



4164-01-P

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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.

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