

QUALIFIED HEALTH CLAIM PETITION

**REDUCED RISK
of
HEART DISEASE
from
CORN OIL
and
CORN OIL-CONTAINING
PRODUCTS**

Part I

Petitioner

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I. OVERVIEW, BACKGROUND AND REGULATORY RATIONALE

A. Overview

The undersigned, ACH Food Companies, Inc. (ACH), submits this Qualified Health Claim Petition (Petition) pursuant to Section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") (21 U.S.C. §343(r)(4)) (Petition). This Petition includes two parts. Part I is this document. Part II of the Petition is the separately bound Summary of Scientific Data/Evidence Analysis prepared by Dr. Constance J. Geiger, PhD, RD, CD (Geiger Evidence Analysis). Both Part I and Part II were prepared pursuant to Food and Drug Administration (FDA) Interim Guidance Documents.¹

This Petition requests FDA to exercise its enforcement discretion to permit a qualified health claim (QHC) for corn oil and corn oil-containing products. It is based on the demonstrated ability of corn oil to lower total and low density lipoprotein (LDL) cholesterol when substituted for higher saturated fat products or otherwise included in the diet. Lowering of total and LDL cholesterol has been recognized by FDA as a biomarker for coronary heart disease (CHD) in several FDA health claim reviews. These include:

- Dietary saturated fat and cholesterol (§101.75)
- Fruits, vegetables, and grain products that contain fiber (§101.77)
- Soluble fiber from certain foods (§101.81)
- Soy protein (§101.82)
- Plant sterol/stanol esters (§101.83)

Corn oil is among a class of plant-derived oils that share the characteristic of being high in unsaturated fatty acids (UFAs), which consist of monounsaturated fatty acids (MUFAs) and polyunsaturated fatty acids (PUFAs). FDA has previously authorized a QHC for the monounsaturated fat content of olive oil and CHD, and a similar request for the UFA content of

¹ "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food ..." (July 10, 2003) (Part I) and "Interim Evidence-based Ranking System for Scientific Data" (July 10, 2003) (Part II).

canola oil has been filed recently.² Olive oil, canola oil and corn oil share a high UFA content, but the relative amounts of the MUFA and PUFA components are different. Olive and canola oils are MUFA-predominant; corn oil is PUFA-predominant. Corn oil also contains 136 mg of plant sterols per 14 g, which is more than twice the amount in canola oil and more than ten times the amount in olive oil.

Because the total and LDL cholesterol lowering effect of corn oil derives from the combined contributions of the MUFAs, PUFAs and phytosterols in corn oil, Petitioner is not seeking to associate QHCs for corn oil and CHD with any particular corn oil component or components. Instead, the Petition requests QHCs for corn oil as an individual food, i.e., without an association to any particular component.

In conclusion, the Petitioner requests that FDA exercise its enforcement discretion to allow QHCs that educate the consumer about the important public health benefits relating to heart disease that can be derived from a) the substitution of corn oil for animal fats (solid fats) and other oils that are composed of high levels of saturated fatty acids and b) including corn oil in the diet. Based upon the scientific evidence presented in this Petition, the two QHCs requested are:

The “Substitution Claim”:

Substituting corn oil for solid fats may reduce your risk of heart disease

or

Substituting corn oil for fats high in saturated fat may reduce your risk of heart disease

² FDA Docket 2006Q-0091 - Qualified Health Claim (QHC) for Unsaturated Fatty Acids from Canola Oil and Reduced Risk of Coronary Heart Disease.

The “Inclusion Claim”:

Scientific evidence establishes that including corn oil-containing foods in your diet may reduce your risk of heart disease. To achieve such benefits, include slightly less than 1 tablespoon (12 grams) of corn oil per day in your diet while not increasing calories, saturated fat or cholesterol. One serving of this product contains x grams of corn oil. Although there is scientific evidence supporting the claim, the evidence is not conclusive.

B. Background

FDA acknowledges the sound scientific base of knowledge that plant-derived oils high in UFAs provide a significant benefit to public health when they are substituted for solid fats high in saturated or *trans* fat. In a 2003 speech entitled "Changing the American Diet: Imperatives and Opportunities," delivered to the Harvard School of Public Health,³ former Commissioner of Food and Drugs Mark McClellan recognized the importance to public health of recommendations to replace saturated fat in the diet with unsaturated fat:

Considerable recent research, including controlled feeding and epidemiologic studies, has provided pretty good evidence that replacing saturated and trans fats with mono- and poly-unsaturated fats can significantly reduce important health risks. According to some studies, this substitution can potentially reduce the risk of heart disease by up to 30 to 40 percent. That is a big impact.

A week after that speech, FDA issued the Final Report of FDA’s Task Force on Consumer Health Information for Better Nutrition (Task Force Report).⁴ The Task Force Report highlighted four key areas where FDA intended to provide better nutrition information and health messages to consumers. Based on the press release issued with the announcement,⁵ a key area targeted for better nutrition information was to communicate to consumers:

- The benefits of replacing solid fats that are high in saturated and trans fats with vegetable oils containing unsaturated fats for reducing the risk of heart disease.

