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Food and Drug Administration
College Park, MD 20740

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Linda D. Meyers, PhD
Deputy Director, Food and Nutrition Board
Institute of Medicine
National Academy of Sciences
500 Fifth Street, NW
Washington, DC 20001

Dear Dr. Meyers,

We have received a notification under section 303 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) that identified the following statement from *Diet and Health: Implications for Reducing Chronic Disease Risk* (National Research Council, National Academy Press, 1989) as an authoritative statement:

Diets high in plant foods – i.e., fruits, vegetables, legumes, and whole grains cereals – are associated with a lower occurrence of coronary heart disease and cancers of the lung, colon, esophagus, and stomach.

This statement appears on page 8 in the executive summary of the report. The notification mentioned the recommendation from the Committee on Diet and Health that total fat intake be reduced to 30% or less of calories, with less than 10% of total calories derived from saturated fat. Other statements regarding total fat intake were cited from the executive summary as well and are following:

Intake of total fat *per se*, independent of the relative content of the different types of fatty acids, is not associated with high blood cholesterol levels and coronary heart disease. A reduction in total fat consumption, however, facilitates reduction of saturated fatty acid intake; hence, in addition to reducing the risk of certain cancers, and possibly obesity, it is a rational part of a program aimed at reducing the risk of coronary heart disease. (page 7)

and

A large and convincing body of evidence from studies in human and laboratory animals shows that diets low in saturated fatty acids and cholesterol are associated with low risks and rates of atherosclerotic cardiovascular diseases. High-fat diets are also linked to a high incidence

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of some types of cancer and, probably, obesity. Thus, reducing total fat and saturated fatty acid intake is likely to lower the rates of these chronic diseases. Fat intake should be reduced by curtailing the major sources of dietary fats rather than by eliminating whole categories of foods. For example, by substituting fish, poultry without skin, lean meats, and low- or nonfat dairy products for high-fat foods, one can lower total fat and saturated fatty acid intake while ensuring an adequate intake of iron and calcium – two nutrients of special importance to women. Dietary fat can also be reduced by limiting intake of fried foods, baked goods containing high levels of fat, and spreads and dressings containing fats and oils. (page 13)

The authoritative statement mentioned above is the basis for the following health claim notification that we recently received:

Diets rich in whole grain foods and other plant foods, and low in saturated fat and cholesterol, may help reduce the risk of heart disease.

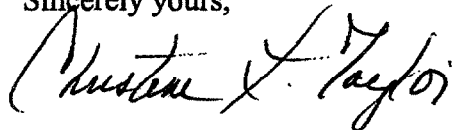
As history, in 1999, the same authoritative statement concerning whole grains was used to support the following health claim (<http://www.cfsan.fda.gov/~dms/flgrains.html>):

Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol, may help reduce the risk of heart disease and certain cancers.

For purposes of bearing the 1999 claim, the food must meet the technical definition of “low fat” in 21 CFR 101.62(b)(2), which states that a low fat product contains less than 3 grams of total fat per reference amount. However, the current notification does not expressly reference the low fat definition, but emphasizes a flexible approach to total fat intake.

Our review of the notification includes consideration of the NAS policy concerning authoritative statements. We understand that your policy is related only to the identification of a statement as authoritative and not to the evaluation of the wording of the claim itself. With this letter, we are offering the Academy the opportunity to elaborate or otherwise comment, especially whether the cited authoritative statement is currently in effect.

Sincerely yours,



Christine L. Taylor, Ph.D.
Director,
Office of Nutrition Policy, Labeling
and Dietary Supplements
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and Applied Nutrition