



INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

SUSANNE A. STOIBER
Executive Director

2004 MAY 11 12:02

May 5, 2004

Ms. Laura Tarantino
Acting Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
College Park, Maryland 20740

Dear Ms. Tarantino:

I am in receipt of your letter of March 2, 2004 requesting comments on a notification received by your office regarding the use of a statement from the DRI Macronutrient report as an authoritative statement supporting a health claim under the Food and Drug Modernization Act of 1997 (FDAMA).

The National Academies, including the Institute of Medicine (IOM), are not in a position to review individual claims that may be made on the basis of IOM or National Research Council (NRC) reports. This policy was established by the NRC Governing Board in May 1997, when the Board 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.

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."
(emphasis added)

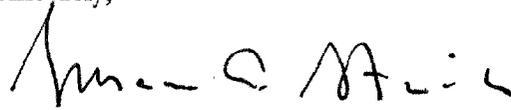
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In terms of your review of claims based on IOM reports, it is important to know that all statements that might be considered as findings, conclusions or recommendations are contained in the Executive Summary of the reports or in "boxed" pages at the beginning of individual chapters. No other language in our reports should be interpreted as the authoritative statement of the IOM or NRC.

Sincerely,

A handwritten signature in black ink, appearing to read "Susanne A. Stoiber". The signature is fluid and cursive, with a large initial 'S' and a distinct 'A'.

Susanne A. Stoiber
Executive Director

cc:
Paula Trumbo
Linda Meyers