SUPPLEMENTAL PRELIMINARY REGULATORY IMPACT ANALYSIS FOR PROPOSED RULES ON:

"FOOD LABELING: REVISION OF THE NUTRITION AND SUPPLEMENT FACTS LABELS"

AND

"FOOD LABELING: SERVING SIZES OF FOODS THAT CAN REASONABLY BE CONSUMED AT ONE EATING OCCASION; DUAL-COLUMN LABELING; UPDATING, MODIFYING, AND ESTABLISHING CERTAIN REFERENCE AMOUNTS CUSTOMARILY CONSUMED; SERVING SIZE FOR BREATH MINTS; AND TECHNICAL AMENDMENTS"

DOCKET NO. FDA-2012-N-1210
DOCKET NO. FDA-2004-N-0258

REGULATORY FLEXIBILITY

UNFUNDED MANDATES

PAPERWORK REDUCTION

Executive Summary

The Proposed Nutrition Facts and Supplement Facts Labels Rule (the Proposed NFL Rule) amended our labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. We are proposing revisions to the Proposed NFL Rule that would amend our labeling regulations for conventional foods and dietary supplements. We are proposing text for the footnote to be used on the Nutrition Facts label, and exemptions to the proposed footnote requirement. We are also proposing that manufacturers declare, in addition to the absolute amount of added sugars, the percent DV for added sugars on the Nutrition Facts and Supplement Facts labels. The original Preliminary Regulatory Impact Analysis (original PRIA) captures the costs associated with these changes; thus, this analysis only revises the benefits estimates. In total, we estimate that these proposed rules will generate annualized costs of $0.2 billion (at both 3 and 7 percent discount rates) and annualized benefits of $2.1 billion (at 7 percent) and $2.3 billion (at 3 percent). This represents an annual increase in net benefits from the original PRIA's estimates of approximately $0.2 billion per year.

Table of Contents

Analysis of Economic Impacts

The Food and Drug Administration (FDA or we) has examined the impacts of certain nutrition labeling proposed rules under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Unfunded Mandates Reform Act of 1995 (Public Law 104-4), and The Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The proposed rules are:

1. Title: Food Labeling: Revision of the Nutrition and Supplement Facts Labels. (Docket No. FDA-2012-N-1210) ("Proposed NFL Rule")
2. Title: Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments (Docket No. FDA-2004-N-0258) ("Proposed Serving Size Rule")

Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We published two proposed rules on nutrition labeling in the Federal Register on March 3, 2014 (79 FR 11879; 79 FR 11989) but developed one comprehensive Preliminary Regulatory Impact Analysis (PRIA) that presents the benefits and costs of the two proposed nutrition labeling rules taken together. We believe that the cumulative impact of the proposed rules on nutrition labeling, taken as a whole, represents a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Additional costs per entity from the proposed rules are small, but not negligible, and as a result we conclude that the proposed rules on nutrition labeling, taken as a whole, would have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. We have determined that the proposed rules on nutrition labeling, taken as a whole, meet this threshold.

I. Revisions to The Proposed Rules

The Proposed NFL Rule would amend our labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. The Proposed Serving Size Rule would amend our regulations on serving sizes based on newer consumption data and other current scientific evidence. A detailed listing of the changes associated with the proposed rules is provided in the original PRIA (Ref. 1).

In a Supplemental Notice of Proposed Rulemaking, we are proposing revisions to the Proposed NFL Rule that would amend our labeling regulations for conventional foods and dietary supplements. We are proposing text for the footnote to use on the Nutrition Facts label

and exemptions to the proposed footnote requirement. We are also proposing that manufacturers declare, in addition to the absolute amount of added sugars, the percent DV for added sugars on the Nutrition Facts and Supplement Facts labels. The original PRIA captures the costs and benefits associated with the former changes, and the costs associated with the latter change. Thus, only the latter change requires us to revise the original PRIA's benefits estimates.

In this supplemental PRIA we discuss the impact of the mandatory added sugar percent DV declaration and present the annualized costs and annualized benefits of the revised proposed rules. For a detailed analysis of the provisions of the proposed rules that are not being revised, refer back to the original PRIA for the proposed rules (Ref. 1).

