

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 101**

[Docket No. FDA-2013-P-0047]

RIN 0910-AH43

Food Labeling: Health Claims; Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Interim final rule; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the regulation authorizing a health claim on the relationship between dietary saturated fat and cholesterol and risk of coronary heart disease (CHD) to permit raw fruits and vegetables that fail to comply with the “low fat” definition and/or the minimum nutrient content requirement to be eligible to bear the claim. We are taking this action in response to a petition submitted by the American Heart Association (the petitioner). The amendment expands the use of this health claim to certain fruits and vegetables that are currently ineligible for the health claim.

DATES: This interim final rule is effective December 19, 2016. Interested persons may submit either electronic or written comments by March 6, 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-2013-P-0047 for “Food Labeling: Health Claims; Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease.” 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.” 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 <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 20740-3835, 240-402-1450.

SUPPLEMENTARY INFORMATION:**Executive Summary****Purpose of the Regulatory Action**

This interim final rule amends the regulation authorizing a health claim on the relationship between dietary saturated fat and cholesterol and risk of coronary heart disease (CHD). The interim final rule permits raw fruits and vegetables that fail to comply with the “low fat” definition and/or the minimum nutrient content requirement to be eligible to bear the claim. Health claims, in general, must meet certain nutrient requirements that we establish to ensure that health claims are used on foods with nutritional value. For example, except where provided for in other regulations, foods bearing a health claim must contain one or more of vitamin A, vitamin C, iron, calcium, protein, or fiber at or above 10 percent of the Reference Daily Intake (RDI) or Daily Reference Value (DRV), before any nutrient addition (§ 101.14(e)(6) (21 CFR 101.14(e)(6)). Additionally, for foods bearing health claims related to CHD, the food often must be a “low fat” food (see e.g., §§ 101.75(c)(2)(ii) and 101.81(c)(2)(iii)(D)). An unintended consequence of these general requirements is that some foods that are generally considered to contribute to a healthy diet are ineligible to bear certain health claims. A small number of fruits and vegetables, for example, are ineligible to bear the dietary saturated fat and cholesterol and risk of CHD health claim because they do not meet the requirement to have 10 percent of the RDI or DRV of certain nutrients and/or they do not meet the definition of a “low fat” food. However, consumption of fruits and vegetables is encouraged by dietary recommendations, and low saturated fat and low cholesterol fruits and vegetables should not be excluded

from bearing this health claim. To address this unintended consequence, this interim final rule includes provisions that exempt raw fruits and vegetables from:

(1) Needing to meet the 10 percent nutrient content requirement in § 101.14(e)(6).

(2) Needing to meet the definition for a “low fat” food in § 101.62.

The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by clarifying, among other things, FDA’s authority to regulate health claims on food labels and in food labeling. Using that authority, in 1993 we issued § 101.75, which authorizes a health claim about the relationship between diets low in saturated fat and cholesterol and a reduced risk of CHD (58 FR 2739, January 6, 1993).

Section 403(r)(4) of the FD&C Act (21 U.S.C. 343(r)(4)) establishes a mechanism for any person to petition us to issue a regulation relating to a claim that characterizes the level of any nutrient or the relationship of any nutrient to a disease or a health-related condition. We received a petition, under section 403(r)(4) of the FD&C Act, requesting that we amend the dietary saturated fat and cholesterol and risk of CHD health claim to permit raw fruits and vegetables, as well as single-ingredient or mixtures of frozen or canned fruits and vegetables that contain no added fat or sugars, which fail to comply with the “low fat” definition and/or the minimum nutrient content requirement, to be eligible to bear the claim. This interim final rule responds to that petition.

Summary of the Major Provisions of the Regulatory Action in Question

Under the interim final rule, raw fruits and vegetables are exempt from needing to meet the minimum nutrient content requirement of the general principles for health claims and from the requirement specifically included in the dietary saturated fat and cholesterol and risk of CHD health claim that a food meet the definition for “low fat” to be eligible to bear the claim. Current FDA regulations, at § 101.75(c)(1), state that all requirements set forth in § 101.14 must be met. The interim final rule revises § 101.75(c)(1) to provide an exemption for raw fruits or vegetables from meeting the minimum nutrient content requirement in § 101.14(e)(6).

