



MAR 26 2002

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Mr. James Gibbons
Senior Vice President
Natural Organics, Inc.
548 Broadhollow Road
Melville, New York 11747

Dear Mr. Gibbons:

This is in response to your letter of February 5, 2002 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)).

The products **Ultra Sugar Control** and **Sugar Control** use the claim "...for healthy sugar balance." 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. The same principle applies to your claim about healthy sugar balance; that is, a claim that does not establish that the claim is about blood sugar that is already within normal limits implies that the products are intended to treat elevated blood sugar or diabetes, which is a disease. Moreover, the names (i.e., the use of the term "sugar control") of the products themselves are disease claims because they too imply that the products are intended to treat elevated blood sugar or diabetes.

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 statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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, 7520 Standish Place, Rockville, Maryland 20855.

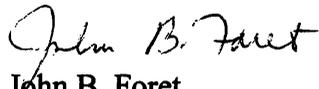
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Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement

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-300

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

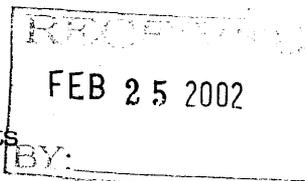
FDA, New York District Office, Office of Compliance, HFR-NE140

NATURAL ORGANICS INC.

548 Broadhollow Road, Melville, NY 11747 • Telephone: (631) 293-0030

February 5, 2002

CERTIFIED MAIL
Return Receipt Requested



Office of Nutritional Products, Labeling and Dietary Supplements
HFS-810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Dear Sir/Madam:

This letter is submitted pursuant to Section 406 (r)(6) of the Federal Food, Drug, and Cosmetic Act for the purpose of notifying the agency of statements being made in connection with the marketing of dietary supplements which are being distributed by this company.

The text of the statement that is being made is as follows:
Nutritional Support for Healthy Sugar Balance and Overall Well-Being.

The names of the products are as follows:

Citrimate
Ultra Sugar Control
Sugar Control

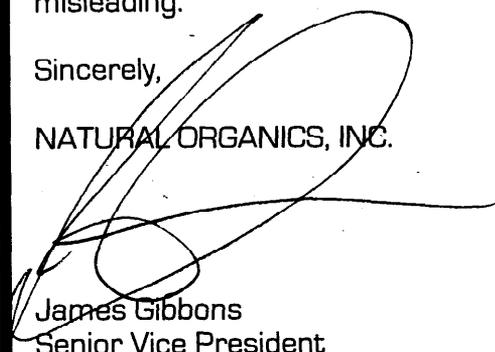
The dietary ingredients for which this statement is being made are:

- For the Citrimate product, the ingredients are Chromium, *Garcinia cambogia* fruit.
- For the Ultra Sugar Control product, the ingredients are Chromium, Citrimax, L-Glutamine, L-Alanine, *Gymnema sylvestre* Leaf.
- For the Sugar Control product, the ingredients are Chromium, L-Glutamine, L-Alanine.

It is certified that the information contained in this notice is complete and accurate and that the firm has substantiation that the statements are truthful and not misleading.

Sincerely,

NATURAL ORGANICS, INC.


James Gibbons
Senior Vice President

Accounting Fax:
(631) 249-2022

Administrative Fax:
(631) 293-0349

Customer Service Fax:
(888) 665-0628

Executive Fax:
(631) 293-8520

Human Resources Fax:
(631) 293-8703

Sales Fax:
(631) 293-2934

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