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MEMORANDUM

From: Steven B. Steinborn
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Re: **FDA Announces Qualified Health Claim for Consuming Oils with High Levels of Oleic Acid to Reduce Coronary Heart Disease Risk**

The U.S. Food and Drug Administration (FDA) last month announced it would exercise enforcement discretion over two qualified health claims characterizing the relationship between the reduced risk of coronary heart disease (CHD) and the consumption of oleic acid in edible oils (containing at least 70% of oleic acid per serving) when consumed in place of saturated fats (SFA). 1/ Oleic acid is the most common monounsaturated fatty acid (MUFA) and can be found naturally in numerous food sources, including edible oils, meat, cheese, nuts, seeds, eggs, pasta, milk, olives, and avocados. 2/ Oleic acid has been used as food or as components of food, such as olive oil, by man for many years, and has been approved as a direct additive to foods. 3/

To be eligible to bear the high oleic acid edible oils and CHD qualified health claim, the high oleic acid-containing oil must contain 5 grams of oleic acid per reference amount customarily consumed (RACC). 4/ Eligible products may bear either of the following two approved qualified 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)."

1/ Press Announcement, Statement from FDA Commissioner Scott Gottlieb, M.D., on a new qualified health claim for consuming oils with high levels of oleic acid to reduce coronary heart disease risk (*hereinafter* "Commissioner's Statement"), available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626210.htm; FDA Response to Petition for Authorized Health Claim For Oleic Acid In Edible Oils And Reduction In The Risk Of Coronary Heart Disease, available at: https://www.fda.gov/downloads/Food/LabelingNutrition/UCM624755.pdf.
2/ FDA Response at 4-5.
3/ FDA Response at 5.
4/ FDA Response at 14.

"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."

This language addresses the agency's concern that consumers realize the health benefits come not from consuming oils high in oleic acid alone, but rather from "replac[ing] fats and oils higher in SFA" with oils high in oleic acid in such a way that does not increase caloric intake. 5/

Background

A health claim characterizes the relationship between a substance and a disease or health-related condition, including the relationship between a substance and a reduction in risk of contracting a particular disease or health-related condition. 6/ FDA relies on health claims both to inform consumers and to encourage the food industry to reformulate products. 7/ FDA permits the use of "authorized health claims" and "qualified health claims." 8/ Authorized health claims must satisfy the "validity requirement"— i.e., meet the "significant scientific agreement" standard – and are formalized through notice-and-comment rulemaking. 9/ Qualified health claims differ in that they are supported by some scientific evidence, but do not meet the "significant scientific agreement" standard. 10/ FDA does not "approve" qualified health claims through rulemaking. 11/ Rather, FDA, through a letter of enforcement discretion, will agree not to object to the use of a claim (i.e., will exercise enforcement discretion), provided appropriate disclaimer language is incorporated into the qualified claim "to convey the limits on the level of scientific evidence supporting the relationship or to prevent the claim from being misleading in other ways." 12/

FDA considers all available data, both provided in the petition and elsewhere, to determine whether scientific evidence supports the relationship between the substance and the disease. 13/ "FDA

5/ FDA Response at 14-15.
6/ 21 C.F.R. 101.14.
7/ Commissioner's Statement.
8/ 21 C.F.R. 101.14(c); Guidance for Industry: FDA's Implementation of "Qualified Health Claims": Questions and Answers; Final Guidance ("Qualified Health Claims Questions & Answers") (May 12, 2006), available at: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053843.htm; Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements ("Interim Procedures for Qualified Health Claims") (July 2003), available at: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053832.htm.
9/ 21 C.F.R. 101.14(c) (requiring claims be supported by the totality of publicly available scientific evidence).
10/ Qualified Health Claims Questions & Answers.
11/ Qualified Health Claims Questions & Answers.
12/ Qualified Health Claims Questions & Answers; FDA Response at 12. The requirements for submitting a petition are set out in 21 C.F.R. 101.70.
13/ FDA Response at 2.

focuses its review on reports of human intervention and observational studies." 14/ Though other types of data and information cannot by themselves support a health claim relationship, the agency often relies on them to develop an understanding of the substance or the disease. 15/ A review of FDA's finding is useful in understanding how the agency evaluates nutrition health science.