Current FDA regulations, at § 101.75(c)(2)(ii), establish requirements regarding the nature of the food, except for fish and game meats; the food must meet all nutrient content requirements

of § 101.62 for a “low saturated fat,” “low cholesterol,” and “low fat” food. We are amending § 101.75(c)(2)(ii) to provide an exemption from meeting the nutrient content requirements of § 101.62 for “low fat” if the food is a raw fruit or vegetable.

I. Background

A. The Nutrition Labeling and Education Act of 1990

The 1990 amendments amended the FD&C Act in a number of important ways. Among other changes, the 1990 amendments clarified our authority to regulate health claims on food labels and in food labeling. Under this authority, we issued several regulations, including § 101.14, *Health claims: General requirements* (58 FR 2478 at 2533), which sets forth general principles for the authorization and use of health claims, and § 101.70, *Petitions for health claims* (58 FR 2478 at 2534), which sets forth a process for petitioning us to authorize health claims about substance-disease relationships, and sets out the types of information that any such petition must include. Among other provisions, the general principles for health claims include requirements for determining the eligibility of a food to bear a health claim. Examples include disqualifying nutrient levels (§ 101.14(a)(4)), which are specific nutrient thresholds not to be exceeded by a food bearing a health claim as required by § 101.14(e)(3), and also a minimum nutrient content requirement (§ 101.14(e)(6)) to ensure that a food bearing a health claim provide meaningful nutritive value as determined by meeting specific nutrient content levels.

B. Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease Health Claim

When implementing the 1990 amendments, we also conducted a review of evidence for a relationship between dietary saturated fat and cholesterol and risk of CHD. Based on the totality of the publicly available scientific evidence, we concluded that there was significant scientific agreement among qualified experts that diets low in saturated fat and cholesterol may reduce the risk of CHD. Therefore, we authorized a health claim about the relationship between diets low in saturated fat and cholesterol and a reduced risk of CHD (§ 101.75; 58 FR 2739 at 2757, January 6, 1993). Among the specific requirements included in § 101.75 are requirements that, in addition to the general requirements set forth in § 101.14, foods must meet all of

the nutrient content requirements in § 101.62 for a “low saturated fat,” “low cholesterol,” and “low fat” food in order to be eligible to bear the health claim, except that fish and game meats (*i.e.*, deer, bison, rabbit, quail, wild turkey, geese, and ostrich) may meet the requirements for “extra lean” in § 101.62.

II. Petition and Grounds

We received a petition from the American Heart Association (Docket No. FDA–2013–P–0047) on October 1, 2012, under section of 403(r)(4) of the FD&C Act. The petition requested that we amend the dietary saturated fat and cholesterol and risk of CHD health claim (§ 101.75) to permit raw fruits and vegetables, as well as single-ingredient or mixtures of frozen or canned fruits and vegetables that contain no added fat or sugars, which fail to comply with the “low fat” definition and/or the minimum nutrient content requirement, to be eligible to bear the claim. In addition, the petition requested that we issue an interim final rule by which fruits and vegetables that fail to comply with the “low fat” definition and/or the minimum nutrient content requirement could be eligible to bear the claim before publication of a final rule. Section 403(r)(4) of the FD&C Act establishes a mechanism for any person to petition us to issue a regulation relating to a claim that characterizes the level of any nutrient or the relationship of any nutrient to a disease or a health-related condition. On January 10, 2013, we notified the petitioner that we had completed our initial review of the petition, that the petition had been filed for further action in accordance with section 403(r)(4) of the FD&C Act, and that the filing date was January 9, 2013. Under the FD&C Act, if we do not act, by either denying the petition or issuing a proposed regulation to authorize the health claim, within 90 days of the date of filing for further action, the petition is deemed to be denied unless an extension is mutually agreed upon by us and the petitioner (21 U.S.C. 343(r)(4)(A)(i) and § 101.70(j)(3)(iii)). On April 9, 2013, we mutually agreed with the petitioner to extend the deadline to October 7, 2013. Later, through subsequent agreements, we mutually agreed to extend the deadlines several times, with the last deadline being March 17, 2017.

