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

April 14, 2006

Dear Ms. Anderson:

Comment on FDA Draft *Guidance for Industry and FDA Staff: Whole Grains Label Statements*

Reference: Docket No. 2006D-0066

Please accept this letter for consideration by the Food and Drug Administration for inclusion of flax within the "whole grain" label statement ("Draft Guidance").

There is widespread recognition that diet plays a role in the development of chronic disease and is believed to play a role in 5 of 10 of the leading causes of death. Beginning in the 1980s, a rapid expansion in scientific knowledge regarding the role of flax *(Linum usitatissimum* L.) as a potential preventive food for several disease and chronic conditions began to emerge. Although flax provides numerous essential nutrients, most health research interest has focused primarily on three of the most physiologically-active components: (1) the omega three essential fatty acid, alpha-linolenic acid (ALA), (2) lignans, a major class of phytoestrogens and (3) soluble fibre primarily in the form of mucilage.

We understand that the FDA Draft *Guidance for Industry and FDA Staff: Whole Grains Label Statements* ("Draft Guidance") is intended to provide guidance to industry about what the agency considers to be "whole grain" and assist manufacturers in labeling their products. The Draft Guidance states that cereal grains that consist of intact, ground, cracked or flaked caryopsis whose principal anatomical components - the starchy endosperm, germ and bran - are present in the same relative proportion as they exist in the intact caryopsis - be considered a whole grain food. The Draft Guidance lists amaranth, barley, buckwheat, bulgur, corn (including popcorn), millet, quinoa, rice, rye, oats, sorghum, teff, triticale, wheat and wild rice as examples of cereal grains. The Draft Guidance indicates that products derived from legumes, oil seeds (sunflower seeds), and roots (e.g., arrowroot) should not be considered whole grains.

However, the general distinction made by the FDA in the Draft Guidance between oil seeds and cereal grains is improper, as not all oil seeds should be excluded. *Whole grain flaxseed is an oil seed that has comparable nutrients to the cereal grains listed by the FDA.* Studies have also has shown that whole grain flaxseed has similar health benefits. Accordingly, the FDA should revise the Draft Guidance to delete "oilseeds" from the list of foods that should not be considered whole grains. In addition, the FDA should indicate that in addition to cereal grains, flaxseed products that consist of intact, ground, cracked or flaked caryopsis whose principal anatomical components are present in the same relative proportion as they exist in the intact caryopsis should also be considered whole grain foods.

2006D-0066 C22

Please find attached to this letter background material to support the revision of the Draft Guidance to include flaxseed as a whole grain

Thank you for your consideration.

Yours respectively,

John Oliver
Chair, Flax Canada 2015

c.c. Kelley Fitzpatrick
Coordinator, Flax Canada 2015

Background:

I. Flaxseed is high in numerous essential nutrients.

A. Composition

An analysis of brown Canadian flax averaged 41% fat, 20% protein, 28% total dietary fiber, 7.7% moisture and 3.4% ash, which is the mineral-rich residue left after samples are burned[1].

B. Dietary Fiber

Whole flax seeds and ground flax are sources of dietary fiber. The fiber fractions in flax can be classified as either dietary fiber or functional fiber. The classification depends on whether they are found intact in flax or are extracted from flax, purified and added to foods and other products[14].

Dietary fiber consists of nondigestible plant carbohydrates and other materials that are found intact in plants. *Functional fiber* consists of nondigestible carbohydrates that have been extracted from plants and that have beneficial effects in humans. *Total fiber* is the sum of dietary fiber and functional fiber. Dietary fiber and functional fiber are not digested and absorbed by the human small intestine and, therefore, pass relatively intact into the large intestine[2]

Total fiber accounts for about 28% of the weight of full-fat flax seeds, with a ratio of soluble to insoluble fiber between 20:80 and 40:60[3]. The major fiber fractions in flax consist of cellulose, which is the main structural material of plant cell walls; mucilage gums, a type of polysaccharide that becomes viscous when mixed with water or other fluids; and lignin, a highly-branched fiber found within the cell walls of woody plants.

The American Dietetic Association has cited the "significant impact" that fiber can have on the prevention of obesity, cardiovascular disease and type 2 diabetes[4]. The primary action of fiber in the body is in the gastrointestinal tract, but not all fiber sources have the same physiological effects. Generally, concentrates of water-soluble fibers delay transit through the stomach and small intestine[5]. Soluble fibers are rapidly broken down (fermented) by bacteria in

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[5] Wolever TMS, Jenkins DJA. 1993. Effect of dietary fiber and foods on carbohydrate metabolism. In: Spiller GA, ed. *CRC Handbook of Dietary Fiber in Human Nutrition*. 2nd ed. Boca Raton, Fla: CRC Press; 111-152.

the large intestine and do not promote laxation. Fibers that are predominantly water insoluble promote laxation and are either slowly or not fermented[6].

