



March 25, 2004

Food and Drug Administration
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Food Labeling: Health Claims and Label Statements— Omega-3 Fatty Acids
and Coronary Heart Disease

Docket No. 2003Q-0401

Dear Sir/Madam:

For over 100 years, Americans have trusted the well-known brands Kraft Foods (Kraft) sells. Today, our brands are found in more than 99% of all U.S. households and are sold in 150 countries around the world. Kraft is a \$30 billion global company, the largest food manufacturer in North America, and the second largest worldwide. We distribute over 18 billion packages of food each year. Therefore, our interest in the regulation of claims on food labels is substantial.

Kraft notes that, under the Interim Guidance for Qualified Health Claims issued last summer, the Agency will soon decide the status of petitions for a health claim about omega-3 fatty acids and heart disease. Since the 1993 rejection of this claim during the NLEA rulemaking, this claim has been reviewed several times. In particular, FDA evaluated the data on omega-3 fatty acids and heart disease and authorized use of this claim for dietary supplements pursuant to rulings in the *Pearson v. Shalala* litigation (letters to J. Emord, October 2000, February 2001, February 2002). Likewise, the American Heart Association (AHA) continues to track and update the database, with a recent evaluation of the benefits of omega-3 fatty acids (*Circulation* 106:2747, 2002—the AHA report). Kraft concurs that the omega-3 claim should now meet the evidentiary standards for a health claim under significant scientific agreement or for a qualified health claim under interim guidance. However, we do not wish to debate the science supporting the omega-3 claim, but rather address some crucial points concerning the requirements of the claim related to food products.

In any proposed rule for an omega-3 fatty acids and heart disease claim, FDA will need to define claim language, the nature of the food, and the level of omega-3 fatty acids per serving. For the purposes of the scientific basis of the claim, omega-3 fatty acids are the sum of eicosapentaenoic acid and docosahexaenoic acid (EPA+DHA) in the food. In addition, FDA will need to provide a rationale for a claim recommending increased intake of specific fatty acids after a decade of messages regarding low fat diets.

Level in food

Suggestion: *FDA should establish an intake of omega-3 fatty acids (EPA+DHA) at 500 mg/d for primary prevention of heart disease in the general population. Foods would be eligible to make the claim with levels of omega-3 fatty acids at 125 mg/serving.*

The AHA has issued a position statement that omega-3 fatty acid intake in the range of 0.5 – 1.8 g/d may be useful in secondary prevention of cardiac mortality (the AHA report). Furthermore, AHA concludes that individuals without coronary heart disease may derive cardio-protective benefits from at least two meals per week of fatty fish rich in omega-3 fatty acids. A dietary pattern including two fish meals per week would suggest a daily intake of omega-3 fatty acids in the range of 0.3 – 0.5 g/d (based on Table 3 in the AHA report), similar to population-based dietary recommendations for several countries as well as from WHO and NATO (the AHA report). In comments to this docket, the Council for Responsible Nutrition (CRN) summarizes evidence published since the 2002 AHA report and offers two heart health claims—one at 500 mg/d omega-3 intake for primary prevention and another at 1 g/d for secondary prevention. We support the use of 500 mg/d of omega-3 fatty acids as an effective level of intake to reduce the risk of heart disease for the general population. This is consistent with epidemiological studies and AHA recommendations. Furthermore, this level of omega-3 intake is at the lower bound of the range associated with secondary prevention and may thus be useful for this population as well.

As with other recent health claims, this daily level of omega-3 fatty acids could be divided among four servings of food per day, with 125 mg of omega-3 fatty acids per serving as a qualifying level for an individual food product [(see 21 CFR 101.81 (soluble fiber) and 101.82 (soy protein)]. This level of omega-3 fatty acids may be incorporated into oil-based foods such as spreads, cheese, mayonnaise and salad dressings, as well as other products such as breads and cereal bars. Dietary survey data indicate that the intake of omega-3 fatty acids (EPA+DHA) in the US is only about 100 – 200 mg/d (the AHA report). Widespread use of omega-3 fatty acids in several foods will allow consumers more choices in addition to fatty fish to increase their intake of this important nutrient. The suggested intake level of 500 mg/d omega-3 fatty acids offers a significant margin of safety relative to the safety level established for these fatty acids (EPA+DHA) in the GRAS affirmation of menhaden oil (62 FR 30751). It seems unlikely that average consumers who change their dietary behaviors to ingest quantities of this nutrient consistent with claim requirements will reach levels of concern to the Agency.

Nature of food eligible to bear the claim

A) General health claim requirement: low fat

Suggestion: *Foods may qualify for the claim if they contain 6.5 grams or less total fat, are low in saturated fat and low in cholesterol, and contain 0.5 grams or less trans fatty acids per reference amount (RACC) and per labeled serving. For mayonnaise-type dressings and spreads (foods with serving size of one tablespoon or 15 grams), total fat must be 6.5 grams or less per RACC and per labeled serving with an exemption from the 50-gram criterion of the total fat disqualifier level.*

