



MAR 13 1998

Rec'd 3/26/98

Mr. Gordon M. Walker  
Regulatory Counsel  
Murdock Madaus Schwabe  
Professional Products, Inc.  
10 Mountain Springs Parkway  
Springville, Utah 84663

Dear Mr. Walker:

This is in response to your letter of May 1, 1997 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 submission states that Murdock Madaus Schwabe Professional Products, Inc. is making the following claim for the product Garlicin CF Pro:

“Garlicin CF Pro promotes the body’s overall health, especially in the cold and flu season.”

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 prevent, treat or mitigate disease, namely the common cold and influenza. 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, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.  
Acting Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0162

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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, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO, KCarson)

HFS-456 (File)

HFS-450 (file, r/f)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:3/12/98

Init:GCF-1:LNickerson:3/12/98

f/t:HFS-456:rjm:3/13/98:docname:mmspro.adv:disc26

 **MMS Pro™**  
MURDOCK MADAUS SCHWABE  
PROFESSIONAL PRODUCTS INC.

rec'd  
6/24/96

June 17, 1996

Linda S. Kahl, Ph.D.  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" St. S.W. (HFS-450)  
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Murdock Madaus Schwabe Professional Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Garlicin® CF Pro. The statement of nutritional support reads as follows:

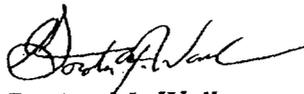
"Garlicin CF Pro promotes the body's overall health, especially in the cold and flu season."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

MURDOCK MADAUS SCHWABE  
PROFESSIONAL PRODUCTS, INC.



Gordon M. Walker  
Regulatory Counsel

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