4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. FDA-2012-N-1210 and FDA-2004-N-0258]

Proposed Rules on Food Labeling: Revision of the Nutrition and Supplement Facts Labels and 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; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing a public meeting to discuss two proposed rules aimed at updating nutrition information and serving size requirements on the nutrition facts labels to provide consumers with information that could be used to maintain healthy dietary practices. The purpose of the public meeting is to inform the public of the provisions of the proposed rules and the rulemaking process (including how to submit comments, data, and other information to both dockets) as well as solicit oral stakeholder and public comments on the proposed rules and to respond to questions about the proposed rules.

DATES: See “How to Participate in the Public Meeting” in the SUPPLEMENTARY INFORMATION section of this document for dates and times of the public meeting, closing dates for advance registration, requesting special accommodations due to disability, and information on deadlines for submitting either electronic or written comments to FDA’s Division of Dockets Management.

ADDRESSES: See "How to Participate in the Public Meeting" in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT:

For questions about registering for this meeting, registering to make oral comments, to register by phone, or to submit a notice of participation by mail, fax, or email: Cindy de Sales, The Event Planning Group, LLC, 7910 Woodmont Ave., Suite 310, Bethesda, MD 20814, 240-316-3207, FAX: 240-316-3201, email: cindy@tepgevents.com.

For general questions about this meeting or for special accommodations due to disability, contact: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1731, email: Juanita.yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Nutrition Facts Label Proposed Rule

After the passage of the Nutrition Labeling and Education Act of 1990 (NLEA) (Pub. L. 101-535), which added section 403(q) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q)), we issued various regulations related to nutrition information on food labels, including regulations requiring the declaration of certain nutrients, regulations specifying the format for nutrition labeling, regulations setting reference values for use in declaring nutrient content for certain nutrients, and regulations exempting certain products from nutrition labeling (see 21 CFR 101.9). In addition, after the passage of the Dietary Supplement Health and Education Act of 1994 (Pub. L. 103-417), we amended our food labeling regulations to establish requirements for the nutrition labeling of dietary supplements (§ 101.9(j)(6) and 21 CFR 101.36).

Section 403(q) of the FD&C Act specifies certain nutrients to be declared in nutrition labeling, and authorizes the Secretary of Health and Human Services to require other nutrients to be declared if the Secretary determines that a nutrient will provide information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices. The Secretary also has discretion under section 403(q) of the FD&C Act to remove, by regulation and under certain circumstances, nutrient information that is otherwise explicitly required in food labeling under this section.

In the Federal Register of March 3, 2014 (79 FR 11879), we published a proposed rule entitled "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" (the Nutrition Facts label proposed rule). In the Nutrition Facts label proposed rule, we proposed to revise our regulations to update, among other things, the nutrients that are required and/or permitted to be declared and the daily values, as applicable, for required and permitted nutrients; 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 update the format of the Nutrition Facts label. We based the proposed rule on the latest science and public health information, dietary recommendations of the most recent consensus reports, and public comments received in response to advance notices of proposed rulemaking.

B. Serving Size Proposed Rule

After the passage of the NLEA, we issued various regulations related to serving size requirements (see § 101.9 and 21 CFR 101.12). Since we established those regulations, developments have compelled us to re-evaluate our regulations on serving sizes and determine whether and what, if any, revisions are needed to ensure that the Nutrition Facts label meets its

intended goal of helping consumers maintain healthy dietary practices. Specifically, such developments include the availability of newer consumption data, research showing that amounts of food consumed by the American public have changed, and recent consumer research on the use and understanding of the Nutrition Facts label.

Therefore, in the Federal Register of March 3, 2014 (79 FR 11989), we published a proposed rule entitled "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" (the serving size proposed rule). In the serving size proposed rule, we proposed to amend the definition of a single-serving container; require dual-column labeling for certain packages; update and modify certain reference amounts customarily consumed (RACCs); add several food products and food product categories to the RACCs for the general food supply; amend the label serving size for breath mints; and make technical amendments to various aspects of the serving size regulations.

II. Purpose and Format of the Public Meeting

FDA is holding the public meeting on the Nutrition Facts label and serving size proposed rules to inform the public of the provisions of the proposed rules and the rulemaking process (including how to submit comments, data, and other information to both dockets) as well as solicit oral stakeholder and public comments on the proposed rules and to respond to questions about the proposed rules. In general, the meeting format will include introductory presentations by FDA with time to hear stakeholder perspectives, questions and public comments.

III. How to Participate in the Public Meeting

The meeting will be held on June 26, 2014, from 8:30 a.m. to 5 p.m. Eastern Standard Time (EST) at the Jefferson Auditorium, U.S. Department of Agriculture (USDA), Wing 5 Entrance, 14th and Independence Ave. SW., Washington, DC 20024. FDA encourages all persons who wish to attend the meeting to register in advance of the meeting. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited.

