subjects randomized to receive a lower percentage of calories from fat tend to have a modest reduction in body weight compared to individuals given higher amounts of fat. However, longer-term studies (one year or longer) have shown that fat consumption within the range of 18 – 40% of energy has little or no effect on body fatness. The authors also note that obesity in the U.S. has increased dramatically at a time when fat intake (expressed as a percent of energy) has decreased substantially.

Observational data on the association between olive oil and indicators of obesity are limited, but tend to support the conclusions expressed by Willett and Leibel (2002). González *et.al.* (2000) found an inverse association between olive oil consumption and BMI among 25,814 Spanish women when expressed as grams per day ($p<0.0001$), but not as percent of energy ($p = 0.2402$). Olive oil was not related to BMI among 15,635 men in the same population. Ferro-Luzzi *et.al.* (2002) published a review paper that concluded increasing obesity rates in Greece are associated with high fat intakes, but the paper was strongly criticized by Trichopoulos (2002) for being "unscientific" and failing to adequately address the effect of physical inactivity on obesity. Garaulet *et.al.* (2001) found that central obesity was inversely correlated with the concentration of MUFAs in adipose tissue from 84 obese subjects, and Fernández-Jarne *et.al.* (2002) found no difference in BMI between 171 CHD patients and an equal number of healthy controls despite a significant difference in olive oil consumption.

Recent experimental data show that dietary fat need not be restricted in order to achieve and maintain significant weight reduction for up to 1.5 years. McManus *et al.* (2001) reported that subjects fed a moderate-fat, weight-reduction diet containing olive oil and other sources of

unsaturated fatty acids were significantly more likely to remain compliant, and lost more weight after 18 months than subjects fed a low-fat, high-carbohydrate diet. This increased adherence to a weight loss regimen was attributed largely to increased palatability of the foods in the moderate-fat diet.

In addition, two randomized intervention studies designed to test the safety and efficacy of carbohydrate-restricted diets (Foster *et.al.*, 2003; Samaha *et.al.*, 2003) found that subjects who were instructed to limit intake of carbohydrates but permitted *ad libitum* consumption of fat and protein, lost more weight than subjects instructed to consume a low-fat, high-carbohydrate diet.

The reason why olive oil does not appear to contribute to excess weight gain is not clearly understood. However, Piers *et.al.* (2002) reported increased postprandial fat oxidation rates after a high olive oil meal than after a high SFA (cream) meal in humans, which suggests there may be a metabolic effect. In addition, olive oil may be more satiating than other dietary fats. A recent small study (Wansink and Linder, 2003) showed that restaurant patrons consumed 23% less bread when it was served with olive oil than when it was served with butter.

In conclusion, a considerable body of data suggest that daily incorporation of 13.5 grams of olive oil into a low-saturated fat diet is unlikely to contribute to weight gain or obesity. Data from the 1994-96 and 1998 CSFII surveys show that olive oil consumers (either as the pure oil or from the pure oil and that derived from foods) do not consume more calories than subjects whose diets did not contain olive oil. In addition, there were no differences in BMI between olive oil consumption groups including all foods, and a significantly lower BMI among consumers of

pure olive oil vs. non-consumers. Furthermore, the observational data suggest that dietary MUFAs (and olive oil in particular) are not associated with BMI, and may be inversely associated in some populations. The experimental data clearly show that moderate- or high-fat diets can result in greater weight loss than low-fat, high-carbohydrate regimens. Finally, as the CSFII data show, olive oil is eaten with a variety of foods. This usage pattern suggests that consumers encouraged to include 13.5 grams of olive oil per day into a moderate-fat diet that is low in SFA and cholesterol are likely to substitute it for other dietary fats that are higher in SFAs as is intended by the claim. The NAOOA, therefore, believes that the proposed claim is unlikely to contribute to excess energy intake or obesity.

IX. PROPOSED MODEL HEALTH CLAIM

The following model statements are recommended for the proposed claim:

> "Monounsaturated fats from 13.5 grams per day of olive oil (one tablespoon) may reduce your risk of heart disease when included in a moderate-fat diet low in saturated fat and cholesterol."

> "Moderate-fat diets low in saturated fat and cholesterol that include monounsaturated fats from olive oil (13.5 grams, or one tablespoon) per day may reduce your risk of heart disease."

The disclaimer statement, "See nutrition information for fat and saturated fat content," would appear as part of the claim without any intervening material and in the same type size and boldness for products that are essentially pure olive oil.