The petitioner explained that some of our requirements for the dietary saturated fat and cholesterol and risk of CHD health claim prevent a number of fruits and vegetables from being eligible to bear the claim. The minimum nutrient content requirement for all

health claims requires that, to be eligible to bear a health claim, a food contains 10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed (RACC) prior to any nutrient addition (see § 101.14(e)(6)). Although most fruits and vegetables meet this minimum requirement for one or more of the described nutrients, a small number of fruits and vegetables do not meet the minimum nutrient content requirement. For example, grapes, plums, beets, and cucumbers do not contain 10 percent of the RDI or DRV of vitamin A, vitamin C, iron, calcium, protein, or fiber per RACC. Additionally, the dietary saturated fat and cholesterol and risk of CHD health claim requires that a food bearing the claim meet all of the nutrient content requirements of § 101.62 for “low saturated fat,” “low cholesterol,” and “low fat” (§ 101.75(c)(2)(ii)). Again, most fruits and vegetables meet the requirement for “low fat,” but at least one fruit, avocados, does not meet the requirement and therefore is not eligible to bear the claim, even though the fruit meets the requirements for “low saturated fat” and “low cholesterol.”

The petition requested that fruits and vegetables, as a category of foods, be exempted from meeting the minimum nutrient content requirement and the “low fat” requirement for the dietary saturated fat and cholesterol and risk of CHD health claim. The petition asserted that, based on the scientific evidence, fruits and vegetables as a group contribute to reduced risk of CHD regardless of their inherent fat content or their ability to meet 10 percent of the RDI or DRV of vitamin A, vitamin C, iron, calcium, protein, or fiber per RACC. The petition described the scientific evidence relating consumption of fruits and vegetables and risk of CHD, including large observational studies (*e.g.*, the Women’s Health Study) (Ref. 1) and intervention studies on fruit and vegetable intake and surrogate endpoints for CHD risk (*e.g.*, low-density lipoprotein concentration) (Ref. 2). Additionally, the petition detailed the numerous current public health recommendations, such as the Dietary Guidelines for Americans (DGA) 2010, published by the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) (Ref. 3) and the National Cholesterol Education Program (NCEP) of the National Heart Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH) (Ref. 4), which

consistently encourage fruit and vegetable consumption as an integral part of a healthful diet, regardless of the specific nutrient contents of individual fruits and vegetables.

The petition requested the following specific changes in the regulation governing the dietary saturated fat and cholesterol and risk of CHD health claim:

- Modify § 101.75(c)(2)(ii) to create a new paragraph (A) and remove “low fat” food from the list of nutrient content requirements in § 101.62 a food must meet.
- Modify § 101.75(c)(2)(ii) to create a new paragraph (B) that provides an exemption to the nutrient content requirements of § 101.62 for a “low fat” food if it is a raw fruit or vegetable, or is a single-ingredient or mixture of frozen or canned fruits and vegetables that contains no fats or sugars in addition to the fats or sugars inherently present in the fruit or vegetable product.
- Modify § 101.75(c)(1) to exempt raw fruits and vegetables, or single-ingredient or mixtures of frozen or canned fruits and vegetables from meeting the requirement of § 101.14(e)(6).

In addition, the petition requested that we issue an interim final rule under section 403(r)(7)(A) of the FD&C Act, stating that the evidence is compelling and the potential to encourage fruit and vegetable consumption is important for public health and that issuing an interim final rule would allow affected fruit and vegetable products to become eligible to bear these health claims as expeditiously as possible.

III. Decision To Amend the Health Claim

A. Current Dietary Recommendations for Fruit and Vegetable Intake

The DGA, issued every 5 years by USDA and HHS, sets forth the Federal Government’s official recommendations regarding healthy eating and construction of a healthful diet (Ref. 5). The 2015–2020 DGA is the most recent version. At the core of the 2015–2020 DGA, as stated in Chapter 1 (“Key Elements of Healthy Eating Patterns”), “is the importance of consuming overall healthy eating patterns, including vegetables, fruits, grains, dairy, protein foods, and oils—eaten within an appropriate calorie level and in forms with limited amounts of saturated fats, added sugars, and sodium.” Key recommendations of the 2015–2020 DGA are to “Shift to consume more vegetables” and “Shift to consume more fruits.” For example, Chapter 2 (“Shifts Needed to Align With Healthy Eating

Patterns”) of the 2015–2020 DGA discusses intakes and states that “For most individuals, following a healthy eating pattern would include an increase in total vegetable intake from all vegetable subgroups, in nutrient-dense forms, and an increase in the variety of different vegetables consumed over time.” Chapter 2 likewise states that “To help support healthy eating patterns, most individuals in the United States would benefit from increasing their intake of fruits, mostly whole fruits, in nutrient-dense forms.”

