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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the reopening of the comment period for certain documents associated with the proposed rule to 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. We also are reopening the comment period for a supplemental proposed rule to revise the Nutrition Facts and Supplement Facts labels. We are taking this action due to technical difficulties at the Federal eRulemaking Portal.

DATES: Submit either electronic or written comments on the supplemental proposed rule and related documents by October 23, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-N-1210 for this rulemaking. Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper 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, 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, email: Philip.Chao@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of March 3, 2014 (79 FR 11879), we published a proposed rule that would amend our labeling regulations for conventional foods and dietary supplements to provide updated nutrition information. In the Federal Register of July 27, 2015 (80 FR 44302), we reopened the comment period through September 25, 2015, for the proposed rule 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. We also issued a supplemental proposed rule (80 FR 44303) with a comment period through October 13, 2015. The supplemental proposal included two additional consumer studies pertaining to the declaration of added sugars and alternative footnote statements. We proposed text for the footnotes to be used on the Nutrition Facts label, after completing our consumer research in which we tested various footnote text options for the label. We also proposed to establish a Daily Reference Value of 10 percent of total energy intake from added sugars and to require the declaration of the percent Daily Value for added sugars on the label. The supplemental proposed rule also provided additional rationale for the declaration of the amount of added sugars on the label. We explained that we were taking these actions based, in part, on

the science underlying a new report released by the 2015 Dietary Guidelines Advisory Committee.

More recently, in the Federal Register of September 10, 2015 (80 FR 54446), we issued a notice clarifying: (1) The consumer studies on the added sugars declaration and the alternative footnote statements in the supplemental proposal relate to topics on which we sought comment and (2) the consumer studies on the format published in a separate notice in July 2015 were included for comment, and were placed in the docket at that time. We also stated that, in response to requests for the raw data for each of these consumer studies that are relevant to the summary memoranda for the studies, we were making the raw data available for comment. We extended the comment period for the two consumer studies pertaining to the proposed changes to the Nutrition Facts label formats (originally scheduled to close on September 25, 2015) to October 13, 2015, to coincide with the end of the comment period for the supplemental proposed rule.

However, on October 13 and 14, 2015, the Federal eRulemaking Portal, http://www.regulations.gov, experienced technical difficulties which sometimes prevented the electronic submission of comments. Therefore, we are reopening the comment period for the consumer studies and the supplemental proposal; the reopened comment period will close on October 23, 2015.

Dated: October 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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