DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

JUN 5 2001

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 304 of the Food and Drug Modernization Act of 1997 (FDAMA) that identifies the following statement from *Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline* (Food and Nutrition Board, Institute of Medicine, National Academy of Sciences (NAS), 1998) as an authoritative statement:

> "Choline functions as a precursor for acetylcholine, phospholipids and the methyl donor betaine. The primary criterion used to estimate the Adequate Intake (AI) for choline is the prevention of liver damage as assessed by measuring serum alanine aminotransferase levels. The AI for adults is 550 mg/day of choline for men and 425 mg/day for women. There are no nationally representative estimates of the intake of choline from food or food supplements. Choline in the diet is available as free choline or is bound as esters such as phosphocholine, glycerophosphocholine, sphingomyelin, or phosphatidylcholine. The critical adverse effect from high intake of choline is hypotension, with corroborative evidence on cholinergic side effects (e.g., sweating and diarrhea) and fishy body odor. The Tolerable Upper Intake Level (UL) for adults is 3.5g/day."

This statement appears as the Summary on page 390 of Chapter 12, which is titled Choline. The statement was included as part of the basis for the following proposed nutrient content claims characterizing the level of choline in a food or dietary supplement:

01Q-0352

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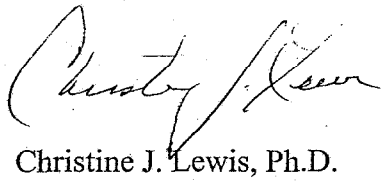
Good source of choline	**Contains choline**
Provides choline	**Excellent source of choline**
Rich in choline	**High in choline**
Added choline	**More choline**
Enriched with choline	**Fortified with choline**

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 claims.

Sincerely,



Christine J. Lewis, Ph.D.
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Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition