

## Notification Letter

September 1, 2004

Office of Nutritional Products  
Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Pkwy.  
College Park, MD 20740

Re: Notification Letter for Atkins CARDIO-Folin Dietary Supplement

To Whom It May Concern:

This letter notifies the Food and Drug Administration that within the past 30 days our company has begun to market CARDIO-Folin Dietary Supplement, with the following structure/function claims included on the label and in labeling for the product:

Claims:

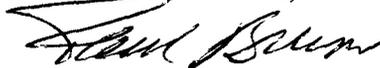
1. Supports overall cardiovascular and circulatory health
2. B-complex vitamins benefit the energy production pathway of all tissues in the body, including cardiovascular tissues.
3. These key vitamins, along with other vital nutrients, help the body maintain normal homocysteine levels, an important marker associated with good cardiovascular health.

The dietary ingredients of the product that are the subject of the above statements are: Statement 1 applies to all ingredients (Vitamin E, Vitamin B6, Folic acid, Vitamin B12, Magnesium, Coenzyme Q-10, Taurine and Hawthorn berry extract). Statement 2 and 3 refers to Vitamin B6 (as pyridoxine HCl), folic acid (as Metafolin<sup>®</sup> L-methylfolate) and Vitamin B12 (as cyanocobalamin).

The brand name of the product is CARDIO-Folin Dietary Supplement.

It is hereby certified that the information in this notification is complete and accurate, and that our company has substantiation that the above statement is truthful and not misleading.

Very truly yours,  
Atkins Nutritionals, Inc.



Paul Bruns, Ph.D.  
Scientific Affairs Manager

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