We note that the recommendations in the 2015–2020 DGA regarding fruits and vegetables are directed at intakes of fruit and vegetables as a group. Particularly, in the discussions on fruit and vegetable intake throughout the report, the 2015–2020 DGA considers fruits and vegetables as a category of foods when discussing the associations between fruit and vegetable intake and reduced risk of cardiovascular disease or other chronic diseases (Ref. 5). Our reliance on dietary recommendations in this rulemaking and in previous health claim regulations is based on provisions of the 1990 amendments that direct us to issue health claim regulations that take into account the role of the nutrients in food in a way that will enhance the chances of consumers maintaining healthy dietary practices (see section 403(r)(3)(A) and (r)(3)(B) of the FD&C Act and previous health claim regulations for plant sterol/stanol esters and reduced risk of CHD (§ 101.83) and soluble fiber from certain foods and risk of CHD (§ 101.81)). Thus, general eligibility requirements that establish which types of foods are able to bear health claims have been typically determined based on the current dietary recommendations and guidelines at the time. The requirements are established to include foods and categories of foods that are encouraged to be consumed for their benefits to health, while restricting foods whose consumption is not encouraged from bearing health claims (*see* 58 FR 2478 at 2490).

B. Low Fat

Our regulations authorizing CHD-related health claims (§§ 101.75, 101.81, 101.82, and 101.83) require, with a few exceptions, that foods bearing such claims meet: (1) The “low fat” criterion defined by § 101.62(b)(2); (2) the “low saturated fat” criterion defined by § 101.62(c)(2); and (3) the “low cholesterol” criterion defined by § 101.62(d)(2).

The term “low fat” may be used on the label or in the labeling of food, except meal products as defined in § 101.13(l) and main dish products as

defined in § 101.13(m), provided that the food has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons and contains 3 g or less of fat per reference amount customarily consumed; or the food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g of food (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50-g criterion refers to the “as prepared” form) (§ 101.62(b)(2)).

The term “low saturated fat” may be used on the label or labeling of foods, except meal products as defined in § 101.13(1) and main dish products as defined in § 101.13(m), provided that the food contains 1 g or less of saturated fatty acids per reference amount customarily consumed and not more than 15 percent of calories from saturated fatty acids (§ 101.62(c)(2)).

The term “low cholesterol,” under § 101.62(d)(2), may be used on the label or in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that, for foods that have a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contain 13 g or less of total fat per reference amount customarily consumed and per labeled serving, the food contains 20 milligrams or less of cholesterol per reference amount customarily consumed or the food contains 2 g or less of saturated fatty acids per reference amount customarily consumed.

The petition noted that a fruit such as an avocado exceeds the 3 g total fat per RACC criterion of the “low fat” definition and therefore would never be able to bear the health claim for diets low in saturated fat and cholesterol and reduced risk of CHD. According to our nutrient data on the 20 most frequently consumed fruits (§§ 101.42 through 101.45 and appendix C to part 101), avocados contain 4.5 g total fat per RACC and do, indeed, exceed 3 g total fat per RACC. Barring an exemption to the “low fat” requirement, avocados (and any other fruit or vegetable with a total fat content in excess of the criteria for “low fat”) are not eligible to bear the dietary saturated fat and cholesterol and risk of CHD health claim.

In the 1993 final rule authorizing the dietary saturated fat and cholesterol and

risk of CHD health claim (58 FR 2739), we established “low fat” as a qualifying criterion for eligibility for the claim asserting that “while total fat is not as strongly or directly linked to increased risk of CHD . . . it may have significant indirect effects.” We discussed how “low fat foods generally help individuals in reducing their intake of saturated fat and cholesterol” and how excess calories, of which fat contributes more per gram than the other energy nutrients, is associated with two health-related conditions (obesity and diabetes) that are risk factors for heart disease (58 FR 2739 at 2742). In support of these determinations, we noted that, “Low fat diets are recommended in all Federal Government and National Academy of Sciences’ dietary guidelines for reducing the risk of heart disease” (58 FR 2739 at 2742).

