



Transmitted Electronically and by UPS Overnight Delivery

February 16, 2004

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

Re: Comment on Docket 2003Q-0559 (Qualified Health Claim (“QHC”): Monounsaturated fatty acids and reduced risk of coronary heart disease)

Dear Dockets Management Office:

ACH Food Companies Inc. (“ACH Foods”) processes and sells a number of vegetable oil products under the Mazola® brand name. ACH Foods believes that the scientific evidence presented to the FDA in the referenced Petition (“NAOOA Petition”) supports the important role played by the substitution of unsaturated fats for saturated and trans fatty acids in the diet with respect to coronary heart disease (“CHD”). ACH Foods also asserts that it is vitally important to the public health for manufacturers of vegetable oils containing relatively high amounts of unsaturated fatty acids in relation to saturated fatty acids to convey the clear benefit to cardiovascular health that the straightforward dietary substitution of these vegetable oils for oils high in saturated fat provides.

However, ACH Foods believes that it would not be consistent with FDA’s Interim Guidelines for Qualified Health Claims or be in the best interest of public health for FDA to allow a QHC limited to one subset of unsaturated fats (monounsaturated fatty acids (“MUFAs”) from olive oil and olive-oil containing products) when data (some of which is included in the NAOOA Petition and some of which is not) support a broader QHC that includes:

1. Polyunsaturated fatty acids (“PUFAs”); and
2. MUFAs

from vegetable oil sources that contain relatively high levels of unsaturated fat to saturated fat.

In short, the NAOOA petition for a health claim for MUFAs from olive oil to reduce the risk of CHD is based on sound, but highly selective, science that ignores or overlooks data that support the same claim for many other types of vegetable oil. If a QHC were to be approved that is limited to olive oil and certain olive oil-containing products, it would create a situation in which the public might attach undue emphasis on substituting olive oil for saturated fat in the diet to reduce the risk of CHD. This potential void in appropriate health information being conveyed to the public would actually be a disservice to the public, because there is no scientific basis to support an advantage for olive oil in lowering the risk of CHD.

The relative amounts of SFAs, MUFAs, PUFAs and Total UFA in a number of vegetable oils are shown in the following table. Those at the top of the list are high in unsaturated fatty acids relative to SFA, with the relative levels decreasing as one moves down the list:

**Fat Content in 1 Tablespoon of Various Oils**

	SFA	MUFA	PUFA	Total UFA	UFA Percent	Cholesterol	Phytosterols
	(g)	(g)	(g)	(g)		(mg)	(mg)
Oil, safflower, oleic >70%	0.844	10.152	1.952	12.104	93%	0	60
Oil, safflower, linoleic >70%	0.844	1.952	10.149	12.101	93%	0	60
Oil, canola	0.994	8.246	4.144	12.390	93%	0	NR
Oil, sunflower, oleic ≥70%	1.365	11.703	0.532	12.235	90%	0	NR
Oil, sunflower, linoleic <60%	1.374	6.174	5.454	11.628	89%	0	14
Oil, sunflower, linoleic ≥60%	1.401	2.652	8.935	11.587	89%	0	14
Oil, corn	1.727	3.291	7.983	11.274	87%	0	132
Oil, olive	1.816	9.977	1.350	11.327	86%	0	30
Oil, sesame	1.931	5.399	5.671	11.070	85%	0	118
Oil, soybean	1.958	3.169	7.874	11.043	85%	0	34
Oil, peanut	2.281	6.237	4.320	10.557	82%	0	28
Oil, cottonseed	3.522	2.421	7.058	9.479	73%	0	44
Fat, chicken	3.814	5.722	2.675	8.397	69%	11	0
Lard	5.018	5.773	1.434	7.207	59%	12	0
Oil, palm	6.705	5.032	1.265	6.297	48%	0	NR
Fat, beef tallow	6.374	5.350	0.512	5.862	48%	14	0
Oil, cocoa butter	8.119	4.474	0.408	4.882	38%	0	27
Butter oil, anhydrous	7.926	3.678	0.473	4.151	34%	33	NR
Oil, palm kernel	11.084	1.550	0.218	1.768	14%	0	13
Oil, coconut	11.764	0.789	0.245	1.034	8%	0	12

Source: USDA National Nutrient Database for Standard Reference

([http://www.nal.usda.gov/fnic/cgi-bin/nut\\_search.pl](http://www.nal.usda.gov/fnic/cgi-bin/nut_search.pl))

NR=Not Reported

A fair analysis of available data demonstrates that a lowered risk of CHD can be achieved by replacing saturated fats in the diet with any one or a combination of the vegetable oils that contain a high percentage of unsaturated fatty acids listed above rather than olive oil alone. So, to have value to the public, any QHC must recognize that the health benefit is available from a number of vegetable oils, not just olive oil.