³ McClellan, M. Speech before Harvard School of Public Health, July 1, 2003 (Excerpt) (Attachment 1).

⁴ Consumer Health Information for Better Nutrition, Transmittal Memorandum, July 10, 2003 (Attachment 2).

⁵ FDA News P03-54 (July 10, 2003) (Attachment 3).

FDA acknowledged that the firm scientific base that supported these messages

has led to their inclusion in recommendations from various scientific organizations, including such government agencies as the National Cancer Institute and the National Heart, Lung and Blood Institute as well as non-governmental organizations such as the American Heart Association.

Endorsing FDA's program to convey healthier dietary choice messages, somewhat presciently, was National Cancer Institute (NCI) Director (and now Acting Commissioner of Food and Drugs), Andrew C. von Eschenbach, MD, who stated in support:

The NCI will provide strong support for the FDA's initiative to encourage all Americans to make healthier dietary choices through our nutrition science research programs.

This Petition requests FDA to exercise its enforcement discretion to allow a health message on the label of corn oil and corn oil-containing products that is equivalent to one of the health messages that the FDA Task Force has announced it will convey, i.e., to substitute vegetable fats high in unsaturated fats for solid fats. The Evidence Analysis presented in Part II of this Petition establishes that corn oil, when substituted for solid fats or when added to the diet, lowers total and LDL cholesterol. The corn oil data, are, therefore, entirely consistent with the larger body of sound scientific evidence that supports and underlies FDA's decision to communicate, as a part of its health message communication program, a synonymous but broader health message relating to the entire category of vegetable oils high in unsaturated fat.

C. Regulatory Rationale

Cardiovascular disease (CVD) has been and continues to be the primary cause of death in the United States. CHD is considered a type of CVD and in 2003 was the underlying or contributing cause of 58% of deaths (Geiger Evidence Analysis at 5).

The Geiger Evidence Analysis (Part II of this Petition) includes a thorough evaluation of the scientific studies and clinical trials examining the effects of corn oil on reduction of the risk of CHD. The totality of the publicly available evidence presented and analyzed in the Evidence

Analysis, including scientific and public nutrition policy documents, reports, studies and regulations, supports the following QHCs requested by this Petition:

- 1) substituting corn oil for saturated fat may reduce the risk of heart disease; and
- 2) diets containing corn oil may reduce the risk of heart disease.

Importantly, exercising its discretion and permitting the requested QHCs for corn oil will reinforce the health message that FDA has announced that it is committed to deliver to the public: “Substituting vegetable oils for solid fats may reduce your risk of heart disease.”

In conclusion, the Petitioner asserts that the proposed QHCs will further assist consumers in making more healthful dietary decisions and maintaining healthy diets. Such dietary practices will ultimately reduce their risk of heart disease by the 30 to 40% that former Commissioner McClellan predicted in his speech to the Harvard School of Public Health.

II. PRELIMINARY REQUIREMENTS

The proposed QHCs conform with all preliminary requirements for health claims pursuant to 21 C.F.R. §§ 101.14 and 101.70.

A. Corn Oil Is a "Substance"

To be eligible for a health claim pursuant to 21 C.F.R. § 101.14(a)(2), the product for which the claim is sought must be a "substance," which

means a specific food or component of food, regardless of whether the food is in conventional food form or a dietary supplement that includes vitamins, minerals, herbs, or other similar nutritional substances.

Corn oil is extracted from the germ of corn and is a "specific food" within the meaning of this regulation. First commercially produced in 1889,⁶ it is a well-known, long and widely used food in the U.S. and elsewhere.

The QHCs being sought by the Petitioner are proposed to be associated with corn oil, rather than with any specific corn oil component. Corn oil contains at least three major components that almost certainly play a role in its lowering effect on LDL and total cholesterol:

- 59% PUFAs (linoleic acid, an essential fatty acid that the body cannot synthesize);
- 24% MUFAs (oleic acid); and
- 968 mg of phytosterols per 100 g (the highest level of any commercially available vegetable oil).

B. Heart Disease Is a Major US Health Concern

Pursuant to 21 C.F.R. § 101.14(b)(1), a health claim must be associated with a disease or health related condition for which the general US population, or an identified US population subgroup, is at risk. The requested QHCs associate the substitution of corn oil for solid fat, as well as the inclusion of corn oil in the diet, with reduction of the risk of heart disease. As the leading cause of death in the US, CVD is unquestionably a disease for which the general US

⁶ History of Corn Refining, Corn Refiners Association website (Attachment 4).

population is at risk. Recent statistics provided by the American Heart Association support this conclusion.⁷

Even though this Petition and particularly the Geiger Evidence Analysis discuss heart disease with terms that include CVD and CHD, this Petition requests that the QHCs utilize the term “heart disease.” The health message that FDA has stated that it will deliver to the public to describe the relationship of vegetable oil and heart disease (**Substituting vegetable oils for solid fats may reduce your risk of heart disease**) (see Paragraph IB of the Petition), uses the term “heart disease,” so allowing it in the requested QHCs will lend consistency to the health messages.

C. Corn Oil Contributes "Nutritive Value" to the Diet

Pursuant to 21 C.F.R. §101.14(b)(3)(i),

(i) The substance must ... contribute taste, aroma, or nutritive value, or any other technical effect listed in §170.3(o) of this chapter, to the food and must retain that attribute when consumed at levels that are necessary to justify a claim....

The USDA National Nutrient Database for Standard Reference for corn oil provides the nutritional composition of corn oil, both per 100 g and in a tablespoon. Additionally, the Food Chemicals Codex contains a monograph for corn oil. Both documents are attached.⁸

Significantly, linoleic acid, the predominant fatty acid found in corn oil, is an essential fatty acid. The Macronutrient Report (IOM 2002/2005) set an Adequate Intake (AI) for linoleic acid, the predominant n-6 PUFA, at 5% of calories. The Acceptable Macronutrient Distribution Range (AMDR) for linoleic acid has been set at 5 to 10% of energy (Geiger Evidence Analysis at 37).

⁷ Heart Disease and Stroke Statistics 2006 Update (Attachment 5).

⁸ USDA National Nutrient Database for Standard Reference, Release 18 (2005) http://www.nal.usda.gov/fnic/foodcomp/cgi-bin/list_nut_edit.pl (Attachment 6) and National Academy of Sciences, Food Chemicals Codex, Fourth Ed., pp. 110-111 (Attachment 7) (copyrighted publication).

The USDA nutrient composition data, the Codex monograph and the presence of linoleic acid establish that corn oil has taste, aroma and nutritive value.

D. Corn Oil Is Safe and Lawful Under the FD&C Act

Pursuant to 21 C.F.R. §101.14(b)(3)(ii),

The substance must be a food ... whose use at the levels necessary to justify a claim has been demonstrated by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the [FD&C Act].

Corn oil is generally recognized as safe (GRAS). As discussed above, corn oil has been processed and used as food in the US since the late 1800s. Current per capita consumption of corn oil is 6.2 pounds per year, or 7.05% of fat consumption (Geiger Evidence Analysis at 30).

Although not specifically listed as GRAS in FDA regulations, its long history of widespread use worldwide undoubtedly makes it a GRAS substance of the type that is described in 21 C.F.R. §182.1(a):

Sec. 182.1 Substances that are generally recognized as safe

It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, vinegar, baking powder, and monosodium glutamate as safe for their intended use. This part includes additional substances that, when used for the purposes indicated, in accordance with good manufacturing practice, are regarded by the Commissioner as generally recognized as safe for such uses.

Supporting this status is the regulatory synopsis for corn oil in Food Chemical News Guide on-line. This accepted reference source among the food and drug bar cites a submission by FDA to the US House Interstate Commerce Committee in 1958 in which FDA listed corn oil as a GRAS substance.⁹

Finally, Petitioner has no evidence that the ingestion of corn oil, even at increased levels that increased public awareness of its positive effect on heart disease might generate, involves

⁹ The Food Chemical News Guide, on-line search, April, 2006 (Attachment 8) (copyrighted document).

any increased risk. In fact, the *2005 Dietary Guidelines Advisory Committee* (2004), which conducted a systematic review of applicable research, reported no studies showing adverse side effects from the consumption of corn oil, even when higher amounts of corn oil were used (Geiger Evidence Analysis at 37). Additionally, studies show that when substituted for saturated fat in the diet, corn oil has no inherently negative nutritional factors associated with consumption (Geiger Evidence Analysis at 39).

E. Clinical Investigations

To the best of Petitioner's knowledge, all nonclinical studies relied upon in the Petition that were subject to 21 CFR Part 58 when they were conducted complied with the good laboratory practices regulations set forth in that Part. To the best of Petitioner's knowledge, clinical or other human investigations relied upon in the Petition that were subject to 21 CFR Part 56 when they were conducted either complied with the requirements for institutional review set forth in that Part or were not subject to such requirements by operation of 21 CFR § 56.104 or § 56.105. To the best of Petitioner's knowledge, the clinical trials relied upon in the Petition that were subject to 21 CFR Part 50 when they were conducted complied with the requirement for informed consent set forth in that Part.

III. SUMMARY OF SCIENTIFIC DATA

The detailed summary of scientific data for the requested QHCs, required by 21 CFR §101.70(f)B., is contained in Part II of the Petition, a separately bound volume, entitled “Qualified Health Claim Petition: Reduced Risk of Heart Disease From Corn Oil and Corn Oil-Containing Products; Summary of Scientific Data/Evidence Analysis.”

IV. MINIMUM EFFECTIVE DOSE

The Petitioner's calculation of the minimum effective dose (in grams) is explained in detail in the Evidence Analysis (Geiger Evidence Analysis at 35-36 and Appendix R). That proposed calculation is summarized below.

