soap - bar (nondeodorant)	100%	Plastic-sheet
Personal soap/bath need	Soap - liquid	100%	Plastic-label
Personal soap/bath need	Soap - specialty	100%	Plastic-label
Summary of Costs			
Number of UPCs			
	# UPCs		
Brand Type	Uncoordinated	Coordinated	Total
Branded	27,138	0	27,138
Private	6,730	0	6,730
Total	33,868	0	33,868
Costs per Uncoordinated UPC			
	Costs per Uncoordinated UPC		
Brand Type	Low	Midpoint	High
Branded	\$17,367	\$26,852	\$40,822
Private	\$18,096	\$27,724	\$42,083
Total	\$17,511	\$27,025	\$41,072
Costs per Coordinated UPC			
	Costs per Coordinated UPC		
Brand Type	Low	Midpoint	High
Branded	\$0	\$0	\$0
Private	\$0	\$0	\$0
Total	\$0	\$0	\$0
Total Costs			
	Total Costs		
Brand Type	Low	Midpoint	High
Branded	\$471,292,817	\$728,703,804	\$1,107,816,784
Private	\$121,782,826	\$186,585,537	\$283,219,864
Total	\$593,075,643	\$915,289,341	\$1,391,036,648

- **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.

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**.

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>. As obtained on October 11, 2010.

Mykytiuk, A. October 1999. Printing for Flexible Packaging. *Flexible Packaging*. <<http://www.packaginginfo.com>>.

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/>. 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>. As obtained on October 11, 2010.

Appendix A: Industry Interview Materials

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

- Project description used for interviewing trade associations
- Interview guide used for interviewing manufacturers (interview guides for vendors used applicable questions from the manufacturer interview guide)

FDA Labeling Cost Model—2010 Update Project Overview

Under contract with the U.S. Food and Drug Administration (FDA), RTI International 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 regulations that affect labeling for all products under FDA's jurisdiction. Categories of products to be included in the model are the following:

- packaged foods
- dietary supplements
- cosmetics
- over-the-counter (OTC) drugs
- retail medical devices
- pet food
- alcohol beverages
- tobacco products and accessories

RTI will develop the new model using store scanner data obtained from Nielsen and cost information from a variety of industry sources. In particular, we will conduct confidential interviews with industry to obtain estimates of the costs of changing product labels. As part of this effort, we are contacting trade associations that represent the above industries to gain a better understanding of industry-specific practices and sources of information.

The following is a list of topics we would like to discuss with trade associations to the extent that information is available:

- current labeling issues and concerns for the industry
- reasons why manufacturers make labeling changes for nonregulatory purposes
- parts of the label typically affected by nonregulatory labeling changes
- typical frequency of occurrence of nonregulatory labeling changes (e.g., annually)
- packaging types and printing methods commonly used in the industry
- types of analytical tests commonly conducted for products and sources of cost estimates for analytical tests

- extent to which packaging and labeling changes are typically contracted out versus conducted in house by manufacturers
- recommended information sources on the labeling process and associated costs
- availability of guidance materials for industry for complying with FDA labeling requirements
- suggested industry contacts for obtaining estimates of costs associated with labeling changes

Teleconferences with trade association representatives will be scheduled in fall 2009. Information collected during these teleconferences will be instrumental in forming the basis for the cost data collection for the update and expansion of the FDA Labeling Cost Model. We will also conduct confidential interviews with packaging converters, label printers, and product manufacturers to obtain more specific information for use in developing the model.

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

FDA Project Officer

Dr. Andrew Stivers
Center for Food Safety & Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
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RTI International is an independent nonprofit research organization based in Research Triangle Park, North Carolina. Our staff of more than 2,800 provides research and technical expertise to governments and businesses in more than 40 countries in the areas of health and pharmaceuticals, education and training, surveys and statistics, advanced technology, international development, economic and social policy, energy and the environment, and laboratory and chemistry services. More information about RTI is available at www.rti.org.



November 30, 2009

FDA Labeling Cost Model—2010 Update Project Overview and Interview Guide

Under contract with the U.S. Food and Drug Administration (FDA), RTI International¹ 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 regulations that affect labeling of products under FDA's jurisdiction.