Ample scientific support exists in other dockets to support the following QHCs:

- diets substituting vegetable oils high in MUFAs and/or PUFAs for saturated fat may reduce the risk of coronary heart disease”
- diets containing vegetable oils high in MUFAs and/or PUFAs may reduce the risk of coronary heart disease.”

These dockets are 02P-0505 (Health Claim Petition – Nuts and Coronary Heart Disease); 02P-0292 (Health Claim Petition – Walnuts and Coronary Heart Disease); and 2003Q-0401: Qualified Health Claim (QHC) OMEGA-3 Fatty Acids and Coronary Heart Disease Health Claim). ACH Foods requests that these petitions be incorporated by reference in this docket.

Ample precedent exists to approve a QHC applicable to a broader range of foods than that which was initially sought. FDA's approval of a QHC for a broad range of tree nuts and peanuts followed an initial effort to acquire a health claim limited to walnuts. If FDA does not feel that it can approve a QHC for a broader group of vegetable oils than olive oil, then ACH Foods asks that this comment be considered as a separate request for a QHC for vegetable oils containing levels of MUFAs and PUFAs that are high in unsaturated fatty acids relative to saturated fat.

ACH Foods also notes its full agreement with the NAOOA Petition's position that current FDA requirements that disqualify olive and other 100% vegetable oils containing significantly greater amounts of unsaturated fat than saturated fat from making claims are inappropriate and should be eliminated for these oils.<sup>1</sup>

The format of ACH Foods' comment on this docket will be first to discuss the recent, significant and consistent activities of U.S. governmental, international and professional organizations charged with making dietary recommendations to disseminate the benefits to health of substituting unsaturated fats for saturated fats in the diet. This correlates to the discussion in pages 68-82 of the NAOOA Petition. However, because the NAOOA Petition is so overly slanted to the benefits of one category of unsaturated fat – MUFAs (and MUFAs from olive oil in particular), ACH Foods' comment will emphasize what these organizations have said with respect to another category of unsaturated fat – PUFAs.

ACH Foods' comment will then discuss a number of scientific studies, some of which were discussed in the NAOOA Petition and some of which were not, that compare the effect on CHD of two vegetable oil products – olive oil and corn oil when substituted for saturated fat in the diet. The analysis is limited to the two oils only because of time; ACH Foods submits that a similar comparison of olive oil to vegetable oils that, like corn oil, are higher in PUFAs than MUFAs would yield a similar conclusion – that based on current knowledge, the component of a vegetable oil that is most critical to its effect on CHD is its total unsaturated fat content (i.e., both MUFAs and PUFAs), not whether it is higher in one or the other. In conclusion, because the NAOOA Petition requests a QHC for olive oil that would not address in any fashion the needed balance in the intake of MUFAs and PUFAs, it should not be approved unless the QHC is broadened to include other vegetable oils with a high total unsaturated fat content.

This comment will conclude with model qualified health claims that are supported by the data in this comment.

## **I. Statements of U.S. Governmental, International and Professional Health/Scientific Organizations**

Virtually all documents issued by U.S. governmental, international and professional health/scientific organizations that address dietary guidance support: 1) substituting unsaturated fats for saturated fats in the diet and 2) diets containing vegetable oils improving blood lipid profiles and, thereby, decreasing the risk of CHD. The most prominent of these documents are discussed below.

---

<sup>1</sup> NAOOA Petition, pp. 82-91.

## A. FDA

### 1. Existing Health Claims

The FDA has long recognized the benefit of unsaturated fats in the diet. In 1993, pursuant to the Nutrition Labeling and Education Act of 1990, FDA published final regulations for a health claim for diets low in saturated fat and cholesterol reducing the risk of CHD (21 CFR §101.75). The Agency recognized significant scientific agreement among qualified experts that diets low in saturated fat and cholesterol may reduce the risk of heart disease.

FDA also recently approved a health claim for plant sterol/stanol esters and CHD (21 CFR §101.83). The regulation allows a health claim, even though the fat content of the product exceeds levels that would otherwise disqualify it from making the claim. FDA recognized that high blood total and LDL cholesterol are major modifiable risk factors in the development of CHD. The Agency further stated that the scientific evidence established that including plant sterol/stanol esters in the diet helps to lower total and LDL cholesterol levels.

