FDA Approves Health Claim for High Oleic Oils

Author : Dr. Mark Messina

Date : January 10, 2019

A qualified health claim for high oleic oils was recently approved by the U.S. Food and Drug Administration.

With the new health claim consumers now have two soybean oils, conventional or commodity soybean oil, which is high in polyunsaturated fat, and high oleic soybean oil, which is high in oleic acid, that, according to the FDA, lower blood cholesterol levels and risk of coronary heart disease.

Language suggested by the FDA for the new claim is as follows:

“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.”

To be eligible to bear the high oleic acid edible oils and coronary heart disease 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 reference amount commonly consumed (RACC). The basis for the 5-gram criteria is two-fold. First, research suggests the minimum amount of oleic acid needed to replace saturated fat that may result in significant reduction in total cholesterol and LDL-cholesterol is about 15 grams per day. Consuming about 20 grams of the high oleic acid oils (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. Second, it is assumed that it is reasonable to consume 4 “meals” (3 means and a snack) per day, thus, 5 grams per meal will provide the necessary 20 grams of oil.

This reasoning is identical to the reasoning adopted for the soy protein and coronary heart disease claim whereas to qualify for the claim a product must provide at least 6.25 g soy protein per RACC, since 25 g/d soy protein was established by the FDA as the threshold intake for cholesterol reduction.

The claim was based on the result of the seven studies shown in the table.[1-7] None of the intervention studies suggested that edible oils containing high oleic acid, independent of saturated fat displacement in fats and oils, would lower total cholesterol and LDL-cholesterol levels. Therefore, the favorable impact of lowering the total cholesterol and LDL-cholesterol may be due to the decreased levels of saturated fat in fats and oils and not an independent effect of consumption of edible oils containing at least 70% of oleic acid per serving.

Although the FDA concluded that the scientific evidence in support of high oleic acid oil is credible and supports the substance/disease relationship, it was determined that an unqualified claim, that is, a claim wherein there is significant scientific agreement, was unwarranted. This determination was made for the following reasons: 1) small number of studies with a moderate methodological quality 2) small number of participants per study 3) one study providing a liquid formula diet that is not representative of diets consumed by the healthy US population 4) one study that did not show any effect of high oleic acid edible oil and 5) lack of an independent effect of high oleic acid in edible oils (containing at least 70% of oleic acid per serving).

Finally, none of the seven trials upon which the health claim was based intervened with high oleic soybean oil. However, high oleic soybean oil, which is comprised of >70% oleic acid, has been shown to lower LDL-cholesterol as reported by Lichtenstein et al.[8] in 2006 and more recently by David J. Baer (USDA), in work that has been presented but not yet published in final manuscript form.

Author/year/Reference Location Design