Insoluble dietary fiber plays an important role in the relief of constipation, a common problem among many individuals who consume low fiber diets, are inactive, or are using certain medications for other conditions that may promote constipation as a side effect.

Diets high in insoluble fiber result in good colon health, which may have protective effects against colon cancer. Correlation studies that compared colorectal cancer incidence or mortality rates among countries with estimates of national dietary fiber consumption suggest that fiber intake may be protective against colon cancer[7]. When results of 13 case-control studies of colorectal cancer rates and dietary practices were pooled, it was concluded that the results provided substantive evidence that intake of fiber-rich foods is inversely related to risks of both colon and rectal cancer[8].

Diets high in dietary fiber, both soluble and insoluble types, have demonstrated beneficial effects on weight loss. Studies have shown that high fiber foods, such as flax, deliver more bulk in the diet with less energy, which in turn may influence satiety as well as alter certain hormone responses such as cholecystokinin and insulin[9].

C. Phytonutrients

Plant lignans are phenolic compounds formed from the coupling of two cinnamyl alcohols. They are biologically active phytochemicals with apparent anticancer and antioxidant potential. They act in the body as antioxidants and phytoestrogens. Flax is a particularly rich source of a lignan called secoisolariciresinol diglycoside (SDG). SDG is a plant lignan that is converted by bacteria in the colon of humans and other animals to mammalian lignans. Other lignans present in small amounts in flax include matairesinol, pinoresinol and isolariciresinol[10]. Secoisolariciresinol – the form of SDG without the diglycoside linkages – is abbreviated SECO.

The lignans SDG, matairesinol and pinoresinol in flax are converted by bacteria in the colon of humans and other animals to the mammalian lignans, enterodiol and enterolactone. Enterodiol and enterolactone have two metabolic fates: 1) They can be excreted directly in the feces; or 2) After being absorbed from the gut, they can undergo enterohepatic circulation (secreted into bile, reabsorbed from the intestine) and are eventually excreted in the urine in conjugated form. The concentration of enterodiol and enterolactone in urine is related to

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[8] Howe GR, Benito E, Castelleto R, et al. 1992. Dietary intake of fiber and decreased risk of cancers of the colon and rectum: evidence from the combined analysis of 13 case-control studies. *J Natl Cancer Ins;* 84:1887-1896.

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[10] Thompson LU. 2003. Analysis and bioavailability of lignans. In: *Flaxseed in Human Nutrition*, eds Thompson LU and Cunnane SC, 2nd ed, AOCS Press, Champaign, IL, pp. 92-116.

the concentration of plants lignans in the diet—large intakes of plant lignans result in large amounts of enterodiol and enterolactone in the urine of rats and humans[11].

D. Fatty Acids

Flax contains a mixture of fatty acids, but it is rich in polyunsaturated fatty acids, particularly alpha-linolenic acid (ALA or LNA, as it is sometimes abbreviated), the essential omega-3 fatty acid, and linoleic acid (LA), the essential omega-6 fatty acid. ALA constitutes 57% of the total fatty acids in flax, making flax the richest source of ALA in the North American diet[12]. Linoleic acid constitutes 16% of total fatty acids. Flax oil and canola oil have the lowest levels of the nutritionally undesirable saturated fatty acids, at 9% and 7%, respectively. The level of the desirable monounsaturates in flax oil is modest (18%).

Essential fatty acids (EFAs) are required in the diet as they can not be synthesized by humans from the shorter chain fatty acid, oleic acid (C18:1). The two established EFAs are linoleic acid (C18:2, LA) which is converted in the body into longer chain omega-6 fatty acids, and ALA. LA and ALA are components of cellular membranes and act to increase membrane fluidity. These fatty acids are necessary for cell membrane function, as well as for the proper functioning of the brain and nervous system.

EFAs serve as the starting point for the production of a number of important, very active, hormone-like compounds called "eicosanoids". The omega-6 fatty acid LA and the omega-3 fatty acid ALA form different eicosanoids with different activities. LA and ALA also compete with one another for the enzymes responsible for the synthesis of various eicosanoids. Thus, an excess of one family of fatty acids can interfere with the metabolism of the other, reducing its incorporation into tissue lipids and altering their biological effects[13]. A proper balance of the EFAs in the diet is important for the maintenance of good health.

ALA is converted by a series of alternating desaturations and elongations to the long-chain omega-3 fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). The conversion of ALA to EPA is usually described as limited and somewhat slow in humans. In truth, there is great variability in the conversion rate reported by researchers, with one estimate as high as 6% converted to EPA and one as low as 0.2% converted[14]. The 30-fold difference between these conversion rates reflects key differences in the study protocols.