Since we published the final rule for the dietary saturated fat and cholesterol and risk of CHD health claim in 1993, the science related to intake of total fat has evolved, and the current dietary recommendations no longer contain a recommendation encouraging the consumption of diets low in total fat. Beginning with the 2000 DGA, recommendations for total fat intake shifted from recommending diets low in fat to diets moderate in total fat (Ref. 6). The recommendations reflected a shift in focus to types of fat consumed (*i.e.*, saturated versus unsaturated fat) and their relation to effects on blood cholesterol concentrations. The recommendations for moderate fat intake continued through the 2005 DGA (Ref. 7) with even more discussion on types of fat in the diet (*e.g.*, polyunsaturated and monounsaturated fats) and their influence on cardiovascular disease. The discussion on total fat intake in the 2010 DGA (Ref. 3) focused on the importance of staying within the Institute of Medicine (IOM) of the National Academies of Science Acceptable Macronutrient Distribution Range (AMDR) for total fat intake of 20 to 35 percent of energy for adults and an AMDR of 25 to 35 percent of energy for children age 4 to 18 years (Ref. 8). The AMDRs are associated with reduced risk of chronic diseases, such as cardiovascular disease, while providing for adequate intake of essential nutrients (Ref. 8).

The 2015–2020 DGA does not focus on total fat intake, but instead makes recommendations about types of fat. Chapter 1 (“Key Elements of Healthy Eating Patterns”) states that “[a] healthy eating pattern limits . . . [s]aturated fats and *trans* fats . . .” and contains a key recommendation to “[c]onsume less than 10 percent of calories per day from

saturated fats. . . .” In this same chapter, the 2015–2020 DGA notes that “[t]he recommendation to limit intake of calories from saturated fats to less than 10 percent per day is a target based on evidence that replacing saturated fats with unsaturated fats is associated with reduced risk of cardiovascular disease” (Ref. 5, page 15).

As a result of the modifications in the dietary recommendations for total fat intake over the years, we have exempted certain foods at times from needing to meet the “low fat” requirement to be eligible to make a health claim related to CHD if those foods are consistent with dietary recommendations. For example, whole oats are exempt from meeting the “low fat” requirement to be eligible for “Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease” health claim (§ 101.81). In providing the exemption, we discussed that consumption of whole oats was consistent with the recommendations regarding fat intake in the 2005 DGA and that consumption of foods such as whole oats was helpful in reducing the risk of CHD (73 FR 23947 at 23951, May 1, 2008).

We find that not imposing a “low fat” requirement for raw fruits and vegetables is consistent with the 2015–2020 DGA recommendations to increase intake of fruits and vegetables to help support healthy eating patterns (Ref. 5), as well as the 2015–2020 DGA emphasis on types of fat rather than total fat when discussing CHD risk (Refs. 5 and 7). We note that the fruits and vegetables that we are exempting from meeting the definition of “low fat” must still comply with general health claim requirements in order to be eligible to bear the claim, including, but not limited to, the requirement in § 101.14(e)(3) that the level of fat must not exceed the disqualifying nutrient level for total fat in § 101.14(a)(4).

C. Minimum Nutrient Content

In the 1993 final rule on the general requirements for health claims (58 FR 2478), we established the minimum nutrient content requirement for eligibility of foods to bear health claims. We stated that foods bearing health claims should be those consistent with dietary guidelines and that the value of health claims should not be trivialized or compromised by their use on foods of little or no nutritional value. We also stated that claims intended to promote the consumption of food that is incompatible with dietary guidelines would be misleading to consumers (58 FR 2478 at 2521). We developed an approach that would limit health claims to foods that contribute certain nutrients

to the diet and, thus, are sources of more than calories (58 FR 2478 at 2521). We concluded that a food must contain one or more of vitamin A, vitamin C, iron, calcium, protein, or fiber at or above 10 percent of the RDI or DRV, prior to any nutrient addition, noting that most foods consistent with dietary guidelines met this criterion. Therefore, we added § 101.14(e)(6) to state that, except for dietary supplements that are not in conventional food form, the food must contain 10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed before any nutrients are added. We adopted this requirement in light of Congressional intent that health claims be used to help Americans maintain a balanced and healthful diet consistent with dietary guidelines (58 FR 2478 at 2521).