Table 1 illustrates the annualized costs and annualized benefits of the previous proposed rules and the revised proposed rules.

Table 1. Summary of Annualized Costs and Benefits Over 20 Years of Previous and Revised Proposed Rules (in billions of 2011$)

	Benefits	**Costs**	**Net Benefits**
Previous Proposed Rules			
Annualized @ 3%	$2.0	$0.2	$1.8
Annualized @ 7%	$1.9	$0.2	$1.7
Revised Proposed Rules			
Annualized @ 3%	$2.3	$0.2	$2.1
Annualized @ 7%	$2.1	$0.2	$1.9

Notes: Compliance period is 24 months. Analysis assumes that the proposed rules will be enacted together. Costs include relabeling and reformulation costs, which are one-time costs, as well as recordkeeping costs, which recur. Recordkeeping costs, because of their recurring nature, differ by discount rate; however, such costs comprise a very small percentage of total costs.

In the following sections, we discuss how the mandatory added sugar percent DV declaration will impact the estimated costs and benefits of the proposed rules.

II. Need for Regulation

See original PRIA.

III. Revised Costs of the Proposed Rules

The costs associated with the proposed revision to modify the footnote statement were captured in the original PRIA.

The costs associated with the proposed revision to require manufacturers to declare the percent DV for added sugars on the Nutrition Facts and Supplement Facts labels are implicitly captured in the original PRIA, as such costs are subsumed under the minor label change costs estimated in the original PRIA.

Thus, we have not revised our discussion of the costs of the proposed rules that appeared in the original PRIA.

IV. Revised Benefits of the Proposed Rules

The benefits associated with the proposed revision to modify the footnote statement were captured in the original PRIA.

The benefits associated with the proposed revision to require manufacturers to declare the percent DV for added sugars on the Nutrition Facts and Supplement Facts labels were not captured in the original PRIA. This revision will affect the s_1 parameter of the benefits model used to capture the effect of the proposed rules relative to the 1993 rules that implemented NLEA (the details associated with the original s_1 calculation can be found on pp. 48 – 54 of the original PRIA). More specifically, the requirement that manufacturers declare the percent DV for added sugars on the Nutrition Facts and Supplement Facts labels increases the percentage of the label content on products with a single-column label (SCL) changed by the proposed rules from 33 percent to 38 percent. Consistent with our approach in the original PRIA, we assume that the change in label content associated with SCL products is uniformly distributed between 16 percent and 60 percent, with a mean of 38 percent (= [16 + 60] / 2). This produces a revised

mean s_1 of 26.5 percent (= [0.65 x 0.38 x 0.88] + [0.65 x 0.25 x 0.29]). Further consistent with our approach in the original PRIA, we assume that s_1 is distributed uniformly between 0 and 0.265, with a mean of 0.133 (= [0 + 0.265] / 2). As a result of these changes, the primary benefits estimates in Table 13 of the original PRIA, as well as the supporting benefits estimates contained in Table 17 of the original PRIA, change slightly. These changes are illustrated below in Tables 2 and 3, respectively. Table 2 presents the primary benefits estimates, based on the willingness-to-pay (revealed preference) estimates in Abaluck (2011):

Table 2. Estimated Annualized Benefits from Proposed Nutrition Labeling Rules 2013-2032 (in billions of 2011 dollars), Previous vs. Revised Proposed Rules

			90% Confidence Interval	
Benefits:	**Discount Rate**	**Mean**	**Lower Bound**	**Upper Bound**
Previous Proposed Rules				
WTP[a]	3%	$2.0	$0.2	$4.6
	7%	$1.9	$0.2	$4.2
Revised Proposed Rules				
WTP[a]	3%	$2.3	$0.2	$5.3
	7%	$2.1	$0.2	$4.8

Notes: Compliance Period = 24 months. Estimates reflect total U.S. population (children and adults).
[a] Based on Abaluck (2011) willingness-to-pay or revealed preference estimates.