LA is converted to long-chain omega-6 fatty acids also by a series of desaturations and elongations to arachidonic acid (AA), the precursor of eicosanoids, several of

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which promote the clumping (aggregation) of blood platelets, the clotting of blood within blood vessels (thrombosis) and inflammatory reactions. When diets are high in omega-6 fatty acids, AA and its potent eicosanoids are produced in abundance, resulting in an over-active immune system that may contribute to chronic diseases like cancer, stroke, diabetes and coronary heart disease.

E. Other Key Nutritional Facts

Flax is low in carbohydrates (sugars and starches), providing only 1 gram (g) per 100g. For this reason, flax contributes little to total carbohydrate intake. Flax is also gluten-free.

II. The Composition of Flaxseed compares favorably with the composition of the cereal grains listed by the FDA.

Although Flaxseed is an oil seed, the Composition of Flaxseed compares favorably with the composition of the cereal grains listed by the FDA. The composition of flaxseed also compares favorably to corn, another oil seed that is listed as a cereal grain by the FDA. The composition of flaxseed is superior to the composition of sunflower seeds, which the FDA singles out as an example of an oil seed.

III. Flaxseed has been shown to have significant benefits with regard to cardiovascular disease (CVD).

The consumption of 2-6 tbsp of ground flax daily for four weeks reduced blood total and LDL cholesterol significantly in clinical trials. Blood total cholesterol decreased 6-9% and LDL cholesterol decreased 9-18% in studies of healthy young adults[15], men and women with moderately high levels of blood cholesterol[16] and postmenopausal women[17] who ate ground flax. High-density lipoprotein (HDL) cholesterol and triglyceride levels were not affected. The effect of ground flax on blood lipids was confounded in these studies by the fiber content of flax.

Jenkins and colleagues proposed that the mucilage gums are most likely responsible for the lipid-lowering effects of flax[18]. In their study, 29 men and women with high blood cholesterol levels ate muffins made with wheat bran or muffins made with partially defatted flax for three weeks. The subjects ate four muffins daily, which provided 50 g of partially defatted flax. Partially defatted flax contains less than 10% fat by weight, whereas regular flax contains about 41% fat. The subjects' total cholesterol decreased about 5% and LDL cholesterol decreased 8% on the partially defatted flax diet. These data suggest a role for flax

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mucilage gums in lowering blood lipids, but the contribution of ALA to the study findings cannot be ignored—the four flax muffins eaten daily provided a significant amount of ALA (3.5 g/day). In this case, the study design did not allow the researchers to completely separate the effects of the mucilage gums from those of ALA.

The lipid lowering effects of whole flaxseed versus sunflower seed in 38 postmenopausal women were investigated in a double blind, randomized, crossover trial. Subjects consumed 38g of whole flaxseed or whole sunflower seed incorporated into bread or muffins for a six-week period[19]. Following a 2-week washout period, participants resumed treatment for an additional six-week period. LDL cholesterol decreased by 14.7% in the flax group in comparison to the sunflower seed group. No effects on triglyceride or HDL levels were observed in either group.

[19] Arjmandi, B.H., Khan, D.A., Juma, S., et al. 1998. Whole flaxseed consumption lowers serum LDL-cholesterol and lipoprotein (a) concentrations in postmenopausal women. Nutr Res; 18: 1203-1214.

Outline for Comment on FDA Draft *Guidance for Industry and FDA Staff: Whole Grains Label Statements*

Reference: Docket No. 2006D-0066

Comments may be submitted in writing or electronically by April 18, 2006.

Submit to:

Division of Docket Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
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Summary of Argument:

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Outline of Argument:

I. Flaxseed is high in numerous essential nutrients.

A. Composition

An analysis of brown Canadian flax averaged 41% fat, 20% protein, 28% total dietary fiber, 7.7% moisture and 3.4% ash, which is the mineral-rich residue left after samples are burned[1].

B. Dietary Fiber

Whole flax seeds and ground flax are sources of dietary fiber. The fiber fractions in flax can be classified as either dietary fiber or functional fiber. The classification depends on whether they are found intact in flax or are extracted from flax, purified and added to foods and other products[14].

Dietary fiber consists of nondigestible plant carbohydrates and other materials that are found intact in plants. *Functional fiber* consists of nondigestible carbohydrates that have been extracted from plants and that have beneficial effects in humans. *Total fiber* is the sum of dietary fiber and functional fiber. Dietary fiber and functional fiber are not digested and absorbed by the human small intestine and, therefore, pass relatively intact into the large intestine[2]

Total fiber accounts for about 28% of the weight of full-fat flax seeds, with a ratio of soluble to insoluble fiber between 20:80 and 40:60[3]. The major fiber fractions in flax consist of cellulose, which is the main structural material of plant cell walls; mucilage gums, a type of polysaccharide that becomes viscous when mixed with water or other fluids; and lignin, a highly-branched fiber found within the cell walls of woody plants.

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