

DEPARTMENT OF HEALTH & HUMAN SERVICES



OCT 30 2000

Food and Drug Administration
Washington DC 20204

Guy Johnson, Ph.D.
Vice President, Nutrition
Kellogg Company
One Kellogg Square
Battle Creek, Michigan 49016

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Dear Dr. Johnson:

This letter is in follow-up to our meeting on January 18, 2000 and subsequent telephone conversation on August 24, 2000. When we met in January, the Food and Drug Administration (FDA) had just published the final rule regarding structure/function claims on dietary supplements, and, at that time, we were still reviewing the document in consideration of its application to both dietary supplements as well as conventional food.

Since our January meeting, we have been working to delineate further the lines between structure/function claims and disease claims as well as considering the nature of claims' ability to be misleading. We have recently had the opportunity to review the actual label of Kellogg's ALL-BRAN cereal and have concerns regarding both the context and content of the claims "Good news for your heart" and "Scientific studies from around the world suggest that an adequate intake of folic acid...B6 and B12 helps maintain a healthy cardiovascular system. One way these vitamins may work is by keeping a normal blood level of a substance called homocysteine. Available data suggest that normal levels of homocysteine are associated with heart health." These claims link several B vitamins to cardiovascular health. We do not believe that the relationship correlating folic acid, vitamins B6 and B12, and homocysteine levels to "heart health" is clearly established.

Among other things, during our August 24 telephone conference call, we discussed the status of Kellogg cereals with the claims for folic acid, vitamin B6, vitamin B12, homocysteine, and cardiovascular health. Please advise us as soon as possible of your plans as to the current marketing of Kellogg's cereal products that bear these claims.

Sincerely yours,

Christine J. Lewis, Ph.D.
Director

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

cc:

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