In its grant of enforcement discretion in response to the QHC petition for MUFAs from olive oil and CHD (olive oil MUFA QHC),¹⁰ FDA's calculation of the minimum effective dose was based on the predominant fatty acids in olive oil, MUFAs. Utilizing that precedent, the Petitioner calculated the minimum effective dose for corn oil based on the predominant fatty acids in corn oil, PUFAs.¹¹

The minimum effective dose of corn oil that must substitute for saturated fat to justify the requested QHCs was determined by examining data only from the best designed studies.¹² The grams of PUFAs in two diets were compared: the high corn oil diet and the high saturated fat diet. Based on that comparison, the lowest amount of PUFAs from corn oil needed to replace saturated fat that will result in significant reductions in serum total and LDL-cholesterol is 6.6 g, which equates to 11.2 g of corn oil. (Geiger Evidence Analysis at 36).

To determine the amount of corn oil that must be in a food to qualify for the Inclusion Claim, the minimum effective amount must be divided by 4 (the number of daily eating occasions per the olive oil MUFA QHC). Therefore, Petitioner requests that foods containing at

¹⁰ FDA Letter of Enforcement Discretion: MUFAs from olive oil and CHD, Oct. 29, 2004, FDA Docket No. 2003Q-0559 ANS1 (Attachment 9, pp. 20-21).

¹¹ PUFAs had to be used as a marker for corn oil because the studies included in the Evidence Analysis did not consistently provide the amount of corn oil in the control diet or in the other diets tested against the corn oil diet. However, most provided the PUFA content of all diets. (Geiger Evidence Analysis at 36 and Appendix R).

¹² "+" Design Type 1 Studies longer than 21 days that provided fatty acid composition of the diet (Geiger Evidence Analysis at 36).

least 3 g of corn oil (the minimum effective dose of 11.2 g divided by 4 and rounded up) (1.77 g PUFAs) are eligible for the Inclusion Claim.

V. NATURE OF THE FOOD ELIGIBLE TO BEAR THE CLAIMS/ANALYTICAL DATA

A. 100% Refined, Bleached and Deodorized Corn Oil

Corn oil is a well characterized food that is included in Food Chemicals Codex (see Attachment 7). Its nutritional composition is available from USDA National Nutrient Database for Standard Reference (see Attachments 6 and 10). The Petitioner proposes that the food eligible to bear the claims be pure “corn oil.” The minimum effective amount of 11.2 g of corn oil has the following characteristics:¹³

1. Fat Content

It contains 11.2 g of fat, of which 6.124 g are PUFAs; 3.089 g are MUFAS; and 1.45 g are SFAs. Corn oil is *trans* fat free.

2. Phytosterols Content

It contains 108 mg of phytosterols.

3. Vitamin E Content

It contains 1.6 mg of vitamin E.

4. Cholesterol Content

Corn oil is cholesterol free.

5. Sodium Content

Corn oil is sodium free.

B. Corn Oil-containing Foods

The Petitioner requests that corn oil-containing foods eligible to bear the Inclusion Claim include the following foods when formulated with at least 3 g of corn oil:

¹³ USDA National Nutrient Database for Standard Reference, Release 18 (2005)
http://www.nal.usda.gov/fnic/foodcomp/cgi-bin/list_nut_edit.pl (Attachment 10).

1. Vegetable Oil Blends,¹⁴
2. Vegetable Oil Spreads,
3. Dressings for Salads,
4. Shortenings, and
5. Corn oil-containing foods other than those included in 1-4 above.

¹⁴ This category is proposed to be defined as blends of vegetable oils containing ≥ 3 g per reference amount customarily consumed (RACC) of corn oil, which equates to $\geq 21.4\%$ corn oil in the blend.

VI. ENFORCEMENT DISCRETION FACTORS

FDA will have to relieve the QHCs requested in this Petition from all regulatory provisions that would otherwise disqualify the foods from bearing any health claim or a health claim for CHD. It has the authority to do so if it finds that the QHCs will assist consumers in maintaining healthy dietary practices (21 C.F.R. §101.14(e)(3)). Petitioner submits that the information in this Petition meets the needed criteria, and that the QHCs for corn oil and corn oil-containing foods will assist consumers in maintaining healthy dietary practices. Petitioner also submits that such action would be consistent with other instances in which FDA has allowed a health claim for substances that contain certain levels of fat.

The example most relevant to the request in this Petition to exercise enforcement discretion is the FDA's decision to exercise enforcement discretion with respect to the olive oil MUFA QHC (Attachment 9). With the exception of a specific additional category, vegetable oil blends containing corn oil, the categories requested in this Petition are the same as FDA described in the olive oil MUFA QHC. Petitioner submits that enforcement discretion consistent with the manner in which the product categories were dealt with by FDA in the olive oil MUFA QHC is appropriate for the same categories in this Petition, and that the additional category, vegetable oil blends containing corn oil, should be afforded the same enforcement discretion as 100% corn oil.

The criteria and citations to regulations from which such enforcement discretion relief will be needed include those items discussed below.

A. Nutrient Content Criteria for CHD Claims

1. Low Fat

To bear a low fat claim foods must typically contain 3 g or less of fat per reference amount customarily consumed (RACC), or, for foods with a RACC of 30 g or less or 2 tablespoons or less, per 50 g (21 C.F.R. §101.62(b)(2)). Corn oil is essentially 100% fat and obviously does not meet the “low fat” definition; similarly, any corn oil-containing foods are not likely to be “low fat.”