We later published technical amendments to the health claim regulations acknowledging that certain food products that had limited nutritional value may be determined to be appropriate foods to bear a health claim (58 FR 44036, August 18, 1993). We noted that we intended to address such situations in the regulations authorizing specific health claims, such as through an exception to the general requirements expressed in § 101.14(e)(6) (58 FR 44036).

Thus, we have recognized that exemptions to the minimum nutrient content requirement may be necessary in certain situations to help consumers construct overall daily diets that conform to current dietary guidelines and that otherwise promote good health. Multiple such exemptions have already been granted. For example, on August 23, 1996, we exempted noncariogenic carbohydrate sweeteners (carbohydrate sweeteners that do not promote the development of tooth decay) from the minimum nutrient content requirement to be eligible for the “dietary noncariogenic carbohydrate sweeteners and dental caries” health claim (§ 101.80) (61 FR 43433 at 43436). We reiterate that the minimum nutrient content requirements of § 101.14(e)(6) are important, but that an exemption from the minimum nutrient content requirements for fruits and vegetables as a group is warranted for these products to be eligible to bear the health claims authorized in § 101.75, given current dietary guideline recommendations. The value of these health claims will not be trivialized or compromised by their use on fruits and vegetables because current dietary guidelines emphasize that increased intake of fruits and vegetables

is an integral part of creating healthful diets and reducing the risk of chronic disease.

D. Conclusion

We agree with the petitioner that some current requirements for the dietary saturated fat and cholesterol and risk of CHD health claim prevent a number of fruits and vegetables from being eligible to bear the claim. We also agree that fruits and vegetables as a group appear to contribute to a reduced risk of CHD regardless of their inherent fat content or their ability to meet 10 percent of the RDI or DRV of vitamin A, vitamin C, iron, calcium, protein, or fiber per RACC. We previously have exempted foods from needing to meet individual requirements for health claim eligibility when, as here, consumption of the foods is consistent with contemporary science-based dietary recommendations. We conclude that raw fruits and vegetables should be exempt from needing to meet the minimum nutrient content requirement of the general principles for health claims and from the requirement specifically included in the dietary saturated fat and cholesterol and risk of CHD health claim that a food meet the definition for “low fat” to be eligible to bear the claim.

Although the petition requested that a “single-ingredient or mixture of frozen or canned fruits and vegetables that contains no fats or sugars in addition to the fats or sugars inherently present in the fruit or vegetable product” also be exempt from the low fat and minimum nutrient content requirements, we are not including these types of products in the exemptions at this time. We are able to easily determine which foods fall into the category of raw fruits and vegetables. With single-ingredient or mixtures of canned or frozen fruit and vegetable products, however, the categories are very broadly described, and it is difficult to know all of the types of products that may become included in an exemption. There are many food products that could conceivably be considered “fruit or vegetable products,” including products with varying degrees of processing, with numerous possibilities of ingredients in a “mixture,” or with a number of packaging variations. We determine that providing an exemption for raw fruits and vegetables will affect the public health positively, but it is unclear if all single-ingredient and mixtures of frozen or canned fruits and vegetables that contain no fats or sugars in addition to the fats or sugars inherently present in the fruit or vegetable product would have similar effects. Therefore, we

decline to extend any exemptions to this category of fruit and vegetable products at this time. However, we invite comments on this issue. If we receive information related to the possible iterations of canned and frozen fruit and vegetable products and also on their effects on health, we may consider expanding the foods included in the exemption in the future. Indeed, the petition encouraged FDA to proceed with exemptions solely for raw fruits and vegetables if the canned and frozen products required additional consideration.

IV. Description of Amendments to § 101.75

We are revising § 101.75(c) to: (1) Provide an exemption at § 101.75(c)(1) for raw fruits or vegetables from meeting the minimum nutrient content requirement in § 101.14(e)(6), and (2) revise § 101.75(c)(2)(ii) to provide an exemption from meeting the nutrient content requirements of “low fat” if the food is a raw fruit or vegetable.

V. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the interim final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the interim final rule. We believe that this interim final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this interim final rule concerns voluntary claims, we certify that the interim final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in

the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This interim final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Benefits and Costs of the Interim Final Rule

This interim final rule amends the regulation authorizing a health claim on the relationship between dietary saturated fat and cholesterol and risk of CHD by expanding its use to raw fruits and vegetables that do not meet the “low fat” definition (§ 101.62(b)(2)) and/or the minimum nutrient content requirement (§ 101.14(e)(6)). We believe that a business will only incur the additional costs of analyzing the health claim requirements and relabeling a previously ineligible product if the additional revenue it anticipates to generate by attracting more customers to its products is greater than these additional costs. This implies zero net costs from this interim final rule to such businesses, as well as to any businesses that decide not to include new CHD health claims on previously ineligible and now eligible fruits and vegetables.

We have very little data on the current consumer usage of CHD claims on labels and labeling, how these practices would change in response to this interim final rule, or how the consumers will respond to new CHD claims on raw fruits and vegetables that were previously ineligible for such claims. Because of this data gap, we acknowledge that we do not have sufficient evidence at this point to quantify the benefits and the administrative and labeling costs of this interim final rule. Industry will only use a new CHD health claim on the label and labeling of a previously ineligible product if it believes consumers are willing to pay more for such product or buy more of it due to the new CHD claim. If consumers value such new CHD health information, we expect there to be changes in consumer behavior that would result in public health benefits from the reduced annual number of CHD cases. The benefits therefore will only be realized, and labels will only be changed, if the new CHD information on labels and labeling increases consumer demand for the previously ineligible and now eligible for a CHD health claim fruits and vegetables. Otherwise, the firms will not use the CHD health claim on their labels for these fruits and vegetables.

The full analysis of economic impacts is available in the docket for this interim final rule (Ref. 9) and at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

VI. The Paperwork Reduction Act of 1995

This interim final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Analysis of Environmental Impact

We have determined under § 25.32(p) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

We analyzed this interim final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the interim final rule will have a preemptive effect on State law. Section 4(a) of the Executive order requires Agencies to “construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State law conflicts with the exercise of Federal authority under the Federal statute.” Section 403A(a) of the FD&C Act provides that no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce any requirement respecting any claim of the type described in section 403(r)(1) of the FD&C Act made in the label or labeling of food that is not identical to the requirement of section 403(r) of the FD&C Act.

This interim final rule amends the existing food labeling regulations on health claims for dietary saturated fat and cholesterol and risk of CHD (§ 101.75) in the label or labeling of food under section 403(r) of the FD&C Act. Although this interim final rule has a preemptive effect in that it precludes States from issuing any health claim labeling requirements for dietary saturated fat and cholesterol and the risk of CHD, this preemptive effect is consistent with what Congress set forth in section 403A(a) of the FD&C Act. Section 403A(a)(5) of the FD&C Act displaces both State legislative

requirements and State common law duties.

We have complied with all of the applicable requirements under Executive Order 13132 and have determined that the preemptive effects of this interim final rule are consistent with Executive Order 13132.

IX. Issuance of an Interim Final Rule and Immediate Effective Date

We are issuing this rule as an interim final rule, effective immediately, with an opportunity for public comment. Section 403(r)(7) of the FD&C Act authorizes us to make proposed regulations issued under section 403(r) of the FD&C Act effective upon publication pending consideration of public comment and publication of a final regulation, if the Agency determines that such action is necessary for public health reasons. This authority enables us to act promptly on petitions that provide for information that is necessary to: (1) Enable consumers to develop and maintain healthy dietary practices; (2) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or (3) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible. Proposed regulations made effective upon publication under this authority are deemed to be final Agency action for purposes of judicial review. The legislative history indicates that such regulations should be issued as interim final rules (H. Conf. Rept. No. 105–399, at 98 (1997)).

The petition requested that we issue an interim final rule amending § 101.75 to indicate that the evidence is compelling and the potential to encourage fruit and vegetable consumption is important for public health. It noted that we have used this authority to issue interim final rules for health claims a number of times (e.g., 65 FR 54685, September 8, 2000) and using an interim final rule would be consistent with our past practices.