RTI is developing the new model using store scanner data from Nielsen and cost information from a variety of industry sources including trade association, packaging converters, label printers, and product manufacturers. Industry interviews are being conducted to allow us to accurately describe the process of making labeling changes in response to regulation, characterize the frequency of non-regulatory labeling changes, and estimate the typical costs of making labeling changes by category of cost. In designing the model, we are considering three types of labeling changes 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. Andrew Stivers
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
Voice: 301-436-2122
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¹ *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.*

Industry Interview Guide on Product Labeling Costs and Practices

Background/General Questions

1. Approximately how many employees are involved in production operations at your company (including management and administrative staff)?

2. Approximately how many unique products (that is, number of UPCs) does your company produce?

3. What types of packaging materials are most commonly used for products produced by your company?

4. What types of printing methods are most commonly used for label printing for products produced by your company?

Costs of Changing Labels

5. What are the typical numbers of hours for employees, materials costs, or outside consultant costs for **administrative activities** such as review of the regulation, legal review, and marketing approval for each UPC?

<i>Per UPC</i>	No. of Employee Hours	Materials Costs	Outside Consultants Costs
a. Minor change			
b. Major change			
c. Extensive change			

6. What are the typical numbers of hours for employees, materials costs, and outside consultant costs for **graphic design** for a labeling change for each UPC?

<i>Per UPC</i>	No. of Employee Hours	Materials Costs	Outside Consultants Costs
a. Minor change			
b. Major change			
c. Extensive change			

7. What are the typical numbers of hours for employees, materials costs, or outside consultant costs for **prepress activities** such as color separation, color trapping, and film production for each UPC?

<i>Per UPC</i>	No. of Employee Hours	Materials Costs	Outside Consultants Costs
a. Minor change			
b. Major change			
c. Extensive change			

8. What are the typical numbers of hours for employees, materials costs, or outside consultants costs for **recordkeeping activities** involved in changing labels for each UPC? *Please include costs of recordkeeping for label information and package inserts.*

<i>Per UPC</i>	No. of Employee Hours	Materials Costs	Outside Consultants Costs
a. Minor change			
b. Major change			
c. Extensive change			

9. What are the typical per-plate or per-cylinder **engraving costs** for products printed using each type of printing method?
 - a. Offset lithography:
 - b. Flexography:
 - c. Rotogravure:
 - d. Other (please describe):

10. For a full redesign of a product package, how many **plates or cylinders** typically must be engraved?

11. If you could **coordinate** a labeling change required by regulation with a regularly scheduled (or voluntary) labeling change, what would be the change in costs associated with **administrative activities** such as review of the regulation, legal review, and marketing approval compared to Question 5 above?

<i>Per UPC</i>	No. of Employee Hours	Materials Costs	Outside Consultants Costs
a. Minor change			
b. Major change			
c. Extensive change			

Also, are there any other categories of costs that would decrease if the change could be coordinated?

12. If your company had to change a substantial number of labels in a short time period, what would be the typical percentage increase in costs for making the labeling change due to overtime labor and rush charges?
 - a. In 24 months or less:
 - b. In 12 months or less:
 - c. In 6 months or less:

13. If your company had to make an **emergency change** to labeling in 6 months or less, what would be your company's response?
 - a. Is your company likely to use stickers?
 - b. What would be the approximate per package cost of the stickers?
 - c. What would be the approximate per package cost of applying the stickers?

14. If a regulation required a major or extensive labeling change, what types of **market testing** would you conduct and what would be the associated costs?
 - a. Focus groups:
 - i. Would your company conduct focus groups?
 - ii. How many focus groups would be conducted for each product?
 - iii. How many products are typically included in each focus group?
 - iv. What would be the approximate cost per focus group?
 - b. Quantitative studies:
 - i. Would your company conduct quantitative studies?
 - ii. How many studies would be conducted for each product?
 - iii. How many products are typically included in each study?
 - iv. What would be the approximate cost per study?

15. If a regulation required your company to conduct **analytical testing** of products (for example, nutrient content or pathogens), how many samples would you test?

16. Are there **other steps or costs** in the label change process that we have not discussed?

Non-regulatory Labeling Changes

17. What are the typical reasons why your company changes product labeling for nonregulatory reasons?

18. For each of the reasons stated above, what percentage of products is changed in a typical year?

Packaging and Label Inventory

19. How many months worth of packaging or labeling is typically printed when materials are ordered for each general type of material used?

