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OCT 15 2003

Mr. Michael Schwartz
President
Michael's Naturopathic Programs
6203 Woodlake Center
San Antonio, Texas 78244

Dear Mr. Schwartz:

This is in response to your letters of August 26, 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)).

The product Michael's Naturopathic Programs Blood Pressure Factors uses the claim "maintain proper blood pressure." 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 claims about the control of blood pressure; that is, a claim that does not establish that the claims are about blood pressure that is already within normal limits implies that the product is intended to treat elevated blood pressure (hypertension), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood pressure but does not also include a statement about it being intended to affect blood pressure 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 a 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.

975-0163

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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 "Susan Walker". The signature is fluid and cursive, with the first name "Susan" and last name "Walker" clearly distinguishable.

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-300

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

FDA, Dallas District Office, Office of Compliance, HFR-SW140

MICHAEL'S®
NATUROPATHIC PROGRAMS

6203 Woodlake Center • San Antonio, Texas 78244

August 26, 2003

Office of Nutritional Products, Labeling
and Dietary Supplements (HFS-810)
Center for Food and Safety and Applied Nutrition
Food and Drug Administration
5100 Point Branch Pkwy
College Park, MD 20740



Re: 21 U.S.C. Section 343(r)(6),
Notification of Statements on Dietary Supplements

Dear Sir/Madam:

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. §343(r)(6), and in accordance with the provisions of 21 CFR §101.93(a), your Agency is hereby notified that Michael's Naturopathic Programs has made statements of nutritional support for its dietary supplement(s) as follows:

Product Name

Label Statement(s)

Michael's Naturopathic Programs Vision Factors

Contains essential nutrients for proper support and maintenance of eye function

Michael's Naturopathic Programs Joint Mobility Factors

Contains essential nutrients for proper joint function & integrity

Michael's Naturopathic Programs Blood Pressure Factors

Nourishes & supports "feedback" system body uses to maintain proper blood pressure

Michael's Naturopathic Programs Estrogen Factors

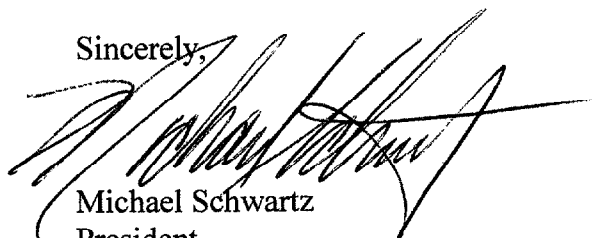
Provides essential nutrients to support the body in maintaining estrogen levels

PHONE: 210-661-8311 • FAX: 210-661-9145

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To the best of my knowledge and based upon information and belief present at the time of the execution of this notice, I certify that the above information is accurate and complete and that Michael's Naturopathic Programs possesses substantiation that the statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Schwartz", written over a white background.

Michael Schwartz

President

Michael's Naturopathic Programs