4164-01-P

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: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled "Use of the Term 'Healthy' in the Labeling of Human Food Products: Guidance for Industry." 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 our 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.

DATES: Submit either electronic or written comments on FDA guidances at any time.

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-2016-D-2335 for "Use of the Term 'Healthy' in the Labeling of Human Food Products: Guidance for Industry." 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.

Submit written requests for single copies of the guidance to the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Vincent de Jesus, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1450.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "Use of the Term 'Healthy' in the Labeling of Human Food Products: Guidance for Industry." We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

Under section 403(r)(1)(A) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(r)(1)(A)), a food is misbranded if it bears claims, either express or implied,

that characterize the level of a nutrient which is of a type required to be declared in nutrition labeling unless the claim is made in accordance with a regulatory definition established by FDA (see section 403(r)(2) of the FD&C Act). Our food labeling regulations at § 101.65(d) (21 CFR 101.65(d)) provide the regulatory definition for use of the term "healthy" or related terms (such as "health," "healthful," "healthfully," "healthfulness," "healthier," "healthiest," "healthily," and "healthiness") as an implied nutrient content claim on the label or in labeling of a food. This definition establishes the following nutrient conditions for bearing a "healthy" claim: (1) Specific criteria for nutrients to limit in the diet, such as total fat, saturated fat, cholesterol, and sodium; and (2) requirements for nutrients to encourage in the diet, including vitamin A, vitamin C, calcium, iron, protein, and fiber. The criteria are linked to elements in the Nutrition Facts label and serving size regulations (see §§ 101.9 and 101.12). The nutrient criteria to use the claim can vary for different food categories (e.g., fruits and vegetables, or seafood and game meat) (§ 101.65(d)(2)).

In the Federal Register of May 27, 2016, we issued final rules updating the Nutrition Facts label and serving size information for packaged foods to reflect new scientific information, including the link between diet and chronic diseases such as obesity and heart disease (see 81 FR 33742, "Food Labeling: Revision of the Nutrition and Supplement Facts Labels"; 81 FR 34000 "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"). Updates to the Nutrition Facts label include changes in the individual nutrients that must be declared and also changes to the DV of other individual nutrients, reflecting changes in recommended intake levels, based on current science.

Because the science supporting public health recommendations for intake of various nutrients has evolved, as reflected in the updated Nutrition Facts Label, FDA intends to exercise enforcement discretion with respect to some of the criteria for bearing the implied nutrient content claim "healthy." In particular, we intend to exercise enforcement discretion with respect to the current requirement that any food bearing the nutrient content claim "healthy" meet the low fat requirement provided that: (1) The amounts of mono- and polyunsaturated fats are declared on the label; and (2) the amounts declared constitute the majority of the fat content.

Similarly, we intend to exercise enforcement discretion with respect to the current requirement that any food bearing the nutrient content claim "healthy" contain at least 10 percent of the DV per RACC of vitamin A, vitamin C, calcium, iron, protein, or fiber, if the food instead contains at least 10 percent of the DV per RACC of potassium or vitamin D.

We are issuing this guidance without prior public comment under 21 CFR 10.115(g)(2) because we have determined that prior public participation is not feasible or appropriate, as this guidance implements a temporary enforcement policy while we update our regulations to be consistent with the final Nutrition Facts Label rule. However, as with all Agency guidances, the public may comment on the guidance at any time.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Use the FDA Web sites listed in the previous sentence to find the most current version of the guidance.

Dated: September 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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