### 2. Task Force on Consumer Health Information for Better Nutrition

In July 2003, the FDA Task Force on Consumer Health Information for Better Nutrition released its Final Report on Qualified Health Claims ("FDA Task Force Report"). The FDA Task Force indicated that FDA would be conducting an evidence-based analysis of the literature concerning the substitution of unsaturated fat for saturated fat.

The Task Force Report acknowledged that substituting unsaturated fat for saturated fat is an important message to communicate to consumers. The Task Force Report cites the *2000 Dietary Guidelines for Americans* recommendation of substituting unsaturated fat for saturated fat:

[A]n increasingly important message for consumers is to substitute foods that decrease the risk of disease for those that do not, in order to build better diets. FDA can seek opportunities, using existing well-recognized government recommendations and partnerships, to identify the appropriate messages about food substitutions. For instance, the booklet 'Dietary Guidelines for Americans' provides an important substitution health message about fats and heart disease: "*Substituting vegetable oils for solid fats may reduce your risk of heart disease.*" (*Emphasis in original*).<sup>2</sup>

## B. Healthy People 2010

Healthy People 2010 is the prevention agenda for the U.S., and is coordinated by HHS and other Federal Agencies. The Healthy People 2010 Report entitled "Nutrition and Overweight" ("FDA/NIH Healthy People 2010") was prepared by FDA and the NIH as co-lead agencies. That report states:

The major vegetable sources of monounsaturated fatty acids include nuts, avocados, olive oil, canola oil, and high-oleic forms of safflower and sunflower seed oil. The major sources of polyunsaturated fatty acids are vegetable oils,

---

<sup>2</sup> FDA Task Force Report, 2003 p. 7.

including soybean oil, corn oil, and high-linoleic forms of safflower and sunflower seed oil and a few nuts, such as walnuts. Substituting monounsaturated and polyunsaturated fatty acids for saturated fatty acids can help lower health risks.<sup>3</sup>

### C. HHS/USDA Dietary Guidelines for Americans

The *Dietary Guidelines for Americans* (“HHS/USDA Dietary Guidelines 2000) are science-based eating and physical activity advice for healthy Americans over the age of 2. The HHS/USDA Dietary Guidelines 2000 have included a fat guideline since their first publication in 1980.

The HHS/USDA Dietary Guidelines 2000 recommend that people “Choose a diet that is low in saturated fat and cholesterol and moderate in total fat.”<sup>4</sup> The Fat Guideline indicates that

“saturated fats ... increase the risk for coronary heart disease by raising the blood cholesterol.... In contrast, unsaturated fats (found mainly in vegetable oils) do not increase blood cholesterol.”<sup>5</sup>

The recommendations for the Fat Guideline say to “choose vegetable oils rather than solid fats (meat and dairy fats, shortening).”<sup>6</sup> The Dietary Guideline provides additional information:

“...unsaturated fats include both *monounsaturated fats* and *polyunsaturated fats*. Olive, canola, and peanut oils are some of the oils high in monounsaturated fats. Vegetable oils such as soybean oil, corn oil and cottonseed oil and many kinds of nuts are good sources of polyunsaturated fats.”<sup>7</sup>

New Dietary Guidelines due to be published in 2005 are currently being worked on at HHS/USDA. As part of that effort, a meeting was held in September, 2003 at which the presenter on fatty acids, Dr. Theresa Nicklas, DrPH, LN, Professor of Pediatrics, Baylor College of Medicine recognized the need to find a balance between MUFA and PUFA intake when substituted for SFA:

“The new DRIs [of the 2000 Macronutrient Report] recommend a total of 20 to 35% fat daily, with lowered amounts of saturated fat. The issue is how to maintain moderate fat intake and also increase unsaturated fatty acids and maintain a balance between monounsaturated fat and polyunsaturated fat. She raised two questions:

1. Are there optimal levels for monounsaturated fat and polyunsaturated fat that should be recommended?
2. Should upper intakes for these two types of fatty acids be established?”<sup>8</sup>

---

3 FDA/NIH Healthy People 2010, ch. 19, p. 19-30.

4 HHS/USDA Dietary Guidelines 2000, p. 14

5 Id.

6 Id.

7 Id.

8 [http://www.health.gov/dietaryguidelines/dga2005/minutes09\\_2324\\_2003.pdf](http://www.health.gov/dietaryguidelines/dga2005/minutes09_2324_2003.pdf), at p. 25

**D. National Heart, Lung and Blood Institute, Expert Panel of the National Cholesterol Education Program (NCEP 2001)**

The NCEP Report recognizes that elevated LDL cholesterol is a major cause of coronary heart disease. For primary prevention of CHD the Expert Panel recommends that intakes of saturated fat and cholesterol be reduced and that polyunsaturated fatty acids can replace saturated fat. Up to 10% of total calories can come from polyunsaturated fatty acids.

Evidence statements: Linoleic acid, a polyunsaturated fatty acid, reduces LDL cholesterol levels when substituted for saturated fatty acids in the diet. ... Controlled clinical trials indicate that substitution of polyunsaturated fatty acids for saturated fatty acids reduces risk for CHD.<sup>9</sup>

In the "Healthy Lifestyle Recommendations for a Healthy Heart," unsaturated oils are listed as a food item that should be chosen more often.<sup>10</sup>

**E. American Heart Association**

The current American Heart Association (AHA) Dietary Guidelines, released in 2000, recognize:

The major food components that raise LDL cholesterol are saturated fatty acids, *trans*-unsaturated fatty acids, and, to a lesser extent, cholesterol. Dietary factors that lower LDL cholesterol include polyunsaturated fatty acids, monounsaturated fatty acids (when substituted for saturated fatty acids), and, to a lesser extent, soluble fiber and soy protein.<sup>11</sup>

Based on the effects of the respective food components on LDL, the AHA Statement's "Major Guidelines" to achieve a "Desirable Blood Cholesterol and Lipoprotein Profile" are to

- Limit the intake of foods with a high content of saturated fatty acids and cholesterol.
- Substitute grains and unsaturated fatty acids from vegetables, fish, legumes and nuts."<sup>12</sup>

**F. The Joint WHO/FAO Expert Report Diet, Nutrition and the Prevention of Chronic Diseases (WHO 2003)**

The 2003 WHO Report addresses the strength of the evidence for preventing chronic diseases, including coronary heart disease. For **linoleic** acid decreasing the risk of CVD, its review classified the evidence as "**convincing**," which is the strongest rating. The evidence for **oleic** acid found in olive oil is "**probable**."<sup>13</sup> The WHO Report contained the following analysis:

---

9 NCEP, p V-11

10 Id. p. V-7.

11 AHA Dietary Guidelines, 2000, p. 2287

12 Id. at p. 2285

13 WHO 2003, pp. 91-92

Fatty acids and dietary cholesterol

The relationship between dietary fats and CVD, especially coronary heart disease, has been extensively investigated, with strong and consistent associations emerging from a wide body of evidence accrued from animal experiments, as well as observational studies, clinical trials and metabolic studies conducted in diverse human populations.

...

The most effective replacement for saturated fatty acids in terms of coronary heart disease outcome are polyunsaturated fatty acids, especially linoleic acid. This finding is supported by the results of several large randomized clinical trials, in which replacement of saturated and trans fatty acids by polyunsaturated vegetable oils lowered coronary heart disease risk.

...

When substituted for saturated fatty acids in metabolic studies, both monounsaturated fatty acids and n-6 polyunsaturated fatty acids lower plasma total and LDL cholesterol concentrations; PUFAs are somewhat more effective than monounsaturates in this respect. The only nutritionally important monounsaturated fatty acid is oleic acid, which is abundant in olive and canola oils and also in nuts. The most important polyunsaturated fatty acid is linoleic acid, which is abundant especially in soybean and sunflower oils. (Citations omitted.)<sup>14</sup>

The WHO/FAO Expert Report (Executive Summary) indicates in that the risk of CVD is reduced by PUFAs. MUFAs are not mentioned:

Cardiovascular disease, the major killers worldwide are to a great extent due to unbalanced diets and physical inactivity. Risk of their main forms, heart disease and stroke, is reduced by eating less saturated and trans fats, and sufficient amounts of (n-3 and n-6) polyunsaturated fats, fruits and vegetables....<sup>15</sup>

**G. Institute of Medicine (IOM Macronutrient Report 2002)**

The Food and Nutrition Board of The Institute of Medicine (part of the National Academies) issued its Report on Dietary References Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids in September 2002 (IOM Macronutrient Report). The Report Brief of the IOM Macronutrient Report (Report Brief, IOM Macronutrient Report) states:

Monounsaturated and polyunsaturated fatty acids reduce blood cholesterol concentration and help lower the risk of heart disease when they replace saturated fatty acids in the diet. People must get two types of polyunsaturated fatty acids, known as alpha-linolenic acid (an omega-3 fatty acid) and linoleic acid (an omega-6 fatty acid), from the foods they eat, since the body cannot make them. A lack of either one will result in symptoms of deficiency.... [I]ndividuals whose diets are naturally high in linoleic acid and longer chain omega-6 fatty acids,

