DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUL 31 2001

8529 '01 AUG -8 P2:21

Mr. Gordon M. Walker
General 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 July 5, 2001 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 **Feverfew Leaf**:

> "...helps maintain normalize [sic] the function of platelets in the blood system by inhibiting platelet aggregation...blocking the formulation [sic] of pro-inflammatory mediators."

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, cure, or mitigate diseases, namely, disorders of platelet aggregation. 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, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
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, Denver District Office, Office of Compliance, HFR-SW240

Murdock
Madaus
Schwabe℠
America's Natural Healthcare Company™

16737

July 5, 2001

Office of Nutritional Products Labeling and Dietary Supplements
Division of Compliance and Enforcement
Dietary Supplements Branch (HFS-811)
Food and Drug Administration
200 "C" St. S.W.
Washington, D.C. 20204

To Whom It May Concern:

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 under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act.

The dietary supplement for which the statement is made is Feverfew Leaf. The dietary ingredient that is the subject of the statement is Feverfew leaf. The statement reads as follows:

> "Feverfew helps maintain normal blood vessel tone. Panthenolide also helps maintain normalize the function of platelets in the blood system by inhibiting platelet aggregation, reducing serotonin release from platelets and blocking the formulation of pro-inflammatory mediators."

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

The information contained in this notice is complete and accurate and the above statement is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

MMS PROFESSIONAL PRODUCTS, INC.

Gordon M. Walker
General Counsel

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Regulatory\STRUCTURE-FUNCTION/MMSPro/Feverfew

10 Mountain Springs Parkway · Springville, Utah 84663 · Phone: 801/489-1500 · Fax: 801/489-1700