20. If your company had to discard unused packaging or labeling, what is the approximate per-package or per-label cost for each general type of material used? *Please include the cost of packaging or labeling material and the cost of disposal.*

Appendix B: Selection of Baseline Year in the Model

To select the baseline year for the FDA labeling cost model, we examined the trends in numbers of UPCs by product type included in the Nielsen ScanTrack data. The time period represented in the data is from approximately the last quarter of 2007 through the third quarter of 2009. To provide an overall picture of the number of UPCs by product type represented in the data over this time period, Table B-1 shows the raw number of active branded UPCs by quarter, and Table B-2 shows the raw number of active private-label products by quarter. The numbers in Table B-1 and Table B-2 include only active UPCs with positive sales volumes in each quarter. Furthermore, note that for private-label products, the counts in Table B-2 represent unique product/size combinations because each record is an aggregate across retailers offering each of the product/size combinations.

To show the general trends in UPCs, Figure B-1 shows the active number of branded UPCs by quarter for each of the seven FDA product types included in the model, and Figure B-2 shows the active number of private-label products (i.e., not number of UPCs) by quarter. In general, across all product types the number of branded UPCs and private-label products trends upward through the third or fourth quarter of 2008 and trends downward thereafter.

Table B-1. Raw Numbers of Active Branded UPCs by Product Type in the Nielsen ScanTrack Data, 2007:Q4–2009:Q3

Year: Quarter	Cosmetics	Dietary Supple- ments	Foods	OTCs	Pet Foods	Retail Medical Devices	Tobacco Products	Grand Total
2007:Q4	59,898	12,229	238,525	9,239	12,383	6,064	5,700	344,038
2008:Q1	65,152	12,834	261,149	9,875	13,259	6,485	5,944	374,698
2008:Q2	63,521	12,656	256,596	9,839	13,433	6,504	5,976	368,525
2008:Q3	62,461	12,641	252,448	9,774	13,630	6,472	5,920	363,346
2008:Q4	62,203	12,456	255,253	9,603	13,180	6,405	5,836	364,936
2009:Q1	57,601	12,116	246,319	9,238	12,822	6,059	5,575	349,730
2009:Q2	53,876	11,689	233,917	8,986	12,379	5,809	5,429	332,085
2009:Q3 ^a	48,505	11,068	218,486	8,500	11,706	5,392	5,008	308,665

^a2009:Q3 represents 10 weeks rather than 13 weeks of sales.

