

Docket No. 00Q-1582

Tab 3



AUG 21 2000

Food and Drug Administration
Washington DC 20204

Allison Yates, Ph.D., R.D.
Director
Food and Nutrition Board
Institute of Medicine
National Academy of Sciences
2101 Constitution Avenue
Washington, DC 20418

Dear Dr. Yates:

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

“Epidemiological and animal studies indicate that the risk of stroke-related deaths is inversely related to potassium intake over the entire range of blood pressures, and the relationship appears to be dose dependent. The combination of a low-sodium, high-potassium intake is associated with the lowest blood pressure levels and the lowest frequency of stroke in individuals and populations. Although the effects of reducing sodium intake and increasing potassium intake would vary and may be small in some individuals, the estimated reduction in stroke-related mortality for the population is large.”

and

“Vegetables and fruits are also good sources of potassium. A diet containing approximately 75 mEq (i.e., approximately 3.5g of elemental potassium) daily may contribute to reduced risk of stroke, which is especially common among blacks and older people of all races. Potassium supplements are neither necessary nor recommended for the general population.”

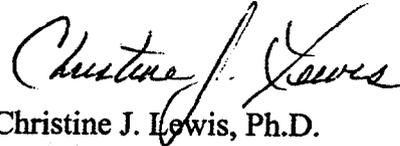
These statements appear on pages 11 and 15 respectively of the Executive Summary of the cited report, and were included as part of the basis for a claim about the relationship of a diet rich in potassium containing foods, blood pressure and stroke. Other statements

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that were part of the text of *Diet and Health: Implications for Reducing Chronic Disease Risk* were also submitted in the notification.

Our review of the notification includes consideration of the NAS policy concerning authoritative statements. We understand that the NAS policy is related only to the determination of identifying 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, based on its criteria, to elaborate or otherwise comment on the cited statements. We also would appreciate any comments you may have on whether the cited statements are currently in effect.

Sincerely yours,

A handwritten signature in cursive script that reads "Christine J. Lewis". The signature is written in black ink and is positioned above the typed name.

Christine J. Lewis, Ph.D.

Director

Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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."