If you preregister and would like to make an oral presentation at the meeting, please submit a request when you preregister. Due to the anticipated high level of interest in presenting public comment and limited time available, FDA will allocate time (typically 3 to 4 minutes) to each speaker to make an oral presentation. Speakers will be limited to making oral remarks; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. We would like to maximize the number of individuals who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at the meeting.

FDA encourages persons and groups who have similar interests to consolidate their information for presentation by a single representative. After reviewing the oral presentation requests, FDA will notify each participant before the meeting if their presentation request is granted, and, if so, the approximate time their presentation is scheduled to begin and remind them of the presentation format (e.g., 3-minute oral presentation without visual media).

While oral presentations from specific individuals and organizations will be limited to a certain length of time due to time constraints during the public meeting, stakeholders may submit electronic or written comments discussing any issues of concern to the dockets for the proposed

rules. All relevant data and documentation should be submitted with the comments to the relevant docket, i.e., Nutrition Facts label proposed rule, Docket No. FDA-2012-N-1210 http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1210-0002, or serving size proposed rule, Docket No. FDA-2004-N-0258 http://www.regulations.gov/#!documentDetail;D=FDA-2004-N-0258-0006.

Table 1 of this document provides information on participation in the public meeting.

Table 1.--Information on Participation in the Meeting and on Submitting Comments to Dockets for the Proposed Rules

	Date	Electronic address	Address	Other information
Attend public meeting	June 26, 2014, from 8:30 a.m. to 5 p.m. EST	Please preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.	Jefferson Auditorium, U.S. Department of Agriculture (USDA), Wing 5 Entrance, 14th and Independence Ave. SW., Washington, DC 20024. Photo ID Required.	Registration check-in begins at 8 a.m.
View Web cast	June 26, 2014, from 8:30 a.m. to 5 p.m. EST	Please preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.		The Web cast will have closed captioning.
Preregister	Register by June 20, 2014	Individuals who wish to participate in person or via Web Cast are asked to preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.	We encourage the use of electronic registration, if possible.[1]	There is no registration fee for the public meeting.
Request special accommodations due to disability	Request by June 12, 2014	Juanita Yates, email: Juanita.yates@fda.hhs.gov.	See For Further Information Contact.	
Request to make oral presentation	Register by June 12, 2014	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm[2]		We will grant requests made on the day of the meeting to make an oral presentation as

[1] You may also register via email, mail, or fax. Please include your name, title, firm name, address, and phone and fax numbers in your registration information and send to: Cindy de Sales, The Event Planning Group, LLC, 7910 Woodmont Avenue, suite 310, Bethesda, MD 20814, 240-316-3207, FAX: 240-316-3201, email: cindy@tepgevents.com.

[2] You may also request to make an oral presentation at the public meeting via email. Please include your name, title, firm name, address, and phone and fax numbers, and send to Cindy de Sales (see FOR FURTHER INFORMATION CONTACT).

				time permits. Information on requests to make an oral presentation may be posted without change to http://www.regulations.gov, including any personal information.
Submit electronic or written comments	Submit comments by August 1, 2014	Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.	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	Identify your comments with the appropriate docket number (Docket No. FDA-012-N-1210 http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1210-0002 for Nutrition Facts label proposed rule or Docket No. FDA-2004-N-0258 http://www.regulations.gov/#!documentDetail;D=FDA-2004-N-0258-0006 for serving size proposed rule). We encourage you to submit electronic comments by using the Federal eRulemaking Portal.

IV. Comments, Transcripts, and Recorded Video

Information and data, including any personal information, submitted to FDA during the public meeting and the comment period for the proposed rules will become part of the administrative record for the relevant rulemaking. This information and data will be accessible to the public at http://www.regulations.gov and between 9 a.m. and 4 p.m., Monday through Friday, at the Division of Dockets Management (see Addresses in table 1).

Regardless of attendance at the public meeting, interested persons may submit to FDA's Division of Dockets Management (see Addresses in table 1) either electronic or written comments. You only need to send one set of comments. Identify the comments with the

appropriate docket number (Docket No. FDA-2012-N-1210 for the Nutrition Facts label proposed rule or Docket No. FDA-2004-N-0258 for the serving size proposed rule). If you have comments pertaining to both proposed rules, submit them separately for each rule to ensure consideration.

The transcript of the proceedings from the public meeting will become part of the administrative record for each of the rulemakings. As soon as the transcript is ready, we will make it available at http://www.regulations.gov and at http://www.fda.gov/Food/. It may also be viewed between 9 a.m. and 4 p.m., Monday through Friday, at the Division of Dockets Management (see Addresses in table 1). The transcript will also be available in either hardcopy or on CD-ROM after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Additionally, FDA will be video recording the public meeting. Once the recorded video is available, you can access it at http://www.fda.gov/Food/.

Dated: May 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-12362 Filed 05/28/2014 at 8:45 am; Publication Date: 05/29/2014]