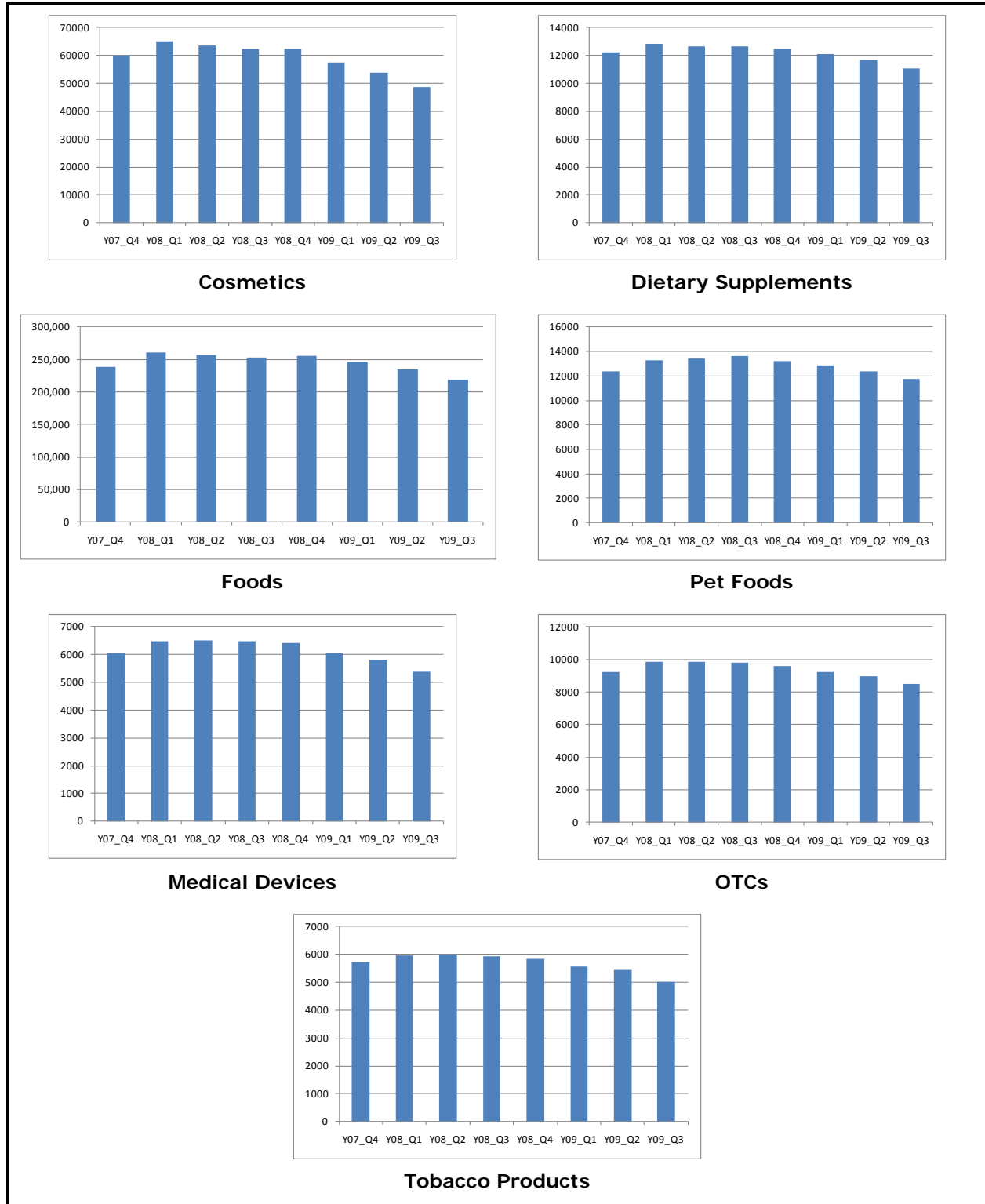
Table B-2. Raw Numbers of Active Unique Private-Label Products by Product Type in the Nielsen ScanTrack Data,^a 2007:Q4–2009:Q3

Year: Quarters	Cosmetics	Dietary Supple- ments	Foods	OTCs	Pet Foods	Retail Medical Devices	Tobacco Products	Grand Total
2007:Q4	3,890	4,333	58,233	2,851	4,242	1,737	69	75,355
2008:Q1	4,347	4,583	62,877	3,005	4,494	1,793	76	81,175
2008:Q2	4,215	4,721	62,891	3,038	4,562	1,816	69	81,312
2008:Q3	3,952	4,790	63,195	3,079	4,609	1,797	66	81,488
2008:Q4	3,849	4,756	64,645	3,073	4,571	1,795	65	82,754
2009:Q1	3,608	4,592	62,463	2,982	4,457	1,734	67	79,903
2009:Q2	3,490	4,435	59,685	2,873	4,356	1,670	67	76,576
2009:Q3 ^b	3,221	4,215	56,745	2,711	4,169	1,622	60	72,743

^aFor private-label products, the counts represent unique product/size combinations rather than number of UPCs. Each record is an aggregate across retailers offering each of the product/size combinations.

^b2009:Q3 represents 10 weeks rather than 13 weeks of sales.

Figure B-1. Trends in the Raw Numbers of Active Branded UPCs in the Nielsen ScanTrack Data, 2007:Q4–2009:Q3^a



^a2009:Q3 represents 10 weeks rather than 13 weeks of sales.

Figure B-2. Trends in the Raw Numbers of Active Unique Private-Label Products in the Nielsen ScanTrack Data,^a 2007:Q4–2009:Q3^b



^aFor private-label products, the counts represent unique product/size combinations rather than number of UPCs. Each record is an aggregate across retailers offering each of the product/size combinations.

^b2009:Q3 represents 10 weeks rather than 13 weeks of sales.

