



JUL 16 2020

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RE: Petition for Authorized Health Claim for Oleic Acid in Edible Oils and a
Reduction in the Risk of Coronary Heart Disease - Docket Number
FDA-2017-Q-0807

Dear Dr. Matulka:

This update letter concerns the qualified health claim petition, submitted on behalf of Corbion Biotech, Inc., that requested that the Food and Drug Administration (FDA or we, or the agency) review a petition for a qualified health claim characterizing the relationship between the consumption of high oleic acid edible oils and reduced risk of coronary heart disease (CHD). The FDA is issuing an update letter to the letter of enforcement discretion we issued on November 19, 2018 (hereinafter, “oleic acid letter of enforcement discretion”).¹ In the oleic acid letter of enforcement discretion, the agency describes several factors that FDA considers in the exercise of its enforcement discretion for this qualified health claim, including a qualifying level of oleic acid to be eligible to bear the qualified health claim. It has come to the agency’s attention that in describing the qualifying level enforcement discretion factor, we incorrectly divided the qualifying level by four eating occasions. This update letter clarifies the qualifying level of oleic acid in edible oils and edible oil blends eligible to bear this qualified health claim. Clarifications described in this update letter do not affect the other enforcement discretion factors that FDA intends to consider for use of this qualified health claim, and this clarification does not impact the qualified health claim language described in the oleic acid letter of enforcement discretion.

As we explained in the oleic acid letter of enforcement discretion, the general requirements for health claims provide that, if the claim is about the effects of consuming the substance at other than decreased dietary levels, the level of the substance must be sufficiently high and in an appropriate form to justify the claim. Where no definition for “high” has been established, the claim must specify the daily dietary intake necessary to achieve the claimed effect (21 CFR 101.14(d)(2)(vii)).

Consistent with these general requirements, we described in the oleic acid letter of enforcement

¹ Letter of Enforcement Discretion - Oleic Acid in Edible Oils and a Reduction in the Risk of Coronary Heart Disease (Docket Number FDA-2017-Q-0807) <https://www.fda.gov/media/118199/download>.

discretion one factor that the agency intends to consider in the exercise of its enforcement discretion for qualified health claims about oleic acid in edible oils was a qualifying level of oleic acid. Specifically, to achieve the benefit the qualified health claim describes, and supportive, but not conclusive credible evidence supports, consumers replace daily consumption of oils that are higher saturated fatty acids (SFAs) with edible oils that are high in oleic acid content (with at least 70% oleic acid per serving). Therefore, to determine an appropriate qualifying level, FDA first determined the minimum effective amount of oleic acid in high oleic acid oils (with at least 70 % of oleic acid per serving) necessary to be replaced in place of saturated fatty acids (SFAs) by calculating the difference in the amount of oleic acid, in grams, between the high oleic acid oils and high-SFAs diets from five controlled studies that demonstrated a reduction in TC and LDL-C (Gillingham et al., 2011; Mata et al., 1997; Kien et al., 2014; Lichtenstein et al., 1993; Zock et al., 1994). The lowest difference that was reported in these studies was used to determine the minimum amount of oleic acid necessary to achieve the relevant benefits. Although, the minimum amount of oleic acid was reported to be lowest in the Lichtenstein et al. (1993) study (about 11 grams of oleic acid per day), the study by Gillingham et al. (2011), with the next lower minimum effective dose, was considered a better representative study for the U.S. population. The Gillingham study included an age group ranging from 18 to 65 years old, while the age range of the subjects in the Lichtenstein study was from 44 to 72 years. Also, the sample size in the Gillingham study (36 males and females) was larger than the Lichtenstein study (15 males and females). For these reasons, the Gillingham study was used to determine the minimum amount of oleic acid consumed per day. Based on our calculation described in the oleic acid letter of enforcement discretion, the minimum amount of oleic acid needed to replace SFAs that may result in significant reduction in TC and LDL-C is about 15 grams per day.

Thus, consuming about 20 grams of the high oleic acid oils or high oleic acid oil blends (containing at least 70% of oleic acid per serving) per day provides about 15 grams of oleic acid. Twenty grams of high oleic acid-containing edible oil is about 1½ tablespoons.

In the oleic acid letter of enforcement discretion, we went further to describe that to be eligible to bear the qualified health claim, the high oleic acid-containing oil must contain 5 grams of oleic acid per Reference Amount Customarily Consumed (RACC). As we described in the oleic acid letter of enforcement discretion, a provision of the general requirements for health claims requires that a health claim enable the public to comprehend the information provided and to understand the relative significance of such information in the context of the total daily diet (see Section 403(r)(3)(B)(iii) of the Act). For health claims, FDA has considered that a typical daily food consumption pattern is composed of 3 meals and a snack or four eating occasions (58 FR 2302-2379; January 6, 1993). We described that four eating occasions per day were used to define the qualifying level for three previous CHD-related health claims: soy protein (64 FR 57700, 57713, October 26, 1999); β-glucan soluble fiber from whole oats (62 FR 3584, 3592, January 23, 1997); and soluble fiber from psyllium seed husks (63 FR 8103, 8109, February 18, 1998). FDA also used this approach to identify 6 grams olive oil, 4.75 grams canola oil, 4.0 grams corn oil, and 5 grams of soybean oil per RACC as the qualifying level for products to bear the qualified health claim for these vegetable oils.