---

14 WHO Report, pp. 82-83

15 WHO/FAO Report, Executive Summary, p.1.

commonly obtained from vegetable oils, have higher blood levels of high-density lipoprotein cholesterol, also protective of cardiovascular disease.<sup>16</sup>

The Report Brief of the IOM Macronutrient Report also provides a basis to differentiate why the health benefits provided by certain vitamins and minerals are distinguishable in many cases from the health benefits involving fats, carbohydrates and proteins:

Unlike vitamins and minerals, which sometimes perform unique functions to meet the body's needs, fats, carbohydrates, and proteins substitute for one another to some extent to meet the body's energy needs.<sup>17</sup>

Thus, in the context of FDA's policy on approval of health claims, while a claim for certain dietary substances may be justified based on their being added to the diet without other dietary modification, in the case of fats, a health claim will almost invariably, based on current knowledge, involve substitution. This fact is important as FDA struggles with health claims involving fatty acids, when its unstated policy has been not to approve health claims when the benefit is involving mere substitution of one food for another.

The full IOM Macronutrient Report discusses the associations among *n*-6 polyunsaturated fatty acids (PUFAs), blood lipids and CHD. The report indicates that *n*-6 PUFAs positively affect blood lipid profiles, thus decreasing the risk for CHD:

Interventional Evidence. From the standpoint of blood lipids concentrations and CHD, higher *n*-6 polyunsaturated fatty acid intake generally alters blood lipid concentrations to result in a decreased risk profile. Controlled trials have examined the effects of substituting *n*-6 fatty acids in the diet to replace carbohydrate or saturated fatty acids. In general, any fat that replaces carbohydrate in the diet raises high-density lipoprotein (HDL) cholesterol and decreased triacylglycerols concentrations, with only small differences between fats. Effects on LDL cholesterol are more striking as *n*-6 fatty acids decrease LDL cholesterol concentrations compared to saturated fatty acids (citations omitted).<sup>18</sup>

The IOM Macronutrient Report also states that the epidemiological evidence supports the relationship between high intakes of *n*-6 PUFAs, reduced LDL and a lower risk of CHD.

However, high intakes of *n*-6 polyunsaturated fats have been associated with blood lipid profiles (e.g., reduced total and low-density lipoprotein (LDL) cholesterol, reduced triacylglycerol, and increased high-density HDL cholesterol concentrations) that are associated with a low risk of coronary heart disease (CHD). Prospective epidemiological evidence suggests that after controlling for other components of the diets, replacing saturated fats with unsaturated fats decreases the risk of CHD (citations omitted)...<sup>19</sup>

The Macronutrient Report Summary indicates that MUFAs are not essential in the diet:

---

<sup>16</sup> Institute of Medicine, Shaping the Future for Health, Dietary References Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids, Report Brief, 2002 (IOM Report Brief), p. 4.

<sup>17</sup> Id. at p. 1

<sup>18</sup> IOM Macronutrient Report 2002, Ch. 11, p. 11-36

<sup>19</sup> Id.

“Saturated fatty acids, monounsaturated fatty acids and cholesterol are synthesized by the body and have no known beneficial role in preventing chronic disease, and thus are not required in the diet.” Therefore, no Adequate Intake (AI), Estimated Average Requirement (EAR) or Recommended Dietary Allowance (RDA) is set.<sup>20</sup>

And the Macronutrient Reports Summary goes on to state that:

The n-6 polyunsaturated fatty acid, linoleic acid, is an essential fatty acid.... The Adequate Intake (AI) for linoleic acid is 17 g and 12 g/day for young men and women, respectively.<sup>21</sup>

## II. Studies Involving Olive Oil and Corn Oil

The studies discussed below contain a comparison between olive oil and corn oil in their respective affects on lipid levels and other relevant findings.

### A. Scientific Documentation

#### 1. Corn Oil vs. Olive Oil in Healthy People

Wagner et al. (2001) compared the effects of PUFAs as corn oil and MUFAs as an olive oil/sunflower oil mixture on plasma lipoproteins in 28 young, healthy males. The corn oil diet had a significantly greater effect on lipoprotein metabolism than did the MUFA mixture. Corn oil significantly reduced triglycerides ( $P < 0.05$ ), VLDL cholesterol ( $P < .01$ ) and LDL cholesterol ( $P < 0.01$ ).