For the purposes of determining a baseline in the model, we selected 2008 because this is the most recent calendar year for which data are available and appears to be generally similar to the end of 2007 and the beginning of 2009. However, based on the data presented in Figure B-1, using 2008 may provide a somewhat higher estimate of the number of branded UPCs than might be expected in a typical year; thus, the model may slightly overestimate the number of UPCs and, therefore, slightly overestimate the total costs of compliance with a labeling regulation.¹ The degree of overestimation could be calculated when later scanner data become available and the difference in the number of actual UPCs could be calculated.

¹ Losses due to discarded inventory are based on the unit sales and, thus, are likewise affected by the year of the scanner data.

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

Table C-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 ^a	
		Deodorant—cologne type	Deodorant—cologne type	
		Deodorant—roll-on	Deodorant—roll-on ^a	
		Deodorant—stick/solid	Deodorant—stick/solid ^a	
		Remaining deodorants	Remaining deodorants ^a	
	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 C-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
			Lip remedies
			Lipstick
			Lip remedies—remaining ^b
			Lip remedies—solid
	Feminine hygiene	Feminine deodorant sprays	Feminine hygiene—deodorant sprays
			Feminine hygiene—miscellaneous ^c
			Foot preparations—remaining
	Foot care	Foot preparations—remaining	Foot preparations—remaining
			Colognes and perfumes
	Fragrances	Men's aftershave/cologne/lotion	Cologne & perfume—women's
			After shave cosmetics—men's
			Cologne/lotion—men's
	Gift sets & kits	Children's cologne & gift sets	Pre-shave cosmetics
			Children's cologne & gift sets
Women's gift sets & skin care packages			
Men's sets			

(continued)

Table C-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 ^d
	Shampoo—bars/ concentrates/and creams ^d		
	Shampoo—combinations		
	Wave setting products	Wave setting products	
	Nailcare/manicure needs	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 C-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 ^e	
		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		Depilatories—men's
				Depilatories—women's
		Shaving cream	Shave cream—other than women's	
			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		
		Suntan preparations—lotions/oils/etc.		
Sunburn aids	Sunburn aids	Sunburn aids		

(continued)

Table C-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
	Protein supplements	Nutritional supplements	Nutritional supplements	
		Protein supplements	Protein supplements	Protein supplements
	Vitamin supplements	Vitamins-B complex w/C	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	
Vitamins/tonics—liquid		Vitamins/tonics—liquid & powder	Vitamins/tonics—liquid & powder	
		Vitamins/tonics—liquid & powder	Vitamins/tonics—liquid & powder	
Foods	Baked goods	Bagels/biscuits/buns/ muffins/rolls—fresh	Bakery—bagels—fresh	
			Bakery—biscuits—fresh	
			Bakery—buns—fresh	
			Bakery—muffins—fresh	
		Bagels/biscuits/buns/ muffins/rolls—frozen	Bakery—rolls—fresh	
			Bakery—biscuits/rolls/ muffins—frozen	
		Baked goods—remaining—fresh	Bakery—bagels—frozen	
			Bakery—remaining—fresh	
		Baked goods—remaining—frozen	Bakery—remaining—frozen	

(continued)

Table C-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 C-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 C-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 C-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—refrigerated	Dough products—cookies & brownies—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 cola diet	
			Soft drinks—low calorie lemon/lime diet	

(continued)

Table C-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 C-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 C-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 total	
		Ice	Ice
		Milk—flavored—refrigerated	Dairy—flavored milk—refrigerated
		Milk—refrigerated	Dairy—milk—refrigerated
Milk—refrigerated total			

(continued)

Table C-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 C-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
				Frozen/refrigerated breakfasts
		Breakfasts—frozen	Frozen/refrigerated breakfasts	
		Cereal—hot	Cereal—hot	
		Hominy grits	Hominy grits	

(continued)

Table C-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	
			Waffle/pancake/French toast—frozen	Frozen waffles & pancakes & French toast
	Candy & gum		Candy—chocolate	Candy—chocolate
				Candy—chocolate—miniatures
				Candy—chocolate—special
				Candy—dietetic—chocolate
			Candy—dietetic	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 C-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
		Honey	Honey
		Jams/jellies	Jams
			Jelly
			Marmalade
			Preserves
			Butter—fruit & honey
		Jams/spreads—remaining	Fruit spreads
			Garlic spreads
			Meat marinades & tenderizers
		Marinades/tenderizers/MSG	Monosodium glutamate & flavor enhancers