The NAOOA believes that these model statements accurately reflect the totality of available science that demonstrates MUFAs from olive oil reduce serum T-C and LDL-C when consumed as part of a moderate-fat diet low in SFAs. The proposed model statements specify the amount of olive oil necessary to achieve the beneficial effect, and clearly state that MUFAs must be included in a diet low in saturated fat. This wording is intended to convey the importance of limiting dietary SFAs, and the fact that olive oil should be "included" in the diet rather than added to it.

X. DETERMINATION OF COMPLIANCE

The proposed claim requires that products contain at least 3.4 grams of olive oil per RACC in order to qualify. In cases where the claim appears on products that are essentially pure olive oil, compliance will be obvious because the RACC for such products is 30 g, and the weight of any non-olive oil ingredients are insignificant. However, for products that are composed primarily of non-olive oil ingredients, compliance with the claim will not be obvious. Furthermore, there are no AOAC approved methods that would allow FDA to determine the olive oil content of such products analytically.

The NAOOA proposes that information supplied by the manufacturer be used to establish compliance when the claim is used on formulated foods that are not essentially pure olive oil.

This approach is similar to that used to determine the eligibility of products to bear the health claim for soy protein and CHD (21 CFR § 101.82 (c)(2)(ii)(B)). This provision requires manufacturers to maintain records such as, "... recipes or formulations, purchase orders for ingredients...", or any other information that reasonably substantiates the claim. In addition, NAOOA proposes that manufacturers choosing to make the claim be required to maintain records sufficient to substantiate the claim for as long as the products are marketed, and to provide these records, on written request, to FDA.

XI. REQUEST FOR INTERIM FINAL RULE

FDA has the authority under Section 403(r)(7) of the Federal Food, Drug, and Cosmetic Act to issue an interim final rule for a health claim if such action is necessary for public health. The NAOOA believes that the three criteria specified by the act that enable FDA to take this approach have been satisfied:

A. "Enable consumers to develop and maintain healthy dietary practices."

The scientific evidence demonstrates that consuming MUFAs from olive oil is a healthy dietary practice. As noted earlier, a meta-analysis of human intervention studies shows that the inclusion of 13.5 grams of olive oil per day in a diet that is low in saturated fat and cholesterol would reduce blood T-C and LDL-C by approximately 5%. This reduction equates to a decrease in CHD incidence of approximately 10%. In addition, such a practice is consistent with recommendations of the NHLBI (National Cholesterol Education Program, 2001), the American Heart Association (Krauss *et.al.*, 2000) and the Dietary Guidelines for Americans (U.S. Department of Agriculture, U.S. Department of Health and Human Services, 2000). The

proposed claim would provide an important new opportunity to educate consumers and would serve as an ongoing reminder about this healthy practice.

B. "Enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food."

Packages of olive oil have not been permitted to provide information on its cardioprotective benefits, which has restricted the dissemination of this information and failed to provide an incentive for the food industry to develop and market additional olive oil-containing products that are low saturated fat and cholesterol. As a result, consumers are generally focused on reducing their intake of total fat rather than substituting MUFAs for SFAs. Twenty-four percent of a sample of 1,001 supermarket shoppers reported that they were "eating less fats/oils," in a recent survey (Food Marketing Institute, 2003), but not a single consumer mentioned reducing their intake SFAs or increasing that of unsaturated fats. Publication of an interim final rule would reinforce this message. In addition, publication of an interim final rule would provide an immediate incentive for food manufacturers to develop additional olive oil-containing foods that are low in SFA and cholesterol.

C. "Ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible"

An interim final rule would shorten the length of time necessary to provide information on the cardioprotective properties of olive oil in labeling by approximately one year. A 10% reduction in CHD incidence could result in a yearly savings of 51,000 lives, prevent 340,000

hospitalizations, and reduce health care costs by $19 billion based on statistics compiled by the American Heart Association (2002).

In conclusion, the NAOOA believes that all three conditions for an interim final rule have been met. FDA took this approach for the sterol/stanol esters health claim (65 FR 54686 at 54713), and we believe the public health rationale to do the same for MUFAs from olive oil is even more compelling.

XII. ENVIRONMENTAL IMPACT ASSESSMENT

The NAOOA chooses to avail itself of the categorical exclusion with respect to an environmental impact assessment provided by 21 CFR § 25.32(p). Accordingly, an environmental impact assessment is not required for this submission.