FDA has not imposed a “low fat” criterion in connection with several health claims, and FDA’s justification for doing so in the first such instance, the plant sterol and stanol esters/CHD health claim (21 CFR §101.83), was explained in a briefing to the FDA’s Food Advisory Committee meeting in April of 2004.¹⁵ Subsequently, in the olive oil MUFA QHC (Attachment 9), the “low fat” criterion was not applied to olive oil and olive oil-containing products.

Therefore, consistent both with the precedent established with several prior authorized health claims and with current dietary guidelines that a diet low in saturated fat and cholesterol is more important than a diet low in total fat, Petitioner is asking for enforcement discretion relating to “low fat” as summarized in the following table:

“Low Fat” Criterion	
Product	Application
Corn Oil	Is not imposed
Vegetable Oil Blends	
Dressings for Salads	
Vegetable Oil Spreads	
Shortenings	
Corn Oil-containing Foods Other Than Those Above	

¹⁵ Food and Drug Administration, Food Advisory Committee, Nutrition Subcommittee, April 27-28, 2004 Briefing Information <http://www.fda.gov/ohrms/dockets/ac/04/briefing/4035b1.htm> (Attachment 11).

2. Low Saturated Fat

Food must contain 1 g or less of saturated fat per RACC and not more than 15% of calories from saturated fat (21 C.F.R. §101.62(c)(2)). A RACC of corn oil contains approximately 1.8 g of saturated fat and 13% calories from saturated fat. Corn oil meets the percentage caloric threshold, but it does not meet the quantitative threshold. Similarly, foods containing corn oil may not be able to qualify for a “low saturated fat” claim.

Therefore, Petitioner requests enforcement discretion relating to low saturated fat as summarized in the following table:

“Low Saturated Fat” Criterion	
Product	Application
Corn Oil	Is not imposed No saturated fat disclosure required
Vegetable Oil Blends	Is not imposed No saturated fat disclosure required unless product contains > 2 g saturated fat per RACC
Dressings for Salads	
Vegetable Oil Spreads	
Shortenings	
Corn Oil-containing Foods Other Than Those Above	

As noted in the table, Petitioner requests that FDA not require a disclosure statement in connection with the Substitution Claim for corn oil. As stated above, the Substitution Claim is modeled on the Dietary Guidance Statement involving the substitution of vegetable oils for fats high in saturated fats. FDA has announced that this important dietary guidance is truthful and nonmisleading without a saturated fat disclosure; it would be inconsistent to require one for corn oil.

With respect to the Inclusion Claim, the Petitioner requests that a disclosure statement for saturated fat not be required for any of the other five categories unless the product contains greater than 2 g of saturated fat. First, an increase of 1 g as the trigger for a disclosure statement is not significant in the context of the total daily diet, when the proposed QHC already includes language that the inclusion of corn oil in the diet should be accompanied by dietary

modifications not to increase saturated fat. Second, the 2 g limit will enable more products not to include it, which is consistent with the science and will assist consumers in maintaining healthy dietary practices, because consumers are more likely to include these products in their diet and cut saturated fat from other sources. Third, a 2 g limit would make the claim consistent with that of Canada, whose definition of “low saturated fat” is ≤ 2 g saturated fatty acids/serving and $\leq 15\%$ of energy value from saturated fatty acids.¹⁶ Finally, there is no desire to hide the saturated fat content of these products, as it is disclosed in the nutrition facts panel.

3. No/Low Cholesterol

To qualify for a “no cholesterol” claim, a food with a RACC of 30 g or less or 2 tablespoons or less, and 13 g or more of total fat (per RACC, per serving or per 50 g), must contain

- Less than 2 mg of cholesterol per RACC and per serving; and
- 2 g or less of saturated fat per RACC (21 CFR §101.62(d)(1)(ii)).

To qualify for a “low cholesterol” claim, a food with a RACC of 30 g or less or 2 tablespoons or less, and 13 g or more of total fat (per RACC, per serving or per 50 g), must contain

- 20 mg or less of cholesterol per RACC and per 50 mg; and
- 2 g or less of saturated fat per RACC (21 CFR §101.62(d)(2)(iv)).

Corn oil is a cholesterol free food and, therefore, qualifies to bear a “no cholesterol” nutrient content claim. Because corn oil contains 14 g of total fat per RACC, the regulation requires it to bear a disclosure, in immediate proximity to the claim, that it contains 14 g of total fat (See §101.62(d)(1)(ii)(D) and (d)(2)(iv)(C)). Petitioner submits that a message addressing

¹⁶ Canadian Food Inspection Agency, 2003 Guide to Food Labelling and Advertising, 7.17 Saturated Fatty Acid Claims (Attachment 12).

total fat content is likely to be interpreted negatively by the average consumer, and thus will work at cross purposes with the health claims requested in this Petition.

A more informative disclosure would say “contains 14 g of total fat, 12 of which are unsaturated fats that may reduce your risk of CHD.” This disclosure is a more positive and meaningful nutritional message than a short disclosure of total fat (and is consistent with US dietary recommendations cited above that the type of fat consumed is more important to CHD risk than is total fat), but such a long disclosure is impractical.