(continued)

Table C-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	Salt—cooking/edible/ seasoned
				Salt—table
		Salt—canning/pickling/ curing		
		Salt—substitutes	Salt substitutes	
		Sandwich spreads/ horseradish/sauerkraut—refrigerated	Horseradish	
			Meat & sandwich spreads—refrigerated	
			Sauerkraut—refrigerated	

(continued)

Table C-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	
		Spices/seasonings—remaining (cont.)	Vegetables—onions—instant	
		Spreads—refrigerated	Garlic spreads—refrigerated	
			Spreads—remaining	
	Dairy foods	Butter		Butter
			Cheese—cottage/farmers/ ricotta	Cheese—cottage
			Cheese—farmers	
			Cheese—ricotta	
		Cheese—grated/shredded	Cheese—grated	
			Cheese—shredded	
		Cheese—natural	Cheese—natural—American cheddar	
Cheese—natural—American colby				
Cheese—natural—brick				
Cheese—natural—mozzarella				
Cheese—natural—remaining				
	Cheese—natural—variety pack			

(continued)

Table C-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 C-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
		Gelatin/pudding—mixes—sweetened total	
		Pudding—refrigerated	Pudding—refrigerated
		Syrups/toppings—shelf stable	Mixes—ice cream Pudding—plum—canned Pudding/pie filling—canned Syrup—chocolate

(continued)

Table C-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		
			Toppings—refrigerated	Toppings—refrigerated	
			Dressings & sauces	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 C-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 C-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	Entrees—frozen	Combination lunches
				Dinners—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 C-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 C-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		
	Fats & oils	Sandwiches—refrigerated/ frozen	Sandwiches—refrigerated/frozen	Spreads—hors d'oeuvres	
				Sandwiches—refrigerated/frozen	
				Cooking sprays	
		Lard/shortening	Lard	Shortening	
				Margarine/spreads	
				Margarine and spreads	
				Olive oil	
		Fruits & vegetables	Oils—olive/salad/cooking	Salad and cooking oil	Vegetables—beans—chili—canned
					Vegetables—beans—garbanzo—canned
					Vegetables—beans—kidney/red—canned
	Vegetables—beans—lima—canned				
				(continued)	

Table C-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
		Fruit—canned	Canned fruit—apple sauce
			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 C-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		
		Raisins		
		Fruit—fresh	Fresh apples	
			Fresh cranberries	
			Fresh fruit—remaining	

(continued)

Table C-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 C-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 C-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 cauliflower	
		Fresh celery	
		Fresh mushrooms	
		Fresh onions	
		Fresh radishes	

(continued)

Table C-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				
Infant formulas	Baby milk and milk flavoring			
Juices—baby	Baby juice			
Meat & poultry	Cracklins—refrigerated	Cracklins—refrigerated		

(continued)

Table C-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	
			Frozen meat—beef steak	
			Meat/poultry—canned	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 C-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
	Pizza	Pizza—frozen	Frozen poultry
		Pizza—refrigerated	Pizza—frozen
	Seafood	Fish—frozen	Pizza—refrigerated
			Seafood—fish—breaded—frozen
		Seafood—canned	Seafood—fish—unbreaded—frozen
			Anchovy paste
			Clam juice shelf stable
			Seafood—anchovies
	Seafood—oysters—canned		
	Seafood—remaining—canned		

(continued)

Table C-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—remaining—frozen
			Seafood—crab—unbreaded—frozen
			Seafood—remaining—breaded—frozen
	Side dishes & starches	Seafood—remaining—unbreaded—frozen	Shrimp—frozen
			Seafood—shrimp—breaded—frozen
			Seafood—shrimp—unbreaded—frozen
			Hors d'oeuvres/snacks—frozen
			Frozen/refrigerated hors d'oeuvres & snacks
Side dishes & starches	Pasta/noodles—dry	Pasta/noodles—dry	
		Oriental noodles	
		Pasta—macaroni	
		Pasta—noodles & dumplings	
		Pasta—spaghetti	
Side dishes & starches	Prepared foods—dry mixes	Dry dinners—pasta	
		Dry dinners—remaining	