#### 2. Corn Oil vs. Olive Oil in Hypercholesterolemic Subjects

Four studies (Lichtenstein et al., 1993; Lichtenstein et al., 1994; Jones et al., 1994; Schwab et al., 1998) on the same sample of middle-aged and elderly hypercholesterolemic subjects found positive effects of diets consistent with NCEP II Guidelines. The diets contained two-thirds of dietary fat from corn, canola or olive oil and examined individual effects of the oils on lowering plasma lipids levels and improving cardiovascular risk profile.

The first study, Lichtenstein et al. (1993), was cited in the NAOOA Petition<sup>22</sup> as supporting the QHC for olive oil based on a 7% lowering of plasma cholesterol. In fact, the study found significant reductions in plasma cholesterol after **each** of the test oil diets compared to baseline, but with greater reductions for corn oil (13%,  $P=0.001$ ) and canola oil (12%,  $P=0.0010$ ) than for olive oil (7%,  $P=0.01$ ). LDL cholesterol significantly decreased ( $P = 0.001$ ) after all the test oil diets compared to baseline. No differences in the decrease of LDL cholesterol existed among the oils: corn (17%), canola (16%) and olive oil (13%). Corn (9%) and canola (7%) both significantly decreased HDL ( $P = .01, 0.05$  and  $.01$ , respectively); however, there were no significant effects on the total/HDL cholesterol ratio. LDL apoB:apoA-1 ratios were significantly reduced after the vegetable oil-enriched diets ( $P=0.001$ ). Even though

---

20 Id., Summary at p. S-4

21 Id.

22 NAOOA Petition, p. 29-30.

differing effects were seen among the 3 oil regimens, the authors concluded that none of the oils had a significant advantage in terms of altering the overall lipoprotein profile.

In the second study, which was not cited in the NAOOA Petition, Lichtenstein et al. (1994) compared rice bran oil to corn, canola and olive oil-enriched diets. LDL concentrations/reductions were not significantly different among the corn, canola and rice bran oil-enriched interventions. However, these three interventions produced a greater reduction in LDL cholesterol ( $P < .001$ ,  $P = 0.01$ , respectively) than did the olive oil-enriched intervention, which also lowered LDL cholesterol. The groups did not vary with respect to their effects on VLDL, HDL, TAG, LDL apo B, apoA-1 and Lp(a), total cholesterol:HDL ratio and LDL apoB:apoA-1 ratios.

In the third study, Jones et al. (1994) found differences in cholesterol synthesis among the four diets in 15 postmenopausal women. Their findings suggested that a more rapid flux of central-pool cholesterol is associated with increased synthesis after the corn oil-enriched diet versus the olive oil-enriched diet. This result suggests different mechanisms control circulating cholesterol levels, depending on the oil consumed.

In the fourth study, Schwab et al. (1998) found:

Plasma total cholesterol concentrations were significantly higher after consumption of the beef tallow, intermediate after consumption of the olive oil and lowest after consumption of diets enriched in canola, corn or rice bran oil.... A similar pattern was observed for LDL cholesterol levels.<sup>23</sup>

Kohlmeier et al. (1988) found that corn oil significantly lowered total cholesterol (-25%), LDL cholesterol (-29.3%) over HOSO ( $P < .01$ ) and HDL cholesterol in 15 healthy men with higher than average cholesterol levels (5.2-6.7 mmol/L). These subjects also had a significantly higher sterol excretion on the corn oil diet than on the sunflower oil diet. Sirtori et al. (1986) found that diets rich in corn oil significantly lowered total, LDL and HDL cholesterol levels versus a diet rich in olive oil in 23 middle-aged patients at high risk for atherosclerosis. LDL cholesterol dropped (9.2%) ( $P < .05$ ) and total cholesterol by about 7.7% ( $P < .05$ ) by the end of the corn oil diet.

### 3. Corn Oil Lipid Lowering Mechanism

Potential mechanisms for the lipid lowering effects of corn oil in healthy people were examined by Ostlund et al. (2002). They found that the phytosterols present in corn oil significantly reduced cholesterol absorption and probably contributed to the ability of corn oil to lower blood cholesterol levels. Wagner et al. (2001) concluded that the hypocholesterolemic effect of corn oil must be related to the phytosterols content.

Kohlmeier et al. (1988) found in 15 healthy men with higher than average cholesterol levels (5.2-6.7 mmol/L) that a corn oil diet resulted in a significantly higher ( $P < .05$ ) endogenous sterol excretion than the sunflower oil diet, which related to the amount of serum cholesterol lowering.

