cost, and assuming that all of the affected entities qualify as small entities, the total annual cost to the industry as a whole is minimal ($19,577.75), and the average cost per affected entity is $63.23.

45. According to SBA guidance, the determination of significance of impact ''should be seen as relative to the size of the business, the size of the competitor's business, and the impact the regulation has on larger competitors.'' [49] The Commission does not consider the estimated burden to be a significant economic impact. As a result, the Commission certifies that the reforms proposed in this NOPR would not have a significant economic impact on a substantial number of small entities.

VI. Comment Procedures

46. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due November 28, 2016. Comments must refer to Docket No. RM16–13–000, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

47. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov*. The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

48. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

49. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

VII. Document Availability

50. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

51. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

52. User assistance is available for eLibrary and the Commission's Web site during normal business hours from the Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov*.

By direction of the Commission.

Issued: September 22, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–23442 Filed 9–27–16; 8:45 am]

BILLING CODE 6717–01–P

[49] U.S. Small Business Administration, *A Guide for Government Agencies: How to comply with the Regulatory Flexibility Act,* at 18 (May 2012), *https://www.sba.gov/sites/default/files/advocacy/rfaguide_0512_0.pdf.*

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; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the establishment of a docket to receive information and comments on the use of the term ''healthy'' in the labeling of human food products. This action is 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. 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. In particular, the petitioners request 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. We invite public comment on the term ''healthy'', generally, and as a nutrient content claim in the context of food labeling and on specific questions contained in this document.

DATES: Submit either electronic or written comments by January 26, 2017.

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; Request for Information and Comments.'' 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: 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

A. What has been FDA's position regarding the use of the term ''healthy?''

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 deemed 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). Section 201(f) of the FD&C Act (21 U.S.C. 321(f)) defines the term ''food'' to mean articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article. Section 201(n) of the FD&C Act (21 U.S.C. 321(n)) provides that labeling is misleading if, among other things, it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual. Section 201(m) of the FD&C Act defines ''labeling'' as all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article.

The definition in 21 CFR 101.65(d) establishes the parameters for use of the implied nutrient content claim ''healthy'' or related terms (such as ''health'', ''healthful'', ''healthfully'', ''healthfulness'', ''healthier'', ''healthiest'', ''healthily'', and ''healthiness'') on the label or in labeling of a food to suggest that a food, because of its nutrient content, may be useful in creating a diet that is consistent with dietary recommendations, if the food meets certain nutrient conditions, and the claim is made with an explicit or implicit claim or statement about a nutrient (*e.g.*, ''healthy, contains 3 grams of fat''). The conditions include specific criteria for nutrients to limit in the diet, such as total fat, saturated fat, cholesterol, sodium, as well as 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 21 CFR 101.9 and 101.12). The nutrient criteria to use this nutrient content claim can vary for different food categories (*e.g.*, fruits and vegetables, or seafood and game meat) (21 CFR 101.65(d)(2)).

In addition, under section 403(a)(1) of the FD&C Act, a food is deemed misbranded if its labeling is false or misleading in any particular.

B. What has prompted FDA to request information and comments?

On July 14, 2016, we released the FVM Program's Strategic Plan for fiscal years 2016–2025. The strategic plan is organized under four goals: Food safety, nutrition, animal health, and organizational excellence (The strategic plan is available on our Web site at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM507379.pdf.*)

FDA's nutrition-related strategic goals include: Providing and supporting accurate and useful nutrition information to consumers so they can choose healthier diets consistent with the Dietary Guidelines for Americans and other evidence-based recommendations; and encouraging and facilitating new products and product reformulation to promote a healthier food supply. A key element in achieving these goals is the modernization of FDA's regulations for nutrition-related labeling claims to reflect current science, provide information in ways that are understandable and useful to consumers, and reduce barriers and encourage industry efforts to develop and introduce healthier food products through innovation or reformulation.

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 are required to be declared and also changes to the Daily Value of other individual nutrients, reflecting changes in recommended intake levels, based on current science. Because the framework for many of FDA's nutrition labeling regulations is linked to elements in the Nutrition Facts label and serving size

regulations, FDA has been planning to update these regulations to align with the updated Nutrition Facts label regulations. These regulations include those for health claims and nutrient content claims (including the implied nutrient content claim ''healthy'').

