

INSTITUTE OF MEDICINE  
NATIONAL ACADEMY OF SCIENCES  
2101 CONSTITUTION AVENUE, N.W. WASHINGTON, DC 20418

FOOD AND NUTRITION BOARD

(202) 334-1732  
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April 30, 1999

Christine J. Lewis, Ph.D., R.D.  
Special Assistant  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
Washington, DC 20204

Dear Dr. Lewis:

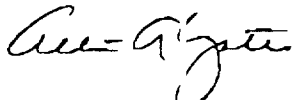
I am responding to your letter of March 12, 1999 regarding the notification you received under section 303 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). This notification identified a statement from *Diet and Health: Implications for Reducing Chronic Disease Risk* (National Research Council, 1989) as an authoritative statement for the purposes of supporting a health claim.

As you are aware, the enclosed National Academy of Sciences (NAS) policy on authoritative statements was developed in response to FDAMA in order to provide guidance to your agency and others about what is considered by the NAS to be authoritative. It is expected that this will assist your agency in determining whether the notification you received regarding use of a statement on p. 8 of the Diet and Health report to support a health claim related to low fat diets rich in whole grain foods and other plant foods is accurate and current. Please be aware that the NAS policy is related only to the determination of identifying a statement as authoritative and not an evaluation of the wording of the claim itself.

I also refer you to my December 22, 1998 letter which provides further guidance on how to interpret the NAS policy. As that letter states, the National Research Council and the Food and Nutrition Board are not in a position to review all notifications submitted to your office.

I hope you will find these comments helpful in evaluating the support for the notification.

Sincerely,



Allison A. Yates, Ph.D., R.D.  
Director

Enclosures (2)

c: C. Garza  
K. Shine  
S. Stoiber

99P-2209

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**Authoritative Statements of the Academy Complex  
with Regard to the Food and Drug Administration Modernization Act of 1997**

**Background**

In fall, 1997, Congress passed and the President subsequently signed the Food and Drug Administration Modernization Act of 1997, which amended the Federal Food, Drug and Cosmetic Act and the Public Health Service Act to "improve the regulation of food, drugs, devices, and biological products..." Title III of that act provided that manufacturers of food products could make nutrient content and /or health claims on the label of a food product 120 days after FDA is notified of the claim and the authoritative statement by a scientific body on which the claim is based (see Sec. 303. Health Claims for Food Products and Sec. 304. Nutrient Content Claims). These provisions were an effort to provide a fast track for establishing the scientific basis for such claims following the Nutrition Education and Labeling Act (NLEA) of 1990, which allowed manufacturers to petition FDA to permit them to make a nutrient content claim with wording approved by FDA and a health claim where "significant scientific agreement existed".

One of the major provisions in this section of the 1997 FDA Modernization Act with regard to food is that this is a notification under which claims are authorized without prior approval by FDA, not a petition by which FDA approves a claim. The claim is to be authorized and can be made with respect to a food if "...a scientific body of the U.S. Government with official responsibility for public health protection or research directly relating to human nutrition (such as the NIH or CDC) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, [about the relationship between a nutrient and a disease or health-related condition] [which identifies the nutrient level] to which the claim refers."

The section indicates that a statement "shall be regarded as an authoritative statement of a scientific body" only if the statement is published by the scientific body and shall not include a statement of an employee made in the individual capacity of the employee.

FDA has the responsibility to challenge the planned use if, for example, they determine it to not be 1) in compliance with Sections 303 or 304 of the Food and Drug Administration Modernization Act of 1997, 2) in compliance with existing general provisions of NLEA, or 3) an accurate representation of the statement on which the claim is based.

A number of reports have been issued by the Academy complex, either as NRC or IOM publications, which might be construed as serving as authoritative statements with regard to nutrient content or health effects of specific foods or food components. Examples include *Carcinogens and Anticarcinogens in the American Diet* (BEST) and *Diet and Health* (FNB).

