DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2012–N–1210]

RIN 0910–AF22

Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Reopening of the Comment Period as to Specific Documents

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period as to specific documents.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening, as to specific documents, the comment period regarding our proposed rule to revise the Nutrition Facts and Supplement Facts labels. We are reopening the comment period for 60 days for the sole purpose of inviting public comments on two consumer studies being added to the administrative record. The consumer studies pertained to proposed changes to the Nutrition Facts label formats.

DATES: The comment period for the proposed rule published March 3, 2014 (79 FR 11879), is reopened for the limited purpose described in this document. Submit either electronic or written comments by September 25, 2015.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. (FDA–2012–N–1210) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2112.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 3, 2014 (79 FR 11879), we published a proposed rule to 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 rule would update the list of nutrients that are required or permitted to be declared; provide updated Daily Reference Values and Reference Daily Intake values that are based on current dietary recommendations from consensus reports; amend requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant and lactating women and establish nutrient reference values specifically for these population subgroups; and revise the format and appearance of the Nutrition Facts label. In the preamble to the proposed rule (79 FR 11879 at 11905, 11947 to 11948, 11952), we indicated that we intended to conduct consumer studies related to proposed changes to the format of the Nutrition Facts label and that we might use the results of the studies to help inform our future actions on certain label-related issues. We also indicated that we would publish the results of the studies when they became available (79 FR 11879 at 11952), and we invited comment on the use of an alternative format design and other format-related issues (79 FR 11879 at 11961).

We recently completed two consumer studies and, as a result, are adding two documents pertaining to those studies to the administrative record and providing an opportunity for public comment. We believe that a public comment period of 60 days is adequate in this case because we are specifically limiting the reopened comment period to comments on the two consumer studies. Comments are invited, and will be considered, only to the extent that they are focused on the two consumer studies being added to the record. These two consumer studies (Refs. 1 and 2) being added to the record are as follows:

1. FDA, Eye-Tracking Experimental Study on Consumer Responses to Modifications to the Nutrition Facts Label Outlined in the Food and Drug Administration's Proposed Rulemaking, June 2015. This was a study in which 160 participants participated in a computer-based research of the potential effects of several possible changes to the label on consumer viewing and use of the label.
2. FDA, Experimental Study of Proposed Changes to the Nutrition Facts Label Formats, June 2015. This was a Web-based experiment, involving more than 5,000 participants, designed to explore whether modifications to the format of the Nutrition Facts label would affect consumers' interpretation of information on the Nutrition Facts label.

After reviewing the comments on the proposed rule, we have tentatively concluded that we do not intend to further consider the alternative format for the Nutrition Facts label. A review of the results of the consumer research made available in this document has not provided information to change our planned approach. Therefore, interested persons who intend to submit comments may wish to focus on the study results relevant to the current and proposed formats.

II. Comments

Interested persons may submit either electronic comments regarding the guidance to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

1. FDA, Eye-Tracking Experimental Study on Consumer Responses to Modifications to the Nutrition Facts Label Outlined in the Food and Drug Administration's Proposed Rulemaking, June 2015.
2. FDA, Experimental Study of Proposed Changes to the Nutrition Facts Label Formats, June 2015.

Dated: July 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17929 Filed 7–24–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2012–N–1210]

Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Proposed Rule To Solicit Comment on Limited Additional Provisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; supplemental notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA or we) is revising certain provisions of the proposed rule, issued in March 2014, that would amend FDA's labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the Nutrition Facts and Supplement Facts labels to assist consumers in maintaining healthy dietary practices (''the NFL/SFL proposed rule''). We are proposing text for the footnotes to be used on the Nutrition Facts label. We are taking this action after completing our consumer research in which we tested various footnote text options for the label. We are also proposing to establish a Daily Reference Value (DRV) of 10 percent of total energy intake from added sugars, proposing to require the declaration of the percent Daily Value (DV) for added sugars on the label, and are providing additional rationale for the declaration of added sugars on the label. We are taking these actions based, in part, on the science underlying a new report released by the 2015 Dietary Guidelines Advisory Committee.

DATES: Submit either electronic or written comments on the supplemental notice of proposed rulemaking by October 13, 2015. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by August 26, 2015, (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5360 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2012–N–1210 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''How to Submit Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5600 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *With regard to the supplemental notice of proposed rulemaking:* Blakeley Fitzpatrick, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–5429, email: *NutritionProgramStaff@fda.hhs.gov. With regard to the information collection:* FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, email: *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Regulatory Action

FDA is revising certain provisions of the proposed rule that published in the **Federal Register** on March 3, 2014 (79 FR 11879), that would amend FDA's labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the NFL/SFL proposed rule.

In the NFL/SFL proposed rule, we proposed to remove the requirement for the footnote listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets and reserved space to provide a proposed footnote. We stated in the preamble of the NFL/SFL proposed rule that we would continue to perform research during this rulemaking process to evaluate how variations in label format may affect consumer understanding and use of the Nutrition Facts label. We also stated that we would publish the results of our research for public review and comment. We are making results of our research available in this document. We are also proposing text for the footnotes to be used on the Nutrition Facts label. We are taking this action after completing our consumer research in which we tested various footnote text options for the label. We are also providing an exemption from the footnote requirement for certain foods.

In addition, the NFL/SFL proposed rule would require the declaration of added sugars as an indented line item underneath the declaration of ''Sugars'' on the Nutrition Facts label. We discussed in the NFL/SFL proposed rule that we were considering whether to use the term ''Total Sugars'' instead of ''Sugars'' on the label if we finalize a declaration of added sugars.

We stated in the NFL/SFL proposed rule that we were planning to conduct a consumer study that would include, among other things, questions regarding the declaration of added sugars on the Nutrition Facts label in order to help enhance our understanding of how consumers would comprehend and use this new information. We also stated that we would publish the results of the study when they become available.

As we prepared to make the consumer study results for the footnote and added sugars declaration available, new information emerged from the ''Scientific Report of the 2015 Dietary Guidelines Advisory Committee'' (the 2015 DGAC report) regarding added sugars. The new information on added sugars led us to reconsider our thinking for not establishing a DRV or requiring the declaration of a percent DV for added sugars on the Nutrition Facts and Supplement Facts labels. Specifically, the 2015 DGAC report provided evidence suggesting a strong association between a dietary pattern of intake characterized, in part, by a reduced intake of added sugars and a reduced risk of cardiovascular disease. The evidence also suggested an applicable