The science underlying FDA's new requirements for the Nutrition Facts label and serving size information is also reflected in the recently published *2015–2020 Dietary Guidelines for Americans* (2015–2020 *Dietary Guidelines*) (Ref. 1). The *Dietary Guidelines* are designed for professionals to help all individuals ages 2 years and older and their families consume a healthy, nutritionally adequate diet. The *Dietary Guidelines* are the foundation of federal nutrition guidance and are fundamental in shaping federal policies and programs related to food, nutrition, and health. Specific recommendations in the *Dietary Guidelines* have evolved over time, as nutrition science has advanced. They provide information and perspectives on consumption of foods from various food groups, as well as the intake of specific macronutrients such as fats and sugars, and micronutrients such as vitamins and minerals. The 2015–2020 *Dietary Guidelines* emphasize the importance of eating patterns as a whole, the combination of foods and drinks that people consume over time. The scientific evidence on which the *Dietary Guidelines* are based and the recommendations in the *Dietary Guidelines* will help inform additional updates to FDA's regulations on nutrition-related claims that are permitted on the food label.

A variety of stakeholders from academia and industry, as well as consumers, have also requested that FDA update additional nutrition labeling regulations for nutrient content and health claims, including the implied nutrient content claim ''healthy''. Some stakeholders have provided specific recommendations on how they believe we should approach such an update. For example, in a citizen petition dated December 1, 2015 (Docket Number FDA–2015–P–4564) (''Kind Citizen Petition''), KIND LLC requested that we make certain changes to existing nutrition claim regulations. A number of these changes specifically related to the nutrient content claim ''healthy''. With regards to ''healthy'', the petition requested that we:

- Amend § 101.65(d)(2) so that the term ''healthy'' or related terms may be used if the food ''meets the following conditions for fat, saturated fat, and cholesterol exclusive of the fat and saturated fat contributed to the food product by the following foods, provided that such foods are used in their whole form or have been processed in such a way that did not materially degrade their nutritional value: Fruits, vegetables, nuts, seeds, legumes, whole grains, and seafood; and the food meets the following conditions for other nutrients;''
- Amend § 101.65(d) (pertaining to general nutritional claims) to ''clarify that a labeling claim that a food is useful in maintaining healthy dietary practices is an implied nutrient content claim only if the claim is immediately adjacent to an implicit claim or statement about a nutrient'';
- Amend § 101.65(b) (pertaining to label statements that are not implied claims) to ''clarify that a statement that claims that a food is useful in maintaining healthy dietary practices and that does not appear immediately adjacent to an explicit or implicit claim or statement about a nutrient is generally not an implied nutrient content claim, but is instead a dietary guidance statement''; and
- While the rulemakings to amend § 101.65 are pending, issue a guidance document to ''clarify that a statement about the usefulness of a food, or a category of foods, in maintaining healthy dietary practices is a dietary guidance statement that is not subject to the requirements in FDA's nutrient content claim regulations unless it is an implied nutrient content claim because it is immediately adjacent to an explicit or implicit claim or statement about a nutrient''.

See Kind Citizen Petition at pgs. 2–5. The petitioner stated that our existing regulatory scheme ''limits the ability of food producers to tell consumers that products containing certain foods—such as nuts, whole grains, seafood, fruits, and vegetables—are healthy, even though they are currently recommended as key components of a healthful diet'' (Kind Citizen Petition at pg. 5). The petitioner said that its request would ''make FDA's regulatory regime consistent with current federal dietary recommendations (as is required by law), consistent with current scientific evidence about the health benefits of certain foods, and would significantly benefit the public health by ensuring that consumers fully understand the dietary value of foods available for purchase'' (id.).

The petitioner asserted that current federal dietary recommendations encourage dietary patterns that are rich in nuts, whole grains, legumes, seeds, fruits, vegetables, and seafood (id. at pgs. 10–14) and that current science also recognizes the health benefits of consuming nutrient-dense foods (id. at pgs. 14–18). The petitioner also asserted that dietary recommendations and scientific evidence now focus on the quality or types of dietary fat consumed instead of reducing total fat consumption (id. at pgs. 18–19).

Thus, the petitioner described its requested changes and actions as being necessary to ''ensure that FDA's requirements are consistent with current federal dietary recommendations and with the most recent scientific evidence, which is essential in providing uniform federal dietary guidance to consumers'' (id. at page 20).