To guide the interpretation of NRC and IOM reports, the NRC Governing Board adopted the following statement of policy on May 13, 1998:

## **Policy Statement**

"In the conduct of studies with regard to relationships between diet and health, and in the course of review of research relating to questions under study, it is possible that reports of the NRC or IOM may describe associations between foods, nutrients, or food components and aspects of health. These statements would not necessarily represent authoritative statements of the NRC or IOM because they might not summarize the totality of the evidence that would be required by the Academy when formulating an authoritative statement. For example, a report may contain descriptions of the work of others or, on occasion, minority reports expressing the views of individuals. Descriptive materials and minority reports, as examples, are not considered authoritative statements of the National Academy of Sciences or any of its subdivisions.

For the purposes of the Food and Drug Administration Modernization Act of 1997, authoritative statements of the National Academy of Sciences or any of its subdivisions, including the National Research Council and Institute of Medicine, are limited to those that represent the consensus of a duly-appointed committee or views of a duly-appointed principal investigator so that they appear explicitly as findings, conclusions, or recommendations in a report that has completed the institutional report review process."

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December 22, 1998

Christine J. Lewis, PhD, RD  
Special Assistant  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
Washington, DC 20204

Dear Dr. Lewis:

I am in receipt of your letter to me of December 10, 1998 requesting comments on a notification received by your office regarding the use of a statement from the 1989 NRC report, *Diet and Health: Implications for Reducing Chronic Disease Risk*. The statement is taken from page 302 of the report and is as follows:

Clinical studies of hyperlipidemics demonstrate that water-soluble fibers, including pectin, guar gum, and oat gum, can markedly reduce serum total cholesterol and LDL cholesterol without affecting serum HDL cholesterol.

Your letter indicates that the intent of the statement is a claim regarding the relationship between soluble fiber from guar gum and coronary artery disease.

As your agency is aware, in May, 1997, the National Research Council Governing Board of the National Academy of Sciences approved the following statement:

"In the conduct of studies with regard to relationships between diet and health, and in the course of review of research relating to questions under study, it is possible that reports of the NRC or IOM may describe associations between foods, nutrients, or food components and aspects of health. These statements would not necessarily represent authoritative statements of the NRC or IOM because they might not summarize the totality of the evidence that would be required by the Academy when formulating an authoritative statement. For example, a report may contain descriptions of the work of others or, on occasion, minority reports expressing the views of individuals. Descriptive materials and minority reports, as examples, are not considered authoritative statements of the National Academy of Sciences or any of its subdivisions.

December 22, 1998

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“For the purposes of the Food and Drug Administration Modernization Act of 1997 (FDAMA), authoritative statements of the National Academy of Sciences or any of its subdivisions, including the National Research Council and Institute of Medicine, are limited to those that represent the consensus of a duly-appointed committee or views of a duly-appointed principal investigator so that they appear explicitly as findings, conclusions, or recommendations in a report that has completed the institutional report review process.”

The intent of this policy statement is to provide general guidance to both individuals and your agency with regard to what types of statements the Academy would consider “authoritative”. The notification statement forwarded to me on December 10 for comment does not meet the definition of “authoritative” contained within the Academy policy statement. Specifically, the statement does not appear in the Executive Summary of the report, which provides this report’s findings, general conclusions and recommendations based on consensus of the committee. The Executive Summary integrates all the evidence reviewed in the total report. No recommendation is made for soluble fiber or guar gum explicitly in the major conclusions or dietary recommendations provided in the Executive Summary. This example illustrates that it is unlikely that isolated statements from summaries of sections or chapters would represent major conclusions or findings because such summaries are not designed to integrate all of the evidence reviewed.

I appreciate the opportunity on behalf of the Food and Nutrition Board to provide these comments. Although the FNB and the NRC are not in a position to routinely review notifications that have been submitted to your office to affirm the extent to which statements are authoritative according to Section 303 of FDAMA, it seemed important to point out that this notification does not meet the definition of “authoritative” contained with the Academy policy statement. I hope you will find these comments useful in your evaluation of the claim regarding the relationship between soluble fiber from guar gum and coronary heart disease.

Sincerely,

Allison A. Yates, PhD, RD  
Director

c: C. Garza  
K. Shine  
S. Stoiber