The NAOOA petition mentions studies that suggest that the oxidative modification of LDL by PUFAs may increase its atherogenicity. Three studies (Schwab et al., 2000; Schwab et

---

<sup>23</sup> Schwab 1998, p. 1705.

al., 1998; Cuchel et al., 1996) on the same group of middle-aged and elderly hypercholesterolemic subjects found no difference in LDL susceptibility to oxidation on reduced fat diets with various fats and forms of fats. Schwab et al. (2000) examined 13 hypercholesterolemic subjects and found dietary cholesterol added to reduced fat diets high in PUFA or SFA both increased LDL susceptibility to oxidation. Schwab et al. (1998) found no differences in the in vitro susceptibility of LDL to oxidation in these subjects consuming reduced-fat diets (30% kcal from fat) enriched with animal or vegetable oils. The dietary interventions included a wide range of fatty acid profiles: corn oil, canola, olive oil, rice bran oil and beef tallow. Cuchel et al. (1996) found replacing corn oil with corn oil margarine in sticks did not affect LDL susceptibility to oxidation.

#### **4. Effect of Corn Oil on Plasma Fibrinogen**

In a secondary study (corn oil was not the primary focus of the study), Radack et al. (1990) found that corn oil (at 5.3 g day linoleic acid from corn oil for 8 weeks) significantly reduced fibrinogen levels in those persons with hyperlipoproteinemia type IIb or IV.

### **III. Model Qualified Health Claims**

A fair assessment of the scientific literature, coupled with the assessment of that literature by U.S. governmental, international and professional health/scientific organizations, supports the following claims:

**Monounsaturated and polyunsaturated fatty acids reduce blood cholesterol concentration and help lower the risk of heart disease when they replace saturated fatty acids in the diet.<sup>24</sup>**

**Controlled clinical trials indicate that substitution of polyunsaturated fatty acids for saturated fatty acids reduces risk for CHD.<sup>25</sup>**

**Type of fat (Polyunsaturated fats and/or monounsaturated fats) from specific oil when substituted for solid fat (saturated or trans) may reduce your risk of heart disease as part of a diet low in saturated fat and cholesterol. The research is supportive but not conclusive. See nutrition information for fat and saturated fat content.**

### **IV. Conclusion**

For the reasons stated above, ACH Foods requests that FDA follow the lead of the above cited

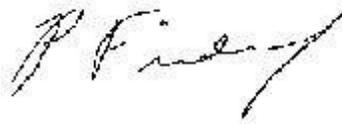
- U.S. governmental agencies;
- international agencies; and
- professional health/scientific organizations

---

<sup>24</sup> IOM Report  
<sup>25</sup> NCEP, p V-11

with public health responsibilities that have in recent years recognized the important role that unsaturated fatty acids play as a substitute for saturated and trans fatty acids in the human diet. The inescapable conclusion to be drawn from the consistent dietary advice those organizations now deliver relating to fat is that the substitution of unsaturated fats for saturated and trans fat in the diet will significantly decrease the incidence of CHD in this country. To make it difficult if not illegal for vegetable oil providers to disseminate this important information to help achieve this dietary objective is simply not in the best interests of public health. It would be similarly counterproductive and potentially confusing to the public to enable only one vegetable oil to make such a claim when available evidence supports a similar claim for a far broader range of products.

Sincerely,

A handwritten signature in black ink, appearing to read "Pete Friedman", written over a light gray rectangular background.

Pete Friedman  
Vice President of Product Development and  
Quality Management

Richard O. Wood  
FDA Group  
Bell, Boyd & Lloyd, LLC  
70 W. Madison St.  
Chicago, IL 60602

Constance J. Geiger, PhD, RD, CD  
President  
Geiger & Associates  
3698 East Gilroy Rd.  
Salt Lake City, UT 84109-3825

### Bibliography

1. AHA Dietary Guidelines 2000, Krauss et al., A Statement for Healthcare Professionals From the Nutrition Committee of the AHA. *Circulation* 2000; 102:2284-99.
2. Cuchel M, Schwab US, Jones PJ, Vogel S, Lammi-Keefe C, Li Z, Ordovas J, McNamara JR, Schaefer EJ, Lichtenstein AH. Impact of hydrogenated fat consumption on endogenous cholesterol synthesis and susceptibility of low-density lipoprotein to oxidation in moderately hypercholesterolemic individuals. *Metabolism*. 1996 Feb;45(2):241-7.
3. FDA Task Force Report, 2003 ([www.cfsan.fda.gov/~dms/nutttfoc.html](http://www.cfsan.fda.gov/~dms/nutttfoc.html))
4. FDA/NIH Healthy People 2010, ch. 19 (Nutrition and Health) (<http://www.healthypeople.gov/Document/pdf/Volume2/19Nutrition.pdf>)
5. HHS/USDA Dietary Guidelines, Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2000 ([http://www.health.gov/dietaryguidelines/dgac/pdf/dgac\\_ful.pdf](http://www.health.gov/dietaryguidelines/dgac/pdf/dgac_ful.pdf))
6. IOM Macronutrient Report Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Chapter 11 Macronutrients) (2002) The National Academies Press (<http://www.nap.edu/catalog/10490.html>)  
  