Given the agency's past approach, we also used this same approach in our oleic acid letter of enforcement discretion in that we considered four eating occasions at which consumers might consume high oleic acid-containing oils, or high oleic-acid containing edible oil blends. Based on our calculations, it was determined that the minimum amount of oleic acid necessary to achieve the relevant benefits, when replacing saturated fatty acids, was about 15 grams per day. Twenty grams of edible oils that contain at least 70% of oleic acid per serving will provide 15 grams oleic acid per RACC. Thus, we divided 20 grams, about 1½ tablespoons, by 4 and determined that to be eligible to bear the qualified health claim, the high oleic acid-containing oil, or the high oleic acid-containing edible oil blend, must contain 5 grams of oleic acid per RACC.

It has come to our attention that this approach of dividing the minimum effective amount (20 grams of edible oils that contain at least 70% of oleic acid per serving) by 4 eating occasions to reach a qualifying level of 5 grams of oleic acid per RACC has led to confusion and is not consistent with the supporting data. Since we determined that the only products that can bear the qualified health claim are edible oils and edible oil blends, there is no need to divide the minimum amount of oleic acid containing at least 70% of oleic acid by 4 eating occasions. A consumer could meet the daily consumption of 1½ tablespoons of high oleic acid edible oils or edible oil blends in a single eating occasion, perhaps when the amount is used in cooking food or using this amount as an ingredient in the preparation of a food. We note that the qualified health claim for high oleic acid-containing edible oils (with at least 70 percent of oleic acid) and CHD is distinct from previous qualified health claim letters of enforcement discretion regarding consumption of vegetable oils and reduced risk CHD (i.e., olive oil,² canola oil,³ corn oil,⁴ and soybean oil⁵) because, as described in the oleic acid letter of enforcement discretion, the only foods eligible to bear the oleic acid qualified health claim are edible oils. This is distinguished from the previous letters of enforcement discretion for vegetable oils and CHD, where the foods eligible to bear the qualified health claim included foods beyond the oil itself, including, for example, salad dressings, vegetable oil spreads, and other vegetable oil-containing foods like baked goods.

Therefore, in this update letter we are providing clarification that that the minimum amount of oleic acid necessary to achieve the relevant benefits, when replacing SFAs, is about 15 grams per day. Thus, consumption of 20 grams of high oleic acid-containing oils or high oleic acid-containing edible oil blends per day provides about 15 grams of oleic acid. Twenty grams of high oleic acid-containing edible oil is about 1½ tablespoons. This qualified health claim language provides information so that consumers can understand the relative significance of the claim in the context of the total daily diet.

As we noted above, this change to the qualifying level does not affect the other enforcement

² Letter of Enforcement Discretion - Monounsaturated Fatty Acids from Olive Oil and Coronary Heart Disease (Docket No. FDA-2003-Q-0080).

³ Letter of Enforcement discretion - Unsaturated Fatty Acids from Canola Oil and Reduced Risk of Coronary Heart Disease (Docket No. FDA-2006-Q-0161).

⁴ Letter of Enforcement Discretion - Corn Oil and Corn Oil-Containing Products and a Reduced Risk of Heart Disease (Docket No. FDA-2006-P-0002).

⁵ Letter of Enforcement Discretion - Soybean Oil and Reduced Risk of Coronary Heart Disease (Docket No. FDA-2016-Q-0995).

discretion factors that FDA will consider for use of the claim, nor the claim language. Therefore, the qualified health claim language remains unchanged from our oleic acid letter of enforcement discretion, and FDA intends to continue to consider exercising its enforcement discretion for the following qualified health claims:


“Supportive but not conclusive scientific evidence suggests that daily consumption of about 1½ tablespoons (20 grams) of oils containing high levels of oleic acid, when replaced for fats and oils higher in saturated fat, may reduce the risk of coronary heart disease. To achieve this possible benefit, oleic acid-containing oils should not increase the total number of calories you eat in a day. One serving of [x] oil provides [x] grams of oleic acid (which is [x] grams of monounsaturated fatty acid).”

“Supportive but not conclusive scientific evidence suggests that daily consumption of about 1½ tablespoons (20 grams) of oils containing high levels of oleic acid, may reduce the risk of coronary heart disease. To achieve this possible benefit, oleic acid-containing oils should replace fats and oils higher in saturated fat and not increase the total number of calories you eat in a day. One serving of [x] oil provides [x] grams of oleic acid (which is [x] grams of monounsaturated fatty acid).”

FDA intends to consider exercising its enforcement discretion for the above qualified health claims when all factors for enforcement discretion identified in the oleic acid letter of enforcement discretion are met,⁶ with the exception of the updated qualifying level as described in this update letter. Qualified health claims on the label or in the labeling of high oleic acid oils are required to meet all applicable statutory and regulatory requirements under the Act, with the exception of the requirement that a health claim meet the significant scientific agreement standard and the requirement that the claim be made in accordance with an authorizing regulation, and any specific exceptions from the general requirements for health claims that has been included in the factors for enforcement discretion identified in this letter. This includes general requirements for health claims in 21 CFR 101.14 (e.g., general requirements set forth in 21 CFR 101.14(e)(3) for disclosure statements that comply with 101.13(h) for saturated fat content, as appropriate).

Sincerely,



 Claudine Kavanaugh, PhD, MPH, RD
Director
Office of Nutrition
and Food Labeling
Center for Food Safety
and Applied Nutrition

⁶ Letter of Enforcement Discretion - Oleic Acid in Edible Oils and a Reduction in the Risk of Coronary Heart Disease (Docket Number FDA-2017-Q-0807) <https://www.fda.gov/media/118199/download>.