Assessment of Scientific Evidence Relating to CHD and Edible Oils High in Oleic Acid

FDA evaluated 27 studies that investigated the relationship between consumption of edible oils with high oleic acid and risk of CHD. 16/ Scientific conclusions could be drawn from seven of the 27 publications. 17/ According to FDA, six studies found diets replacing SFA with oils containing high levels of oleic acid resulted in a modest lowering of the total cholesterol and low-density lipoprotein (LDL) cholesterol. One study showed no significant effect. Most importantly, none of the studies found that eating oleic acid-containing oils alone had beneficial heart effect; rather, they must be used as a replacement for other types of oils high in SFA. 18/

Enforcement Discretion Regarding Other Labeling Claims

"Low" Claims

By their nature, edible oils exceed FDA criteria for "low fat" and "low saturated fat." However, FDA concurs with current dietary guidelines that emphasize diets low in SFA over diets low in total fat, so the agency will exercise enforcement discretion over "low fat" claims. 19/ Similarly, FDA will exercise enforcement discretion over "low saturated fat" claims despite the fact that sunflower oil, safflower oil, and olive oil fail one or both prongs of the saturated fat criteria. 20/ Because the substances are all plant-based, they contain no cholesterol and thus products must meet criteria for "low cholesterol" claims. 21/

Total fat, Saturated Fat, and Cholesterol Criteria for CHD-related Health Claims

Generally, a food may not bear a health claim if that food exceeds any of the disqualifying nutrient levels for total fat, SFA, cholesterol, or sodium. 22/ By their nature, edible oils exceed FDA criteria for "total fat," and olive oil exceeds the criteria for "saturated fat." However, in concurrence with the current dietary guidelines that emphasize the importance of diets low in SFA over diets low in total fat and the existing qualified health claim for olive oil, FDA will not exercise enforcement discretion

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14/ FDA Response at 2.
15/ FDA Response at 2.
16/ FDA Response at 8.
17/ FDA Response at 9; Gillingham et al., 2011; Mata et al., 1997; Choudhury et al., 1995; Kein et al., 2014; Lichtenstein et al., 1993; Mattson and Grundy, 1985; Zock et al., 1994. Other studies were discounted to various shortcomings (e.g., did not report the exact amount of oleic acid used, did not provide a high oleic acid edible oil, did not include a control group, or used an inappropriate control group).
18/ Commissioner's Statement.
19/ FDA Response at 16-17.
20/ FDA Response at 17.
21/ FDA Response at 17.
22/ 21 C.F.R. 101.14(a)(4), (e)(3); FDA Response at 18.

over these claims. 23/ Conversely, FDA will consider disqualifying levels of cholesterol and sodium. 24/

10% Minimum Nutrient Content Requirement

Generally, a food may not bear a health claim if that food does not meet a 10% nutrient content requirement for certain vitamins (vitamin A, vitamin C, iron, calcium, protein, and fiber). 25/ Oleic acid-containing oils do not meet this requirement. However, in keeping with previous decisions, FDA intends to exempt these oils from the requirement because "such exemption[] could assist consumers in maintaining healthy dietary practices." 26/

Conclusion

Subject to changes or developments in scientific information and consumer consumption patterns, FDA intends to exercise enforcement discretion for qualified health claims that meet FDA's criteria and use the approved language.

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We will continue to monitor developments on FDA's approval of health claims. Please contact us if you have any questions.

23/ FDA Response at 19; Letter Responding to Health Claim Petition dated August 28, 2003: Monounsaturated Fatty Acids from Olive Oil and Coronary Heart Disease, available at: http://wayback.archive-it.org/7993/20171114183732/https:/www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072963.htm.

24/ FDA Response at 20.

25/ 21 C.F.R. 101.14(e)(6); FDA Response at 20.

26/ FDA Response at 20-21.