Therefore, based on the considerations above, Petitioner requests that corn oil and corn oil-containing foods qualified to bear “no cholesterol” or “low cholesterol” nutrient content claims not be required to accompany such claims with a disclosure of total fat.

“No/Low Cholesterol” Criterion	
Product	Application
Corn Oil	Is imposed Products do not need to include a “total fat” disclosure if a “no” or “low” cholesterol nutrient content claim is made on the label
Vegetable Oil Blends	
Dressings for Salads	
Vegetable Oil Spreads	
Shortenings	
Corn Oil-containing Foods Other Than Those Above	

B. Disqualifying Levels

21 C.F.R. §101.14(e)(3) provides that a food may not bear a health claim if that food exceeds any of the disqualifying nutrient levels identified in §101.14(a)(4), i.e., total fat, saturated fat, cholesterol or sodium. These four nutrients, and their effect on the claims requested in this Petition, are described below.

1. Total Fat

Disqualifying fat levels for individual foods are above 13.0 g per RACC, per label serving size, and, for foods with a RACC of 30 g or less or 2 tablespoons or less, per 50 g. The request not to disqualify the requested claims for corn oil is consistent with the way in which total fat was handled in the olive oil MUFA QHC. The request not to disqualify the requested claims for vegetable oil blends is also consistent with the treatment in the olive oil MUFA QHC.

“Total Fat” Disqualifying Criterion	
Product	Application
Corn Oil	Is not imposed
Vegetable Oil Blends	
Dressings for Salads	Is not imposed, but if it exceeds the disqualifying level, a disclosure statement to see the Nutrition Panel for total fat content must be included
Vegetable Oil Spreads	
Shortenings	
Corn Oil-containing Foods Other Than Those Above	

2. Saturated Fat

Disqualifying saturated fat levels for individual foods are above 4 g per RACC, per label serving size, and, for foods with a RACC of 30 g or less or 2 tablespoons or less, per 50 g. Corn oil contains 6.5 g of saturated fat per 50 g¹⁷; therefore, because it has a small RACC, corn oil exceeds the disqualifying level for saturated fat. It is also appropriate that vegetable oil blends be excused from the 50 g criterion for the same reason; retaining the upper RACC limit of 4 g of saturated fat for the claim will also insure that a theoretical blend of corn oil with a vegetable oil high in saturated fat, e.g., coconut oil, will not be able to bear a claim.

The approach suggested above, as reflected in the table below, is consistent with the manner in which the saturated fat disqualifying level was addressed in the olive oil MUFA QHC.¹⁸

¹⁷ USDA Nutrient Database for Standard Reference (data: 50 g corn oil) (Attachment 13).

¹⁸ Footnote 9 at pp. 17-18.

“Saturated Fat” Disqualifying Criterion	
Product	Application
Corn Oil	Must meet the 4 g per RACC criterion only
Vegetable Oil Blends	
Dressings for Salads	Must meet both criteria
Vegetable Oil Spreads	Must meet the 4 g per RACC criterion only
Shortenings	
Corn Oil-containing Foods Other Than Those Above	Must meet both criteria

3-4. Cholesterol and Sodium

Consistent with FDA’s handling of the olive oil MUFA QHC, Petitioner has no objection to these two disqualifying levels being imposed on corn oil and corn oil-containing foods.

“Cholesterol and Sodium” Disqualifying Criteria	
Product	Application
Corn Oil	Is imposed
Vegetable Oil Blends	
Dressings for Salads	
Vegetable Oil Spreads	
Shortenings	
Corn Oil-containing Foods Other Than Those Above	

C. 10 Percent Minimum Nutrient Content Requirement

21 C.F.R. §101.14(e)(6), which is intended to prevent the use of health claims on foods with minimal nutrition value, provides that a conventional food may not bear a health claim unless it contains, prior to any nutrient addition, at least 10% of the Daily Value for vitamin A, vitamin C, iron, calcium, protein or dietary fiber per RACC. Corn oil provides nutritional value, but does not meet the 10% minimum nutrient content requirement. Consistent with FDA’s prior handling of other CHD health claim petitions, particularly the olive oil MUFA QHC (Attachment 9 at pp. 18-19), the Petitioner requests that the 10% minimum nutrient content requirement not be imposed to disqualify corn oil, vegetable oil blends, dressings for salads and shortenings from bearing the requested claims.

“10 Percent Minimum Nutrient Content” Disqualifying Criterion	
Product	Application
Corn Oil	Is not imposed
Vegetable Oil Blends	
Dressings for Salads	
Vegetable Oil Spreads	Is imposed
Shortenings	Is not imposed
Corn Oil-containing Foods Other Than Those Above	Is imposed

D. Trans Fat

Corn oil does not contain *trans* fatty acid (TFA), so a TFA disqualifying level would not impact the claims for corn oil requested in this Petition. But the Petitioner believes that a disqualifying level of 1 g per RACC of TFA is appropriate for corn oil-containing foods, because FDA recognizes that science supports a relationship between TFA intake and risk of CHD.¹⁹

In its letter announcing its exercise of enforcement discretion for the olive oil MUFA QHC, FDA declined the petitioner’s request to establish a disqualifying level of 1 g of TFA per RACC for olive oil-containing foods (Attachment 9 at 19-20). FDA pointed to its pending rulemaking related to the establishment of nutrient content claims for TFA as the rationale for this portion of its response, and stated that it would consider the request in the olive oil MUFA QHC in the context of that rulemaking. Because a final rule has not yet issued with respect to nutrient content claims for TFA, the Petitioner has no expectation that FDA will respond any differently to a request in this Petition related to a TFA disqualifying level for corn oil-containing foods. Therefore, Petitioner requests that corn oil-containing foods be treated similarly to other QHCs permitted for products containing high UFA vegetable oils when and if a disqualifying level is set for TFA and CHD-related claims is established.

