



DEC 23 2005

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Michael Lelah, Ph.D.  
Technical Director  
NOW Foods  
395 S. Glen Ellyn Road  
Bloomington, Illinois 60108

Dear Dr. Lelah:

This is in response to your letter of November 3, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that NOW Foods is making the claim "[S]uch as abdominal obesity..." for the product Super Cortisol Support.

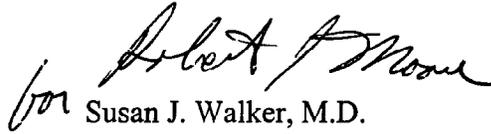
21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product (i.e., that it will prevent a consequence of stress that is itself a disease, i.e., a type of obesity) suggests that it is intended to treat, prevent, or mitigate disease, namely obesity. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Susan J. Walker".

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling  
and Dietary Supplements

Center for Food Safety  
and Applied Nutrition

**Copies:**

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Chicago District Office, Office of Compliance, HFR-CE640



November 3, 2005

*Nutrition for Optimal Wellness*

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutritional Products, Labeling, and Dietary Supplements  
Division of Nutritional Programs and Labeling  
200 C Street SW  
Washington, DC 20204

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Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Super Cortisol Support, a dietary supplement.

Statements being made in the labeling of Super Cortisol Support:

- (1) NOW<sup>®</sup> Super Cortisol Support is an herbal and nutritional formula designed to support healthy adrenal function and maintain healthy cortisol levels. The adrenal glands help the body respond and adjust to stress generated from both internal and external forces. Under chronic stress, cortisol can be overproduced, resulting in weight gain and difficulty in managing healthy blood sugar levels. Super Cortisol Support combines adaptogenic herbs with Chromium, Corosolic Acid and Relora<sup>®</sup> to help the body manage the negative effects of stress such as abdominal obesity, overeating and low energy levels.
- (2) Enhances Energy Levels
- (3) Supports Weight Management

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. NOW Foods possesses substantiation that the statements are truthful and not misleading.

Michael Lelah, Ph.D.  
Technical Director  
NOW Foods  
395 S. Glen Ellyn Rd.  
Bloomington, IL 60108

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