

2006-0066

April 13, 2006

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

To Whom It May Concern:

The AmeriFlax Board of Directors strongly urges the FDA to reconsider the exclusion of oilseeds in the FDA Draft *Guidance for Industry and FDA Staff: Whole Grains Label Statements* ("Draft Guidance").

Whole grain flaxseed is an oilseed that has comparable nutrients to the cereal grains listed by the FDA. Because of this fact, we believe that FDA should include whole grain flaxseed in its definition of whole grains. All oilseeds are not nutritionally equal and we believe that FDA has made an improper distinction of whole grain flaxseed by generally categorizing it as "oilseed" with no other health attributes. Indeed, the nutritional components of whole grain flaxseed compare exceedingly well with cereal grains such as corn, which, in the American diet, functions as much as an oilseed as it does a whole grain.

Whole flaxseed and ground flaxseed are rich in many powerful nutrients including dietary fiber, omega 3 fatty acid (alpha linolenic acid) and phytoestrogenic compounds known as lignans. Flaxseed is also an outstanding source of many other essential nutrients including protein, folate, potassium and other important minerals.

Flaxseed has been highly recognized for its benefits in the treatment of a variety of human conditions and diseases. One of the strongest cases for adding more whole grains in the diet is the beneficial effect of fiber. Whole grain flaxseed, in addition to contributing high quality protein and omega 3 fatty acid, is rich in fiber and has been scientifically proven to be highly beneficial in the diets of the convalescent and elderly.

It is also known to have significant benefits with regard to cardiovascular disease (CVD). In addition it appears to have protective effects in inflammatory disorders such as rheumatoid arthritis and a positive effect on immune functions, which is the body's ability to defend itself against infection. A review of the literature also indicates an

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inhibitory effect of dietary ALA on tumor incidence and growth in animal models using chemically induced, transplantable and spontaneous tumors. These results have been seen with cancers of the breast, colon and pancreas.

Formulating foods for health is one of the leading trends in the food industry and flaxseed has become an important ingredient in many of these new "functional foods". Eliminating whole grain flaxseed from the *Whole Grains Label Statement* would inhibit food processors and bakeries from using flaxseed as an ingredient and would rob health conscious consumers of a truly nutritious functional food.

AmeriFlax represents United States flaxseed producers and processors. Flaxseed is a vital crop for North Dakota producers. Within the past five to 10 years, the rediscovered health benefits of this old world crop have created a vast interest in flaxseed as a consumer food, a food industry ingredient and an animal feed.

Please consider our request to include whole grain flaxseed as part of the definition of "whole grain" in the FDA *Whole Grain Label Statement*. If you have further questions please feel free to contact Kaye Effertz at the AmeriFlax office at 701-663-9799 or e-mail: keffertz@ameriflax.com

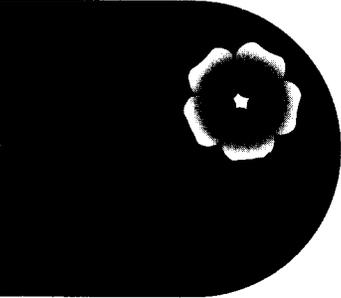
Thank you and we look forward to working with you.

Sincerely,


Jan Topp

AmeriFlax President

AmeriFlax Board of Directors



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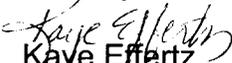
To: FDA
From: Kaye Effertz, AmeriFlax
Date: 4/13/06
Re: FDA Whole Grain Label Statement

To Whom it May Concern:

The following is a letter from AmeriFlax in response to the FDA Draft Guidance for Industry and FDA Staff: Whole Grains Label Statement.

AmeriFlax is the trade organization that represents over 3,500 United States flaxseed producers and processors. AmeriFlax is funded by the North Dakota Oilseed Council's producer check-off and the organization is located in Mandan, North Dakota.

Thank you and please contact AmeriFlax for further questions.


Kaye Effertz
AmeriFlax