¹⁹ 68 Federal Register 41507, 41508 (July 11, 2003) (ANPR/Food Labeling: Trans Fatty Acids in Nutrition Labeling...).

E. Context of the Total Daily Diet

A general requirement for health claims is that the public must be able to comprehend the claim and to understand its significance in the context of the total daily diet 403(r)(3)(B)(iii) of the FD&C Act, 21 U.S.C. §343(r)(3)(B)(iii). (See also 21 C.F.R. §101.14(d)(2)(v)). In the case of heart disease, FDA typically requires information on a diet low in saturated total fat and cholesterol. But FDA has made exceptions. In the exercise of enforcement discretion with respect to the petition relating to a QHC for Omega-3 Fatty Acids and CHD,²⁰ the FDA did not require the QHC to be accompanied by a message about diets low in saturated fat and cholesterol.

Because dietary implementation of the requested Substitution Claim will reduce the intake of saturated fat and cholesterol, there is no positive benefit to be gained by requiring inclusion of a reference to diets low in saturated fat and cholesterol. Additionally, the Substitution Claim would then also vary from the health message that FDA has committed to deliver to the public associating the substitution of vegetable oil for solid fat with reduction in the risk of heart disease.

The proposed Inclusion Claim incorporates language to assist the consumer in understanding the claim in the context of the total daily diet, and therefore, specific reference to a diet low in saturated fat and cholesterol is unnecessary.

“Context of the Total daily Diet” Disqualifying Criterion	
Product	Application
Corn Oil	Is not imposed
Vegetable Oil Blends	
Dressings for Salads	
Vegetable Oil Spreads	
Shortenings	
Corn Oil-containing Foods Other Than Those Above	

²⁰ Docket Nos. 91N-0103 and 2003Q-0401 (2004).

F. Discussion

Ample precedent exists for FDA to not apply any of the above factors to deny a health claim for corn oil or corn oil-containing foods. As mentioned above, the most recent, relevant precedent was FDA's exercise of enforcement discretion with respect to the olive oil MUFA QHC. FDA's discussion and conclusions relating to 100% olive oil (as opposed to olive oil-containing foods) in its response to that petition apply equally to corn oil.

VII. ANALYTICAL

Petitioner is not aware of any official method to quantify the amount of corn oil in any food product. However, the QHCs for which enforcement discretion is sought relate to a discrete, identifiable food product, corn oil. Therefore, FDA will be able to verify the presence of corn oil in a product bearing a QHC on the same basis that it established in 21 C.F.R.

§101.82(c)(2)(ii)(B), the health claim regulation for soy protein and CHD:

FDA will base its calculation on information identified and supplied by manufacturers, such as nutrient data bases or analyses, recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the ratio of soy protein to total protein. Manufacturers must maintain records sufficient to substantiate the claim for as long as the products are marketed and provide these records, on written request, to appropriate regulatory officials.

VIII. PROPOSED MODEL QUALIFIED HEALTH CLAIMS

The Petitioner submits that credible scientific evidence presented in this Petition support the requested qualified health claims. The Petitioner also submits that the level of scientific support for the claim is accurately communicated by the claim language presented below:

A. The Substitution Claim

When either of the following label claims is included on the label of 100% corn oil --
Substituting corn oil for solid fats may reduce your risk of heart disease and
Substituting corn oil for fats high in saturated fat may reduce your risk of heart disease --
this Petition requests that the claim not be accompanied by qualifying language. The basis for not including qualifying statements with the Substitution Claim is threefold. First, when corn oil is substituted 1:1 for fats high in saturated fat, the difference in caloric intake is nutritionally insignificant, i.e., the suggested dietary substitution does not result in any nutritionally significant increase in caloric intake. Second, any referral statements would have no nutritional relevance to the dietary substitution message, because total fat intake remains the same and saturated fat intake is decreased. Finally, qualifying language would make the claim inconsistent with the synonymous health message that FDA has announced to the public that it will deliver:

Substituting vegetable oil for solid fats in your diet may reduce your risk of heart disease.²¹

B. The Inclusion Claim

Petitioner submits that the Inclusion Claim for corn oil-containing foods,
Including corn oil-containing foods in your diet may reduce your risk of heart disease,

²¹ Supra, footnote 5.

is a “B” level claim that is truthful and not misleading if it is accompanied by qualifying language that educates the consumer about the need to include corn oil in the diet without increasing total caloric, saturated fat or cholesterol intake. Thus, the entire claim and qualifying language would be:

Scientific evidence establishes that including corn oil-containing foods in your diet may reduce your risk of heart disease. To achieve such benefits, include slightly less than 1 tablespoon (12 grams) of corn oil per day in your diet while not increasing calories, saturated fat or cholesterol. One serving of this product contains x grams of corn oil. Although there is scientific evidence supporting the claim, the evidence is not conclusive.²²

As so qualified, this claim informs the consumer that including corn oil-containing foods in an otherwise corn oil-free diet will require the elimination of some other calories.