As stated in the original PRIA, Abaluck (2011) generates his willingness-to-pay (revealed preference) estimates from a data set that contains only women. Thus, Table 3 presents supporting benefits estimates based on the willingness-to-pay (revealed preference) estimates in Abaluck (2011), but applied only to women:

Table 3. Estimated Annualized Benefits from Proposed Nutrition Labeling Rules for Women 2013-2032 (in billions of 2011 dollars), Previous vs. Revised Proposed Rules

			90% Confidence Interval	
Benefits:	**Discount Rate**	**Mean**	**Lower Bound**	**Upper Bound**
Previous Proposed Rules				
WTP[a]	3%	$0.8	$0.1	$1.9
	7%	$0.8	$0.1	$1.7

Revised Proposed Rules				
WTP[a]	3%	$1.0	$0.1	$2.2
	7%	$0.9	$0.1	$2.0

Notes: Compliance Period = 24 months.
[a] Based on Abaluck (2011) willingness-to-pay or revealed preference estimates.

V. Regulatory Options

The regulatory options considered in the original PRIA remain the same (for a detailed discussion of the regulatory options for the proposed rules, see the original PRIA). However, as a result of the mandatory added sugar percent DV declaration, the benefits estimates contained in Tables 26 and 27 of the original PRIA will change slightly. These changes are illustrated in Tables 4 and 5 below. These tables provide a comparison of annualized benefits, costs, and net benefits by regulatory option and by whether the rules are enacted together or separately, under both the previous and revised proposed rules.

Table 4. Summary of Annualized Net Benefits by Regulatory Option 2013-2032 (in billions of 2011 dollars), Previous vs. Revised Proposed Rules, Rules Enacted Together

Option	Discount Rate	Benefits	Costs	Net Benefits
Previous Proposed Rules				
1 – No New Federal Regulatory Action	3%	$0	$0	$0
	7%	$0	$0	$0
2 – Proposed Rules	3%	$2.0	$0.2	$1.8
	7%	$1.9	$0.2	$1.7
3 – Proposed Rules – 3 Year Compliance Period	3%	$2.0	$0.1	$1.9
	7%	$1.8	$0.1	$1.7
4 – Proposed Rules – 4 Year Compliance Period	3%	$2.0	$0.04	$2.0
	7%	$1.8	$0.1	$1.7
5 – Proposed Rules – DV for Sodium of 1,500 mg or 1,900 mg	3%	$2.0	$0.2	$1.8
	7%	$1.9	$0.2	$1.7
Revised Proposed Rules				
1 – No New Federal Regulatory Action	3%	$0	$0	$0
	7%	$0	$0	$0
2 – Proposed Rules	3%	$2.3	$0.2	$2.1
	7%	$2.1	$0.2	$1.9
3 – Proposed Rules – 3 Year Compliance Period	3%	$2.3	$0.1	$2.2
	7%	$2.0	$0.1	$1.9

4 – Proposed Rules – 4 Year Compliance Period	3%	$2.2	$0.04	$2.2
	7%	$2.0	$0.1	$1.9
5 – Proposed Rules – DV for Sodium of 1,500 mg or 1,900 mg	3%	$2.3	$0.2	$2.1
	7%	$2.1	$0.2	$1.9

Notes: Costs include relabeling and reformulation costs, which are one-time costs, as well as recordkeeping costs, which recur. Recordkeeping costs, because of their recurring nature, differ by discount rate; however, such costs comprise a very small percentage of total costs.

Table 5. Summary of Annualized Net Benefits by Regulatory Option 2013-2032 (in billions of 2011 dollars), Previous vs. Revised Proposed Rules, Rules Enacted Separately