Summary: <http://books.nap.edu/books/0309085373/html/1.html#pagetop>  
Chapter 11 <http://books.nap.edu/books/0309085373/html/609.html#pagetop>
7. Jones PJ, Lichtenstein AH, Schaefer EJ, Namchuk GL. Effect of dietary fat selection on plasma cholesterol synthesis in older, moderately hypercholesterolemic humans. *Arterioscler Thromb*. 1994 Apr;14(4):542-8.
8. Kohlmeier M, Riesen W, Schlierf G. Metabolic changes in healthy men using fat-modified diets. I. Disposition of serum cholesterol. *Ann Nutr Metab*. 1988;32(1):1-9.
9. Lichtenstein AH, Ausman LM, Carrasco W, Gualtieri LJ, Jenner JL, Ordovas JM, Nicolosi RJ, Goldin BR, Schaefer EJ. Rice bran oil consumption and plasma lipid levels in moderately hypercholesterolemic humans. *Arterioscler Thromb*. 1994 Apr;14(4):549-56.
10. Lichtenstein AH, Ausman LM, Carrasco W, Jenner JL, Gualtieri LJ, Goldin BR, Ordovas JM, Schaefer EJ. Effects of canola, corn, and olive oils on fasting and postprandial plasma lipoproteins in humans as part of a National Cholesterol Education Program Step 2 diet. *Arterioscler Thromb*. 1993 Oct;13(10):1533-42.
11. NCEP Report, Nat'l Cholesterol Education Program, Nat'l Heart, Lung, and Blood Inst., NIH, Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), Final Report, V. Adopting Healthful Lifestyle Habits to Lower LDL Cholesterol and Reduce CHD Risk, Sept. 2002.  
<http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf>

12. Ostlund RE Jr, Racette SB, Okeke A, Stenson WF. Phytosterols that are naturally present in commercial corn oil significantly reduce cholesterol absorption in humans. *Am J Clin Nutr.* 2002 Jun;75(6):1000-4.
13. Radack K, Deck C, Huster G. The comparative effects of n-3 and n-6 polyunsaturated fatty acids on plasma fibrinogen levels: a controlled clinical trial in hypertriglyceridemic subjects. *J Am Coll Nutr.* 1990 Aug;9(4):352-7.
14. Schwab US, Ausman LM, Vogel S, Li Z, Lammi-Keefe CJ, Goldin BR, Ordovas JM, Schaefer EJ, Lichtenstein AH. Dietary cholesterol increases the susceptibility of low density lipoprotein to oxidative modification. *Atherosclerosis.* 2000 Mar;149(1):83-90.
15. Schwab US, Vogel S, Lammi-Keefe CJ, Ordovas JM, Schaefer EJ, Li Z, Ausman LM, Gualtieri L, Goldin BR, Furr HC, Lichtenstein AH. Varying dietary fat type of reduced-fat diets has little effect on the susceptibility of LDL to oxidative modification in moderately hypercholesterolemic subjects. *J Nutr.* 1998 Oct;128(10):1703-9.
16. Sirtori CR, Tremoli E, Gatti E, Montanari G, Sirtori M, Colli S, Gianfranceschi G, Maderna P, Dentone CZ, Testolin G, et al. Controlled evaluation of fat intake in the Mediterranean diet: comparative activities of olive oil and corn oil on plasma lipids and platelets in high-risk patients. *Am J Clin Nutr.* 1986 Nov;44(5):635-42.
17. Wagner KH, Tomasch R, Elmadfa I. Impact of diets containing corn oil or olive/sunflower oil mixture on the human plasma and lipoprotein lipid metabolism. *Eur J Nutr.* 2001 Aug;40(4):161-7.
18. WHO 2003 Report; Diet, Nutrition and the Prevention of Chronic Diseases, Joint WHO/FAO Expert Consultation, WHO Technical Report Series 916, 2003  
[http://www.who.int/hpr/NPH/docs/who\\_fao\\_expert\\_report.pdf](http://www.who.int/hpr/NPH/docs/who_fao_expert_report.pdf)