Consumers desiring to follow dietary advice to increase the intake of omega-3 fatty acids in a food-based dietary pattern are now essentially limited to increasing intake of fatty fish. Consumers may increase their intakes of fatty fish to obtain the levels of omega-3 fatty acids required for cardiovascular benefits. However, among the commonly consumed top twenty cooked fish having significant levels of EPA+DHA (about 1 g/serving or more), none would qualify for a claim based on current health claim criteria. The limited number of fish with high levels of omega-3 fatty acids (various salmon and rainbow trout) average about 7 g fat, 1.5 g saturated fat, and 60 mg cholesterol per serving, whereas cooked mackerel is higher at about 15 g fat, 3.5 g saturated fat, and 65 mg cholesterol per serving. Indeed, only tuna canned in water, probably the most popular fish for a broad range of consumers, would meet current criteria to make a heart health claim (see 21 CFR 101, App. D and the AHA report, Table 3). Although increased fish consumption is recommended for improving dietary patterns, it is obvious that these fatty fish rich in omega-3 fatty acids are not particularly low fat foods. Furthermore, it is unreasonable to expect that consumers will consume one serving per day of such a limited variety of sources of this nutrient. It is more likely that consumers will improve their dietary intake of omega-3 fatty acids if this nutrient is available in a variety of foods, especially foods bearing a health claim.

Currently, all approved health claims related to heart disease have criteria for low fat, low saturated fat, and low cholesterol. Since 1993, there has been a considerable shift in the scientific consensus about total fat and heart disease. Indeed, closely limiting intake of saturated fat to less than 10% of calories is the preferred option to reduce CHD risk, whereas total fat intake may moderately range a few calories percent away from the long-prescribed 30% of calories (S.M. Grundy, *Ann. Rev. Nutr.* 19:325, 1999). This approach is incorporated into the *Dietary Guidelines for Americans 2000*, with a recommendation to limit intake of saturated fat and cholesterol and to maintain a moderate intake of total fat. The concept has received further support in the Institute of Medicine report *Dietary References Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (2002).

FDA recently authorized a claim for whole grain foods under the notification procedure of the FDA Modernization Act based on the current views about the relationship between fat and heart disease (letter to Kraft Foods, December 2003). The idea of a moderate fat level was built into the food eligibility requirements after review of the supporting science indicated that the benefits of whole grains were not solely related to low fat dietary patterns. We note that the important scientific studies on the relationship between omega-3 fatty acids and heart disease are also not related to only low fat dietary patterns (Dr. Wm. Harris, co-author of the AHA report, personal communication). These rather potent bioactive components of the diet appear to be effective in many types of diets. We suggest that FDA use the moderate fat approach in developing a health claim for foods and omega-3 fatty acids. Consistent with the Kraft whole grain claim, we suggest that foods eligible for the claim contain less than or equal to 6.5 g total fat, be low in saturated fat and low in cholesterol, and contain less than or equal to 0.5 g trans fatty acids per RACC and per labeled serving. We note that for many foods with serving sizes of 30 g or less or 2 tablespoons or less, this approach will keep the fat, saturated fat and cholesterol levels below the disqualifying levels in 21 CFR 101.14.

However, for some foods such as mayonnaise-type dressings and spreads, this will not be the case. These oil-based foods are natural carriers of ingredients containing omega-3 fatty acids. Consumers use these foods to enhance the flavor and texture of other foods, such as breads, vegetables and fruits, which are consistent with a healthy diet. As well, these foods are typically consumed in small quantities (one tablespoon or 15 g). Dietary surveys indicate that these foods enjoy widespread use among consumers. Thus, addition of omega-3 fatty acids to these foods offers the potential to incorporate this important nutrient into a normal diet with minimal disruption to normal eating behaviors. We suggest that these particular products may qualify for a claim if they meet the moderate fat criterion suggested above for other foods (6.5 g per RACC and per labeled serving), but are exempted from the 50-gram criterion of the total fat disqualifier level.

Since mayonnaise-type dressings and spreads are traditional fat/oil based foods, omega-3 fatty acid-containing ingredients will replace other fats in current products. The use of these new foods containing omega-3 fatty acids will not increase consumption of fat since they will be used in the same manner as traditional products. Furthermore, this less stringent requirement should allow more products to qualify for a claim, increasing consumer food choices and improving the likelihood that consumers will increase their consumption of beneficial omega-3 fatty acids.

B) General health claim requirement: the “jelly bean rule”

Suggestion: *For purposes of this claim, FDA should eliminate the minimum nutrient content requirement for the dressings for salads and mayonnaise-type dressings.*

The minimum nutrient requirements set forth in 21 CFR 101.14(e)(6) would generally preclude the use of the omega-3 fatty acids claim on these dressings. Consumers seldom rely on these products to provide protein, fiber, calcium, iron, or vitamins A and C in their diets. The presence of these six nutrients bears no relationship to the benefit provided by omega-3 fatty acids. The exception suggested here would apply only to a limited number of foods. However, with addition of omega-3 fatty acids at levels required for a claim, these foods could have significant potential to improve the overall nutrition profile of consumers. Application of the “jelly bean rule” to restrict use of the omega-3 fatty acids health claim is counterproductive in this case. Informing consumers about the benefits of omega-3 fatty acids outweighs the need for these foods to contribute certain nutrient levels and justifies a limited exception to the “jelly bean rule.” FDA has waived this requirement in select instances [sugar alcohols and dental caries (21 CFR 101.80); stanol/sterol esters and heart disease (21 CFR 101.83)].

We encourage FDA to evaluate these ideas as development of the omega-3 fatty acids and heart disease claim moves forward. Imaginative resolution of these complex issues is critical as new scientific evidence continues to demonstrate the importance of specific fatty acids to cardiovascular health.

Respectfully submitted,



Ronald J. Triani
Sr. Director, Global Scientific & Regulatory Affairs
Kraft Foods Global, Inc.