Option	Discount Rate	Benefits	Costs	Net Benefits
Previous Proposed Rules				
1 – No New Federal Regulatory Action	3%	$0	$0	$0
	7%	$0	$0	$0
2 – Proposed Rules	3%	$2.0	$0.2	$1.8
	7%	$1.9	$0.3	$1.6
3 – Proposed Rules – 3 Year Compliance Period	3%	$2.0	$0.1	$1.9
	7%	$1.8	$0.2	$1.6
4 – Proposed Rules – 4 Year Compliance Period	3%	$2.0	$0.05	$2.0
	7%	$1.8	$0.1	$1.7
5 – Proposed Rules – DV for Sodium of 1,500 mg or 1,900 mg	3%	$2.0	$0.2	$1.8
	7%	$1.9	$0.3	$1.6
Revised Proposed Rules				
1 – No New Federal Regulatory Action	3%	$0	$0	$0
	7%	$0	$0	$0
2 – Proposed Rules	3%	$2.3	$0.2	$2.1
	7%	$2.1	$0.3	$1.8
3 – Proposed Rules – 3 Year Compliance Period	3%	$2.3	$0.1	$2.2
	7%	$2.0	$0.2	$1.8
4 – Proposed Rules – 4 Year Compliance Period	3%	$2.2	$0.05	$2.2
	7%	$2.0	$0.1	$1.9
5 – Proposed Rules – DV for Sodium of 1,500 mg or 1,900 mg	3%	$2.3	$0.2	$2.1
	7%	$2.1	$0.3	$1.8

Notes: Costs include relabeling and reformulation costs, which are one-time costs, as well as recordkeeping costs, which recur. Recordkeeping costs, because of their recurring nature, differ by discount rate; however, such costs comprise a very small percentage of total costs.

VI. Regulatory Flexibility Analysis

See original PRIA.

VII. Unfunded Mandates

See original PRIA.

VIII. Paperwork Reduction Act of 1995

This supplemental notice of proposed rulemaking contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501-3520). As explained in the NFL/SFL proposed rule, we performed the necessary analyses to examine the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C.601-612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and the PRA (44 U.S.C. 3501-3520). We provided a preliminary regulatory analysis (PRIA) of the NFL/SFL proposed rule (see Ref. 187 of the NFL/SFL proposed rule) for public input (79 FR 11879 at 11959). A description of the information collection provisions of the NFL/SFL proposed rule was given in the PRIA of the NFL/SFL proposed rule with an estimate of the annual third-party disclosure burden. A description of the information collection provisions of the supplemental notice of proposed rulemaking is given in the Description section of this document with an estimate of the annual third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use

of automated collection techniques, when appropriate, and other forms of information technology.

Title: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed At One-Eating Occasion

Description: This supplemental notice of proposed rulemaking proposes two changes to the third party disclosure requirements discussed in the analysis of the NFL/SFL proposed rule: a percent DV labeling requirement as well as footnote requirements.

Description of Respondents: The likely respondents to this information collection are manufacturers of retail food products marketed in the United States whose products contain (1) a mixture of naturally occurring and added sugars or (2) a mixture of non-digestible carbohydrates that do and do not meet the proposed definition of dietary fiber. The likely respondents to this information collection also include manufacturers of retail food products marketed in the United States whose products contain (1) mixtures of different forms of vitamin E or (2) both folate and folic acid.

We estimate the burden of the information collection provisions of the supplemental notice of proposed rulemaking as follows. After careful review of the burden estimate analysis provided in the PRIA for the NFL/SFL proposed rule, we tentatively conclude that our previous estimate of the burden hours has not changed meaningfully as a result of this supplemental notice of proposed rulemaking. Thus, we have calculated no additional burden related to the proposed percent DV labeling requirement for added sugars described in this supplemental notice of proposed rulemaking.

With regard to the proposed footnote labeling requirements in this supplemental notice of proposed rulemaking, we note that the text of the footnote statements would be supplied by FDA

in the final regulation. We tentatively conclude that the proposed footnote provisions in this supplemental notice of proposed rulemaking do not constitute a "collection of information" under the PRA (44 U.S.C. 3501-3520). Rather, the proposed footnote provisions are a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)). Thus, we have calculated no additional burden related to the proposed footnote labeling requirements in this supplemental notice of proposed rulemaking.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the title, "Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed At One-Eating Occasion."

In compliance with the PRA (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until we obtain OMB approval. We will publish a notice concerning OMB approval of these requirements in the Federal Register.

Reference List

1. U.S. Food and Drug Administration. "Preliminary Regulatory Impact Analysis (PRIA) for the Food Labeling: Revision of the Nutrition and Supplement Facts Labels Notice of Proposed Rulemaking (Docket No. FDA-2012-N-1210) and Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments Notice of Proposed Rulemaking (Docket No. FDA-2004-N-0258)", 2014. Available at http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1210-0002.