We are satisfied that all three criteria in section 403(r)(7)(A) of the FD&C Act have been met for the amendment to the dietary saturated fat and cholesterol and risk of CHD health claim to permit raw fruits and vegetables that fail to comply with the “low fat” definition and/or the minimum nutrient content requirement, to be eligible to bear the claim. First, we conclude that these amendments for eligibility for foods to bear these health claims could help enable consumers to develop and maintain healthy dietary practices. Second, these amendments to this health claim will enable consumers

to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food. Third, these amendments to this health claim will ensure that scientifically sound nutritional and health information regarding the benefits of fruit and vegetable intake and reduction of CHD risk can be provided to consumers as soon as possible. The past few editions of the DGA have been moving away from a focus on total fat and have instead communicated to consumers the need to focus on type of fat consumed instead of total amount of fat. Recent editions of the DGA have also encouraged increased intake of fruits and vegetables for a healthful diet. Prompt issuance of an interim final rule that reflects the current recommendations is necessary for consumers to be able to have the most current information on nutrition and diet. Consumers will be better able to construct healthful diets if they have prompt access to information that is consistent with the current recommendations on fat content and on consumption of fruits and vegetables. Therefore, we are using the authority in section 403(r)(7)(A) of the FD&C Act to issue an interim final rule amending the general requirements for the health claim for dietary saturated fat and cholesterol and risk of CHD and to make the interim final rule effective immediately.

This regulation is effective upon publication in the **Federal Register**. We invite public comment on this interim final rule. We will consider modifications to this interim final rule based on comments made during the comment period. We will address comments and confirm or amend the interim final rule in a final rule.

X. References

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

1. Liu, S., J.E. Manson, I.M. Lee, et al. "Fruit and Vegetable Intake and Risk of Cardiovascular Disease: The Women's Health Study." *The American Journal of Clinical Nutrition*, 72: 922–928, 2000.
2. Appel, L.J., T.J. Moore, E. Obarzanek, et al. "A Clinical Trial of the Effects of Dietary Patterns on Blood Pressure." DASH Collaborative Research

Group. *The New England Journal of Medicine*, 336: 1117–1124, 1997.

3. U.S. Department of Health and Human Services and U.S. Department of Agriculture. "Dietary Guidelines for Americans, 2010. 7th Edition," 2010. Available at <http://health.gov/dietaryguidelines/2010/>.

4. "Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report." *Circulation*, 106: 3143–3421, 2002.

5. 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/>.

6. U.S. Department of Health and Human Services and U.S. Department of Agriculture. "Nutrition and Your Health, Dietary Guidelines for Americans," 2000. Available at <http://health.gov/dietaryguidelines/2000.asp>.

7. U.S. Department of Health and Human Services and U.S. Department of Agriculture. "Dietary Guidelines for Americans, 2005. 6th Edition," 2005. Available at <http://health.gov/dietaryguidelines/dga2005/document/default.htm>.

8. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)." Chapter 8, "Dietary Fats: Total Fat and Fatty Acids," 2002.

9. FDA/CFSAN, Food Labeling: Health Claims; Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease, Regulatory Impact Analysis, FDA–2013–P–0047.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

- 1. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

- 2. Section 101.75 is amended by revising paragraphs (c)(1) and (c)(2)(ii) to read as follows:

§ 101.75 Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease.

* * * * *

(c) * * *

(1) All requirements set forth in § 101.14 shall be met, except § 101.14(e)(6) with respect to a raw fruit or vegetable.

(2) * * *

(ii) *Nature of the food.* (A) The food shall meet all of the nutrient content requirements of § 101.62 for a "low saturated fat" and "low cholesterol" food.

(B) The food shall meet the nutrient content requirements of § 101.62 for a "low fat" food, unless it is a raw fruit or vegetable; except that fish and game meats (*i.e.*, deer, bison, rabbit, quail, wild turkey, geese, and ostrich) may meet the requirements for "extra lean" in § 101.62.

* * * * *

Dated: December 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29997 Filed 12–16–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 878, 880, and 895

[Docket No. FDA–2015–N–5017]

RIN 0910–AH02

Banned Devices; Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling. Consequently, FDA is banning these devices.

DATES: This rule is effective on January 18, 2017.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the