



DEC 29 2004

Mr. Jim Roza
Director, Quality Assurance
NOW Foods
395 S. Glen Ellyn Road
Bloomington, Illinois 60108

Dear Mr. Roza:

This is in response to your letters of October 28, 2004 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 letters state that the following statements, among others, will be made for the product Chitosan: "[H]ealthy...serum cholesterol levels."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Therefore, because the claim you are making for this product represents that the product is intended to affect blood cholesterol but does not also include a statement about it being intended to affect blood cholesterol that is already in the normal range, it is an implied disease claim.

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 suggests that it is intended to treat, prevent, or mitigate a disease. 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.

975-0163

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Please contact us if we may be of further assistance.

Sincerely yours,

for Robert Moore

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



We Make Quality Affordable

December 01, 2004

DEC 16 2004

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

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 Chitosan, 500 mg Caps, a dietary supplement.

Statements being made in the labeling of Chitosan:

(1) Chitosan is a dietary fiber derived from the shells of crustaceans that has been shown in non-clinical studies to bind to fat and cholesterol in the digestive tract. NOW Chitosan contains LipoSan Ultra, a patented high-density of Chitosan that binds up to five times more fat than conventional Chitosan according to laboratory testing. A published clinical study has demonstrated that LipoSan Ultra, taken as directed, may aid in the support of healthy body weight and serum cholesterol levels. NOW has also included Chromium in this formula. Chromium is an essential trace mineral that works with insulin to support healthy blood glucose levels and plays an important role in the proper utilization of protein, fat, and carbohydrates.

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.

Jim Roza
Director, Quality Assurance
NOW Foods
395 S. Glen Ellyn Rd.
Bloomington, IL 60108

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A handwritten signature of Jim Roza, written in black ink, positioned above a horizontal line.

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