



AUG 31 2006

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Mr. James J. Gormley
Scientific & Regulatory Liaison
Nutrition21, Inc.
4 Manhattanville Road
Suite 202
Purchase, New York 10577-2197

Dear Mr. Gormley:

This is in response to your letter of August 11, 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)). Your submissions state that Nutrition21, Inc. is making the following claims, among others, for the product **Diachrome™** :

- “Advanced nutrient-based support for type 2 diabetes”
- “Helps maintain blood sugar control”
- “Promotes healthy cholesterol”
- “Clinical research has shown that Diachrome® can help promote healthy blood sugar and cholesterol in as little as 30 days”

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 this product suggests that it is intended to treat, prevent, or mitigate disease (see 21 CFR 101.93(g)). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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 20852.

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Please contact us if we may be of further assistance.

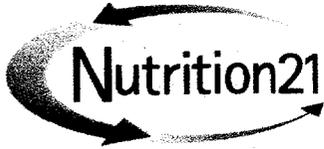
Sincerely yours,

A handwritten signature in cursive script, appearing to read "Vasilios Frankos".

Vasilios H. Frankos, Ph.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

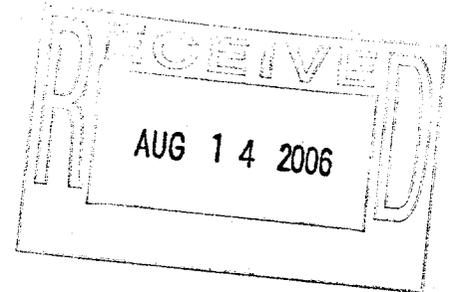
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, New York District Office, Office of Compliance, HFR-NE140



James J. Gormley
Scientific & Regulatory Liaison
Direct 914-701-4511
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E-mail: jgormley@nutrition21.com

August 11, 2006

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: Diachrome®

Dear Sir or Madam:

Pursuant to Section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act (FDC Act) and to Food and Drug Administration regulation 21 CFR § 101.93, Nutrition 21, Inc. is providing marketing notification of the following product and labeling claims.

Name of dietary supplement: Diachrome®

Distributor: Nutrition 21, Inc.
4 Manhattanville Road
Suite 202
Purchase, NY 10577

Dietary ingredients: Chromium picolinate and biotin

Statements of nutritional support:

1. Advanced nutrient-based support for type 2 diabetes
2. Helps maintain blood sugar control
3. Promotes healthy cholesterol
4. Clinical research has shown that Diachrome® can help promote healthy blood sugar and cholesterol in as little as 30 days

2006-6603
Arms

Nutrition 21, Inc.

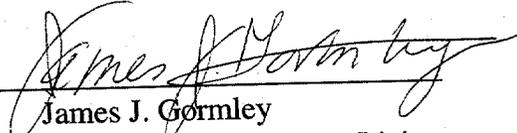
#1755

5. Supports healthy triglyceride levels

6. Promotes healthy lipids

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

By


James J. Gormley
Scientific & Regulatory Liaison