XIII. CONCLUSION

The NAOOA respectfully requests that FDA issue an interim final rule authorizing the use of the proposed claim as quickly as possible. The totality of evidence presented in this petition clearly demonstrates that including MUFAs from 13.5 grams per day of olive oil in a moderate-fat diet that is low in saturated fat and cholesterol would reduce the risk of CHD. In addition, authorization of the proposed claim would help educate consumers about the importance of using MUFAs to displace SFAs in the diet, and provide an incentive for the food industry to develop more olive oil/MUFA-containing foods that are low in SFA and cholesterol.

XIV. PROPOSED REGULATORY TEXT

§ 101._____ Health claims: monounsaturated fatty acids from certain foods and risk of coronary heart disease (CHD).

(a) *Relationship between diets that are low in saturated fat and cholesterol and that include monounsaturated fatty acids from certain foods and risk of CHD.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease (CHD) is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL) cholesterol levels are associated with increased risk of developing coronary heart disease. High CHD rates occur among people with total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 millimole per liter (mmol/l)) or above and with LDL cholesterol levels of 160 mg/dL (4.13 mmol/l) or above. Borderline high-risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/l) for total cholesterol, and from 130 to 159 mg/dL (3.36 to 4.11 mmol/l) for LDL cholesterol. The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of CHD.

(2) Populations with a low incidence of CHD tend to have relatively low blood total cholesterol and LDL-cholesterol levels. These populations also tend to have dietary patterns that are moderate in total fat composed predominantly of unsaturated (i.e. monounsaturated and polyunsaturated) fatty acids from certain foods, such as olive oil, and also are relatively high in plant foods that contain dietary fiber and other potentially cardioprotective components.

(3) Scientific evidence demonstrates that diets that include monounsaturated fatty acids and are low in saturated fat and cholesterol may reduce the risk of CHD.

(b) *Significance of the relationship between moderate-fat diets that are low in saturated fat and cholesterol and that include monounsaturated fatty acids from certain foods and the risk of CHD.* (1) CHD is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for CHD is a major public heath goal that can assist in reducing risk of CHD. High blood total and LDL cholesterol are major modifiable risk factors in the development of CHD.

(2) Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. One of the major public health recommendations relative to CHD risk is to consume less than 7 percent of calories from saturated fat and 25-35 percent of calories from total fat with up to 20 percent of calories from monounsaturated fatty acids. Recommended daily cholesterol intakes are 300 milligrams (mg) or less per day. Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total- and LDL-cholesterol levels. Monounsaturated fatty acids from certain foods, when included in a low saturated fat and cholesterol diet, also helps to lower blood total- and LDL-cholesterol levels.

(c) *Requirements* – (1) General. All requirements set forth in § 101.14 shall be met, except as set forth in this paragraph. The label and labeling of foods containing the claim shall declare the content of polyunsaturated fatty acids and monounsaturated fatty acids per serving as set forth in § 101.9(c)(2)(iii)-(iv).

(2) *Specific requirements – (i) Nature of the claim.* A health claim associating moderate-fat diets that are low in saturated fat and cholesterol and that include monounsaturated fatty acids from certain foods with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets that are moderate in total fat and low in saturated fat and cholesterol and that include monounsaturated fatty acids from certain foods "may" or "might" reduce the risk of heart disease.

(B) In specifying the disease, the claim uses the terms "heart disease" or "coronary heart disease";

(C) In specifying the substance, the claim uses the term "monounsaturated fatty acids" or "monounsaturated fats" qualified by the name of the eligible source of monounsaturated fatty acids provided in paragraph (c)(2)(ii) of this section. Additionally, the claim may use the name of the food product that contains the monounsaturated fatty acids;

(D) In specifying the fat component, the claim uses the terms "saturated fat" and "cholesterol";

(E) The claim does not attribute any degree of risk reduction for CHD to moderate-fat diets that are low in saturated fat and cholesterol and that include monounsaturated fatty acids from the eligible food sources from paragraph (c)(2)(ii) of this section; and

(F) The claim does not imply that consumption of moderate-fat diets that are low in saturated fat and cholesterol and that include monounsaturated fatty acids from the eligible food sources from paragraph (c)(2)(ii) of this section is the only recognized means of achieving a reduced risk of CHD;

(G) The claim specifies that a daily dietary intake of 10 grams of monounsaturated fatty acids is necessary to reduce the risk of coronary heart disease and/or specifies the amount of one or more food sources from paragraph (c)(2)(ii) of this section that contains 10 grams of monounsaturated fatty acids, expressed in grams and/or units of common household measure;