The Petitioner also submits that the health claim in this message is obscured because of its length. It proposes the following alternative when the main claim (first sentence) is on the principal display panel (PDP):

[Principal Display Panel]

Scientific evidence establishes that including corn oil-containing foods in your diet may reduce your risk of heart disease. See [side/back] panel to learn how to achieve such benefits.

[Side/Back Panel]

Heart Disease Risk Reduction

To achieve benefits, include at least 12 grams (slightly less than a tablespoon) of corn oil per day in your diet while not increasing calories, saturated fat and cholesterol. One serving of this product contains x grams of corn oil. Although there is scientific evidence supporting the claim, the evidence is not conclusive.²³

Splitting the message on separate panels as proposed above achieves two objectives. First, splitting enables a message of a practical length to be placed on the PDP. A short message on the PDP is more likely to be seen, read and understood than a long message. Second, an

²² A saturated fat disclosure statement is proposed to be required if the product contains > 2 g saturated fat per RACC, e.g., “See nutrition information for saturated fat content.”

²³ A saturated fat disclosure statement is proposed to be required if the product contains > 2 g saturated fat per RACC, e.g., “See nutrition information for saturated fat content.”

explanation of how to achieve the benefit included on a side or the back panel is more informative.

Research that is discussed below supports a split health claim as requested in the preceding paragraph. In response to implementation issues raised by FDA's 1993 food labeling regulations, the Keystone National Policy Dialogue on Food, Nutrition and Health²⁴ (Keystone Dialogue) proposed several labeling alternatives to improve the communication effectiveness of health claims. The final report of the Keystone Dialogue suggested a variety of wordings and presentation styles. The report recommended that health claims on food labels be shorter, containing only a statement of the relevant diet-disease relationship without additional qualifying information. A second recommendation was that greater flexibility be given in the placement of the health claim by allowing for split messages on package labels--for example, a short message on the front of the package, with a more detailed message on the back.

In an effort to evaluate model health claims and the recommendations of the Keystone Dialogue, Levy et al.²⁵ conducted an experimental study in 1997 to evaluate consumers' preference for and comprehension of various types and formats of health claims. The study was conducted on 1,403 primary grocery shoppers and involved mock product packages with product appropriate health claims for three products: yogurt, cereal and lasagna.

The results indicated that, in general, short health claims are more effective than long claims in communicating specific disease effects and health benefits ($P<.01$). Short claims, especially on the lasagna product, reduced the likelihood that respondents attributed inappropriate health benefits to the product.

²⁴ The Final Report of The Keystone National Policy Dialogue on Food, Nutrition and Health, Keystone, CO, and Washington, DC (March 1996) (Attachment 14).

²⁵ Levy et al. *Consumer Impacts of Health Claims: An Experimental Study*. Washington, DC: Food and Drug Administration, Center for Food Safety and Applied Nutrition, Division of Market Studies; 1997 (Executive Summary) (Attachment 15).

In addition, the Levy study indicated that split-message claims increased the likelihood that respondents would notice the product nutrient characteristics not mentioned in the claim ($P < .05$). Furthermore, split-message presentations were more compelling than the same health claim on the front of the yogurt package. This difference may be due to the smaller print and packaging size of the yogurt container.

Finally, a review of the consumer comprehension research supports the Levy et al. findings. In a review of the regulatory history of health claims, Geiger (1998)²⁶ concluded that the most effective health claims are concise, appear on the principal display panel of the product and relate to a consumer need to be solved. She also concluded that health claims increase consumers' knowledge about the role of nutrition and health.

In conclusion, concise messages are an effective means of communicating health messages, and, as found in a study conducted by FDA, shorter messages are well accepted by consumers.²⁷ Petitioner respectfully requests that shorter, split messages be permitted in response to this Petition.

²⁶ Geiger CJ. Health claims: History, current regulatory status, and consumer research. *J. Amer. Diet. Assn.* 1998. Vol. 98:11, 1312-1322 (Attachment 16).

²⁷ Levy et al., *supra*, note 18.

IX. CERTIFICATION

Pursuant to 21 C.F.R. §101.70(h), I certify by signing below 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 QHCs.

X. ENVIRONMENTAL ASSESSMENT

The requested QHCs for which enforcement discretion are sought in this Petition are categorically exempted from an environmental impact statement under 21 C.F.R. §25.30 or §25.32.

XI. CONCLUSION

Based on all of the information provided in this Petition, the Petitioner requests that the requested QHCs for corn oil and corn oil-containing food products be authorized.

Respectfully submitted,

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