II. Other Issues for Consideration

We invite interested persons to comment on the petitioner's requests, including the use of the term ''healthy'' as a nutrient content claim in the labeling of human food products; and when, if ever, the use of the term ''healthy'' may be false or misleading. We are particularly interested in responses to the following questions:

- Is the term ''healthy'' most appropriately categorized as a claim based only on nutrient content? If not, what other criteria (*e.g.*, inclusion of foods from specific food categories) would be appropriate to consider in defining the term ''healthy'' for use in food labeling?
- If criteria other than nutrient content (*e.g.*, amount of whole grain) are to be included in the definition of the term ''healthy,'' how might we determine whether foods labeled ''healthy'' comply with such other criteria for bearing the claim?
- What types of food, if any, should be allowed to bear the term ''healthy?'' Should all food categories be subject to the same criteria? Please provide details of your reasoning.
- Is ''healthy'' the best term to characterize foods that should be encouraged to build healthy dietary practices or patterns? What other words or terms might be more appropriate (*e.g.*, ''nutritious'')? We encourage submission of any studies or data related to descriptors used to communicate the overall healthfulness of a food product.
- What nutrient criteria should be considered for the definition of the term ''healthy?'' Should nutrients for which intake is recommended to be limited be included? Should nutrients for which intake is encouraged continue to be included?
- If nutrients for which intake is encouraged are included in the definition, should these nutrients be restricted to those nutrients whose recommended intakes are not met by the

general population, or should they include those nutrients that contribute to general overall health? Should the nutrients be intrinsic to the foods, or could they be provided in part—or in total—via fortification? Please provide details of your reasoning and provide any supportive data or information.

- Are there current dietary recommendations (*e.g.*, the *Dietary Guidelines for Americans*) or nutrient intake requirements, such as those described in the final rule updating the Nutrition Facts label (see 81 FR 33742; May 27, 2016) or those provided by the Institute of Medicine (IOM) in the form of Dietary Reference Intakes (DRI) (*http://www.nationalacademies.org/hmd/Activities/Nutrition/SummaryDRIs/DRI-Tables.aspx*), that should be reflected in criteria for use of the term ''healthy?''
- What are the public health benefits, if any, of defining the term ''healthy'' or other similar terms in food labeling? Please include any data or research related to public health benefits in your reasoning.
- What is consumers' understanding of the meaning of the term ''healthy'' as it relates to food? What are consumers' expectations of foods that carry a ''healthy'' claim? We are especially interested in any data or other information that evaluates whether or not consumers associate, confuse, or compare the term ''healthy'' with other descriptive terms and claims.
- Would this change in the term ''healthy'' cause a shift in consumer behavior in terms of dietary choices? For example, would it cause a shift away from purchasing or consuming fruits and vegetables that do not contain a ''healthy'' claim and towards purchasing or consuming processed foods that bear this new ''healthy'' claim?
- How will the food industry and consumers regard a change in the definition of ''healthy?''
- What would be the costs to industry of the change?

Please provide supporting data, consumer research, and other information to support your comments and responses to these questions.

III. References

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

1. U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015–2020 Dietary Guidelines for Americans, 8th Edition, December 2015, available at *http://health.gov/dietaryguidelines/2015/guidelines/.*

Dated: September 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23365 Filed 9–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 203 and 234

[Docket No. FR–5715–P–01]

RIN 2502–AJ30

Project Approval for Single-Family Condominiums

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement HUD's authority under the single-family mortgage insurance provisions of the National Housing Act to insure one-family units in a multifamily project, including a project in which the dwelling units are attached, or are manufactured housing units, semi-detached, or detached, and an undivided interest in the common areas and facilities which serve the project. The rule would codify requirements for Direct Endorsement lenders to meet in order to be approved for the Direct Endorsement Lender Review and Approval Process (DELRAP) authority for condominiums, and basic standards that projects must meet to be approved as condominiums in which individual units would be eligible for mortgage insurance, as well as particular cases such as Single-Unit Approvals and site condominiums. The rule provides a method by which certain approval standards could be varied efficiently to meet market needs while providing for public comment where appropriate. Currently, single-family condominium project approval is provided under HUD's Condominium Project Approval and Processing Guide and related Mortgagee Letters.

Condominiums under this rule are distinct from condominiums in which the project has a blanket mortgage insured by HUD.

DATES: *Comment due date:* November 28, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (fax) comments are not acceptable.

Public Inspection of Public Comments. HUD will make all properly submitted comments and communications available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, you must schedule an appointment in advance to review the public comments by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the toll-free Federal Relay Service at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*