

High Oleic Acid Edible Oils May Now Claim Reduction of Coronary Heart Disease Risk

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Recently, the Food and Drug Administration (FDA) announced that it had granted a [2016 Citizen Petition](#) seeking a qualified health claim characterizing the relationship between the consumption of oleic acid in edible oils and reduced risk of coronary heart disease (CHD). The Citizen Petition originally requested that FDA approve an authorized health claim; however, the agency concluded that "proposed health claim did not meet the "significant scientific agreement" standard under §403(r)(3)(B)(1) of the [Federal Food, Drug, and Cosmetic] Act for conventional foods (21 CFR 101.14(c))." As such, the petitioner agreed to seek review of the petition as a qualified health claim. A qualified health claim means that the claims "are supported by some scientific evidence, but do not meet the significant agreement standard." See FDA's Questions and Answers on Health Claim Labeling, available [here](#).

Upon reviewing the scientific evidence submitted for the qualified health claim, FDA determined that "there is supportive scientific evidence for a qualified health claim for high oleic acid edible oils and CHD, provided that the qualified health claim is **appropriately worded so as not to mislead consumers**." In a [November 19, 2019](#) statement, FDA noted that "[t]he science behind the new qualified health claim for oleic acid, while not conclusive, is promising." In allowing the claim, FDA reviewed the results from seven small clinical studies that evaluated the relationship between consumption of oils containing high levels of oleic acid (at least 70% per serving) and improved cholesterol levels, which indicated a reduced risk for coronary disease. According to FDA, however, "none of the studies found that eating oleic acid-containing oils had a beneficial heart effect unless they replaced other types of fats and oils higher in saturated fats I the diet."

FDA intends to consider exercising its enforcement discretion for the following qualified health claims on product labels:

"Supportive but not conclusive scientific evidence suggests that daily consumption of about 1 ½ 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 effect, 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 1 1/2 tablespoons (20 grams) of oils containing high levels of oleic acid, may reduce the risk of coronary heart disease. To achieve this possible effect, 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)."

Edible oils must contain at least 70 percent oleic acid in order to meet the criteria for this qualified claim. Some examples of edible oils include: high oleic sunflower oil, high oleic safflower oil, high oleic canola oil, olive oil and high oleic algal oil.