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JUN 20 2006

Mr. Paul Kim
President
Nutra Nano Tech, Inc.
6300 Wilshire Boulevard
Suite 1730
Los Angeles, California 90048

Dear Mr. Kim:

This is in response to your letter dated June 7, 2006 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)).

In your letter, you state that the following statement will be made for the product CholZero™:

“Helps maintain healthy 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. 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 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.

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert J. Moore". The signature is fluid and cursive, with a long horizontal stroke at the end.

Robert J. Moore, Ph.D.
Team Leader, Compliance and Enforcement
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

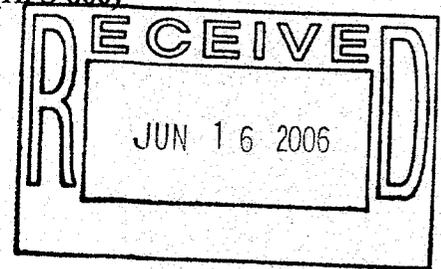
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240



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Ph-323-782-1801
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June 7, 2006

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835



RE: Notification of Structure/Function Claim

To Whom It May Concern:

This letter is notification of use of a structure/function claim on the label of dietary supplement, CholZero™. The required elements are listed below.

Distributor: Nutra Nano Tech, Inc.,
6300 Wilshire Blvd., Suite 1730
Los Angeles, CA 90048, is the distributor of CholZero™.

Structure/Function Claim: "Helps maintain healthy cholesterol levels."

Dietary Ingredient: Phytosterol/Phytostanol blend (proprietary blend named Phytonan™)

Product Brand Name: CholZero™

Sincerely,

Paul Kim
President

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