



MAY - 3 2006

Mr. James Komorowski
Vice President, Technical Services
& Scientific Affairs
Nutrition 21, Inc.
4 Manhattanville Road
Suite 202
Purchase, New York 10577-2197

Dear Mr. Komorowski:

This is in response to your letter of April 14, 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 letter states that the following statements will be made for the product Chromax chromium picolinate:

“Promote healthy cholesterol”
“[S]upports healthy cholesterol....”

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 claims you are making for this product represent that the product is intended to affect blood cholesterol levels but do not also include a statement about it being intended to affect blood cholesterol levels that are already in the normal range, they are implied disease claims.

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 suggest that it is intended to treat, prevent, or mitigate diseases. 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

Page 2 - Mr. James Komorowski

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.

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 stroke extending to the right.

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



AIMS:
2006-3656

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

April 14, 2006

APR 24 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: 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. Optimize your insulin function
3. Optimize your metabolic health
4. Control carbohydrate cravings
5. Fight weight gain
6. Maintain heart health
7. Promote healthy cholesterol
8. Helps maintain healthy blood sugar metabolism
9. Chromium is also a vital part of your natural mechanism for regulating blood sugar and activating various enzymes for energy production.
10. It also supports healthy cholesterol and heart health
11. Promotes healthy blood sugar
12. Supports overall cardiovascular health
13. Helps increase energy

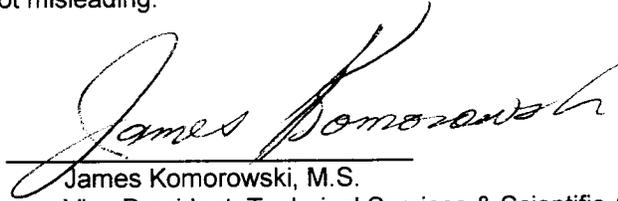
Nutrition 21, Inc.

4 Manhattanville Road, Suite 202 • Purchase, NY 10577-2197 • Phone 914 701-4500 • Fax 914 696-0860 • www.nutrition21.com

#1676

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

A handwritten signature in cursive script, appearing to read "James Komorowski", written over a horizontal line.

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