(ii) *Nature of the substance* – *Cis*-monounsaturated fatty acids as defined in § 101.9(c)(2)(iii), from the food sources listed below:

(1) Olive oil

(2) [Reserved]

(iii) *Nature of the food eligible to bear the claim.* (A) The food product shall contain a minimum of 3.4 grams of olive oil, which contains 2.5 grams of monounsaturated fatty acids as described in paragraph (c)(2)(ii), per reference amount customarily consumed (RACC), as determined by reference to § 101.12. FDA will assess whether the required amount of olive oil is present for products other than those that are essentially pure olive oil as specified in paragraphs (c)(2)(iii)(B), (D) and (F) based on information identified and supplied by manufacturers, such as recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the amount of olive oil in the product. Manufacturers must maintain records sufficient to substantiate the required amount of olive oil for as long as the products are marketed, and must provide these records, on written request, to appropriate regulatory officials;

(B) The food shall meet the nutrient content requirements in § 101.62 for "low saturated fat" food, except for foods that are essentially pure olive oil (including pure olive oil and pure olive oil with a maximum of 1% additional ingredients that include flavors, colors and/or preservatives) are not required to meet this requirement;

(C) The food contains 20 mg or less of cholesterol per RACC and per 50 g if the RACC is 30 g or less or 2 tablespoons or less (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 RACC, the per 50-g criterion refers to the "as prepared" form);

(D) The food must meet the limit for total fat and saturated fat in § 101.14 (a)(4), except for foods that are essentially pure olive oil (including pure olive oil and pure olive oil with a maximum of 1% additional ingredients that include flavors, colors and/or preservatives) provided that label of the food bears a disclosure statement that complies with § 101.13(h);

(E) The food must contain one gram of less of *trans* fat as defined by § 101.9(2)(ii);

(F) The food must meet the minimum nutrient contribution requirement in §101.14 (e)(6) except that foods that are essentially pure olive oil (including pure olive oil and pure olive oil with a maximum of 1% additional ingredients that include flavors, colors and/or preservatives) are not required to meet this requirement; and

(G) The exemptions established by subparagraphs (B), (D) and (F) of this paragraph apply only to olive oil within the scope of those subparagraphs. Other foods that include olive oil as an ingredient are not exempted from any provisions of § 101.14(a)(4) and (e)(6).

(d) *Optional information.* (1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of CHD; elevated blood total and LDL cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease.

(2) The claim may state that the relationship between intake of moderate-fat diets that are low in saturated fat and cholesterol and that include monounsaturated fatty acids from the eligible food source from paragraph (c)(2)(ii) of this section and reduced risks of heart disease is through the intermediate link of "blood cholesterol" or "blood total- and LDL-cholesterol;"

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between moderate-fat diets that are low in saturated fat and cholesterol and that include monounsaturated fatty acids from certain foods and coronary heart disease and the significance of the relationship;

(4) The claim may state that a moderate-fat diet low in saturated fat and cholesterol that includes monounsaturated fatty acids from the eligible food source from paragraph (c)(2)(ii) is consistent with "Nutrition and Your Health: Dietary Guidelines for American," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO);

(5) The claim may state that individuals with elevated blood total- and LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- and LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment;

(6) The claim may include information about the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO).

(e) *Model health claims.* The following model health claims may be used in food labeling to describe the relationship between moderate-fat diets that are low in saturated fat and cholesterol and that include monounsaturated fatty acids from certain foods and reduced risk of heart disease:

(1) Monounsaturated fats from [gram weight of the monounsaturated fatty acid source from paragraph (c)(2)(ii) of this section that provides 10 grams of monounsaturated fatty acids] grams per day of [monounsaturated fatty acid source from paragraph (c)(2)(ii) of this section and, if desired, the name of the food product] may reduce your risk of heart disease when included in a moderate-fat diet low in saturated fat and cholesterol.

(2) "Moderate-fat diets low in saturated fat and cholesterol that include [gram weight of the monounsaturated fatty acid source from paragraph (c)(2)(ii) of this section that provides 10 grams of monounsaturated fatty acids] grams from [name of monounsaturated fatty acid source from paragraph (c)(2)(ii) of this section and, if desired, the name of the food product] per day may reduce the risk of heart disease."

XV. CERTIFICATION

I hereby certify that, to the best of my knowledge, this petition is a representative and balanced submission that includes unfavorable information as well as favorable information known to me to be pertinent to the evaluation of the proposed health claim.

Respectfully submitted,

THE NORTH AMERICAN OLIVE OIL ASSOCIATION

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