



SEP 15 2003 2 61 '03 SEP 23 9 2:00

Mr. James Komorowski
Vice President, Technical Services
and Scientific Affairs
Nutrition21, Inc.
4 Manhattanville Road
Suite 202
Purchase, New York 10577-2197

Dear Mr. Komorowski:

This is in response to your letters of June 25, 2003 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 following products:

Diachrome™

- “Clinically tested safe and effective glucose support for people with diabetes”
- “...help stabilize your blood sugar...”
- “Nutritional support for people at risk of diabetes”
- “A safe and effective way to support blood sugar”
- “...nutritional support for glucose metabolism in people with diabetes or at risk for diabetes”
- “Once-a-day nutritional support for blood sugar control for people with diabetes”

Chromax™

- “Nutritional support for people with Syndrome X”

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 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 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

975-0165

LET/DR

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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 'S. Walker', with a long horizontal flourish extending to the right.

Susan J. Walker, M.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-300

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

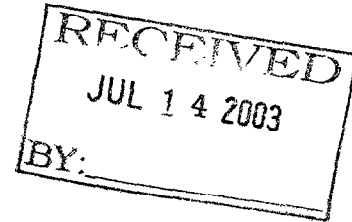
FDA, New York District Office, Office of Compliance, HFR-NE140



James R. Komorowski, MS
VP, Technical Services & Scientific Affairs
Direct- 914-701-4519
Fax -914-696-0860
Email: Jkomorowski@nutrition21.com

June 25, 2003

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
Purchase, NY 10577

Dietary ingredients: Chromium picolinate and biotin

Statements of nutritional support:

1. Diachrome for daily nutritional support
2. Diachrome is patented composition of chromium and biotin, which has been shown to enhance insulin sensitivity and improve blood sugar metabolism
3. Clinically tested safe and effective glucose support for people with diabetes
4. Diachrome is a once daily, non-prescription supplement clinically tested to help stabilize your blood sugar - helping you feel healthier and more energetic.
5. Nutritional support for people at risk of diabetes
6. A safe and effective way to support blood sugar
7. Diachrome™ provides nutritional support for glucose metabolism in people with diabetes or at risk for diabetes
8. Once-a-day nutritional support for people with diabetes

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Nutrition 21, Inc.

9. Once-a-day nutritional support for blood sugar control for people with diabetes

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.

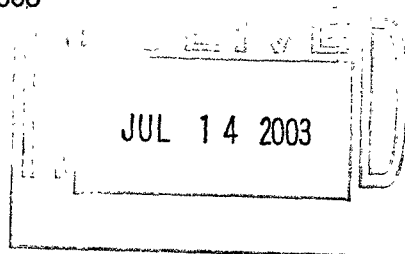
By 
James Komorowski, M.S.
Vice President, Technical Services & Scientific Affairs



James R. Komorowski, MS
VP, Technical Services & Scientific Affairs
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June 25, 2003

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: Chromax® Chromium Picolinate

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: Chromax® chromium picolinate

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

Dietary ingredients: Chromium picolinate

Statements of nutritional support:

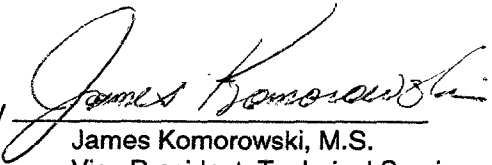
1. Chromium is an essential trace mineral for a healthy metabolism
2. Clinically shown to promote increased energy
3. Clinically shown to promote weight control
4. Clinically shown to promote carbohydrate metabolism
5. Chromium is vital for the management of insulin – the body's master metabolic hormone –for improved carbohydrate, protein, and fat metabolism
6. Chromax supplementation is essential for supporting an active lifestyle, managing your weight, promoting overall good health
7. Chromax can help you feel fit and more energetic
8. Chromax can help you improve your carbohydrate metabolism
9. Nutritional support for people with Syndrome X

Nutrition 21, Inc.

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10. Chromax® can help enhance insulin sensitivity and reduce carbohydrate cravings

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 Komorowski, M.S.
Vice President, Technical Services & Scientific Affairs