Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2016–D–2335]

Use of the Term ''Healthy'' in the Labeling of Human Food Products; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the following public meeting entitled ''Use of the Term 'Healthy' in the Labeling of Human Food Products.'' The purpose of the public meeting is to give interested persons an opportunity to discuss the use of the term ''healthy'' in the labeling of human food.

DATES: The public meeting will be held on March 9, 2017, from 8:30 a.m. until 5:30 p.m. See section III ''How to Participate in the Public Meeting'' in the **SUPPLEMENTARY INFORMATION** section of this document for dates and times of the public meetings, closing dates for advance registration, requesting special accommodations due to disability, and other information regarding meeting participation.

ADDRESSES: The public meeting will be held at the Hilton Washington DC/Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20852.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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–2016–D–2335 for ''Use of the Term 'Healthy' in the Labeling of Human Food Products; Request for Information and Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://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.'' We will review this copy, including the claimed confidential information, in our 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 *https://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 *https://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:

For questions about registering for the meeting or to register by phone: Jim Nakayama, The Nakamoto Group, Inc., 11820 Parklawn Dr., Suite 240, Rockville, MD 20852, 301–468–6535, ext. 212, FAX: 301–468–6536, email: *events@nakamotogroup.com.*

For general questions about the meeting or for special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS–009), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1731, email: *Juanita.yates@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 28, 2016, we published a document inviting public comment on the possibility of redefining the ''healthy'' nutrient content claim for food labeling (81 FR 66562). This action was

consistent with our recently released 2016–2025 Foods and Veterinary Medicine (FVM) Program's strategic plan with specific goals for nutrition and other planned and recent activity including the issuance of final rules updating certain of our nutrition labeling regulations. The document also contained several specific questions on which we sought input (81 FR 66562 at 66564 to 66565). In the **Federal Register** of December 30, 2016, we published a document extending the comment period for the docket to receive information and comments on the use of the term ''healthy'' in the labeling of human food (81 FR 96404); the comment period, which was originally scheduled to end on January 26, 2017, was extended to April 26, 2017.

We also recently announced the availability of a guidance for industry entitled ''Use of the Term 'Healthy' in the Labeling of Human Food Products: Guidance to Industry'' (81 FR 66527). The guidance advises manufacturers who wish to use the implied nutrient content claim ''healthy'' to label their food products as provided by our regulations. More specifically, the guidance advises food manufacturers of FDA's intent to exercise enforcement discretion with respect to the implied nutrient content claim ''healthy'' on foods that have a fat profile of predominantly mono and polyunsaturated fats, but do not meet the regulatory definition of ''low fat,'' or that contain at least 10 percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D.

In addition, we received a citizen petition asking that we update, among other things, our nutrient content claim regulations to be consistent with current federal dietary guidance (see Docket No. FDA–2015–P–4564 (citizen petition from KIND LLC)). In particular, the petitioners requested that FDA amend the regulation defining the nutrient content claim ''healthy'' with respect to total fat intake and amend the regulation to emphasize whole foods and dietary patterns rather than specific nutrients.

II. Purpose and Format of the Public Meeting

We are holding the public meeting to give interested parties an opportunity to discuss the use of the term ''healthy'' in the labeling of human food. At the meeting, following introductory presentations, parties will have an opportunity to participate in their choice of breakout sessions on topics referenced in the notice and related documents and engage in an open comment and question and answer session. We invite interested parties to provide information, share experiences, and raise issues specifically related to the nutrient content claim ''healthy,'' including (but not limited to): ''healthy'' as a nutrient-based claim, food component-based claim, or both; ''healthy'' single definition or definition by category; consumer understanding of and responses to the term ''healthy''; and when, if ever, the use of the term ''healthy'' may be false or misleading. Interested parties may also submit electronic or written comments to the docket by April 26, 2017. The agenda and other documents will be accessible on our FDA public meetings Web site at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm* before the public meeting.

In general, the meeting format will include introductory presentations, perspectives panels, and multiple opportunities for individuals to express their opinions at the meeting through oral presentations, participation in breakout sessions, and submission of electronic or written comments (see **ADDRESSES** for information on submitting comments). There will be an opportunity for parties who are unable to participate in person to join the meeting via Webcast. (See section III for more information on the Webcast option.)

III. How To Participate in the Public Meeting

Due to limited space and time, we encourage all persons who wish to attend the meeting to register in advance. 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. Onsite registration will be accepted, if space permits, after all preregistered attendees are seated.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting should submit a request in advance (see table 1 for details) and provide the specific topic or issue to be addressed. Due to the anticipated high level of interest in presenting public comment and the limited time available, we are allocating 3 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. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make an oral presentation. 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.

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

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 THE DOCKET

Activity	Date	Electronic addresses	Address	Other information
Attend public meeting	March 9, 2017, from 8:30 a.m. to 5:30 p.m.	Preregister at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	.....	Registration check-in begins at 8 a.m.
View Webcast	March 9, 2017, from 8:30 a.m. to 5:30 p.m.	Webcast participants are asked to preregister at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	.....	The Webcast will have closed captioning.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND ON SUBMITTING COMMENTS TO THE DOCKET—Continued

Activity	Date	Electronic addresses	Address	Other information
Advance registration ..	Register by March 2, 2017.	To participate in person 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 to make an oral presentation.	By February 21, 2017	To request to make an oral presentation sign-up at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.		
Submit either electronic or written comments.	Submit comments by April 26, 2017.	*http://www.regulations.gov*	Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.	See **ADDRESSES** for information on submitting comments.
Request special accommodations due to a disability.	Request by February 21, 2017.	Juanita Yates, email: *Juanita.yates@fda.hhs.gov*.	See **FOR FURTHER INFORMATION CONTACT**.	

[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: Jim Nakayama (see **FOR FURTHER INFORMATION CONTACT**).

IV. Transcripts and Recorded Video

Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* The transcript will also be accessible at the Division of Dockets Management (see **ADDRESSES**) and FDA public meetings Web site at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*

Additionally, we will be video recording the public meeting. Once the recorded video is available, it will be accessible on our FDA public meetings Web site at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*

Dated: February 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–03117 Filed 2–15–17; 8:45 am]

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