(continued)

Table C-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		
		Ready-made salads		Gelatin salads—refrigerated
			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 C-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 C-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—canned	
			Soup—dry	Bouillon	
		Sweeteners	Sugar	Instant meals	Instant meals
				Soup mixes—dry & bases	Soup mixes—dry & bases
				Stew mixes—dry	Stew mixes—dry
	Sweeteners	Sugar	Sugar—brown	Sugar—brown	
			Sugar—remaining	Sugar—remaining	
			Sugar—granulated	Sugar—granulated	
			Sugar—powdered	Sugar—powdered	
			Sugar—substitutes	Sugar substitutes	
	Sweeteners	Table syrups/molasses	Molasses	Molasses	
			Syrup—berry/fruit type	Syrup—berry/fruit type	
			Syrup—sorghum & sugar	Syrup—sorghum & sugar	
			Syrup—table		

(continued)

Table C-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 ^a
			Deodorant—roll-on	Deodorant—roll-on ^a
		Deodorant—stick/solid	Deodorant—stick/solid ^a	
		Remaining deodorants	Remaining deodorants ^a	
	Eye care	Contact lens solution	Contact lens solution	
		Eye care—remaining	Eye care—remaining	
		Eye drops & lotions	Eye drops & lotions	

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Table C-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 ^c
			Feminine hygiene—towelettes
	First aid	Adhesive bandages (medicated)	Adhesive bandages ^f
			First aid—germicidal antiseptics
			First aid—hydrocortisones
			First aid—treatments
	Hair care	Hair growth products	Hair growth product
			Shampoo (medicated)
	Oral hygiene		Shampoo—aerosol/liquid/ lotion/powder ^d
			Shampoo—bars/ concentrates/and creams ^d
			Denture adhesives
			Oral care combinations—OTC
			Oral care combinations treatments and PR ^g
	Oral rinse and antiseptic	Oral rinse and antiseptic	
	Toothpaste (fluoride)	Tooth cleaners	

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Table C-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 effervescents	
			Pain remedies—arthritis	
			Pain remedies—back & leg	
			Pain remedies—headache	
			Pain remedies—premenstrual	
			Pain remedies—children's	
			Pain remedies—urinary tract	
			Tranquilizers/calmatives	
			Tranquilizers/calmatives	
			Tranquilizers/calmatives	
	Personal soap/bath need Preparations/remedies			Hand cleaners and hand sanitizers
				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 C-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 ^b
		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
	Suntan preparations—sunscreens & sunblock		Suntan preparations—sunscreens & sunblock

(continued)

Table C-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 incontinence product
		Pet treatments external	Pet treatments external
		Pet treatments internal	Pet treatments internal
		Pet food	Cat food—dry
	Cat food—moist/wet		Cat food—moist type
			Cat food—wet type
			Dog food—dry type
	Dog food—dry		Dog food—dry type
	Dog food—moist/wet		Dog food—moist type
			Dog food—wet type
	Domestic bird food		Pet care—domestic bird food
	Other pet food		Pet care—pet food
	Pet treats		Dog & cat treats

(continued)

Table C-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 pacifier/teether & bottle/nipple brushes
			Nursing accessories
		Baby bottles & nipples	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
			Pregnancy test kits
	Feminine hygiene	Douches	Feminine hygiene—douches
		Remaining feminine hygiene	Feminine hygiene—miscellaneous ^c
		Sanitary belts/panties/ napkins	Sanitary belts and panties
			Sanitary napkins
		Tampons	Tampons

(continued)

Table C-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 ^f
		First aid—gauze & tape	Adhesive tape
			First aid—gauze—rolls
			First aid—gauze pads
			First aid—ice and heat pack
			First aid—thermometers
			First aid—thermometers
	Foot care	Foot comforts products	Foot comforts products
		Foot preparations—remaining	Insoles
	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 ^g
		Oral hygiene appliance and accessory	Oral hygiene appliance and accessory
Oral hygiene brushes		Oral hygiene brushes	

(continued)

Table C-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

^a 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.

^b 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.

^c 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.

^d 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.

^e 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.

^f 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.

^g 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.