

3624 '01 MAR 16 A7:16
FEB 22 2001

Mr. Christian Rochon
President
World Marketing Direct Selling, Inc.
101 Federal Street
Suite 1900
Boston, Massachusetts 02110

Dear Mr. Rochon:

This is in response to your letters of January 10, 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 World Marketing Direct Selling, Inc. is making the following claims, among others, for the following products:

MealAid

“Relief for acid indigestion - gas- stomach pain.

Cholesterlo

“Maintain healthy cholesterol levels”

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, cure or mitigate diseases. 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, 7520 Standish Place, Rockville, Maryland 20855.

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Page 2 - Mr. Christian Rochon

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, New England District Office, Office of Compliance, HFR-NE240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-810
HFS-811 (file)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Nickerson)
f/t:HFS-811:rjm:2/16/01:docname:74120.adv:disc54

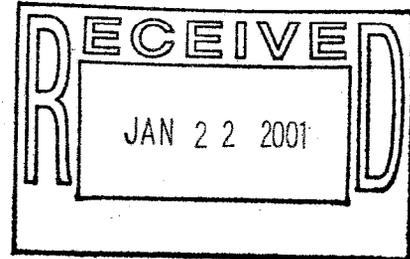
**WMDS****World Marketing Direct Selling, Inc.***Direct Shopping Customer*

Mailing Address:
101 Federal Street
Suite 1900
Boston, MA 02110

www.wmds.net

Telephone: (617) 342-7340
Fax: (617) 342-7339

January 10, 2001



Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

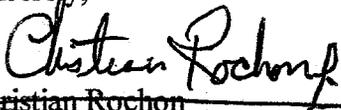
Dear Sir or Madam:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that WMDS, Inc., 50 Maynard Street #119, Attleboro, Massachusetts 02703, within the past 30 days commenced marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

MealAid – Relief for acid indigestion – gas – stomach pain. Increases enzyme levels and aids in digestion

The undersigned certifies that the information contained in this notice is complete and accurate and that WMDS, Inc. has substantiation that this statement is truthful and not misleading.

Sincerely,


Christian Rochon
President

74120

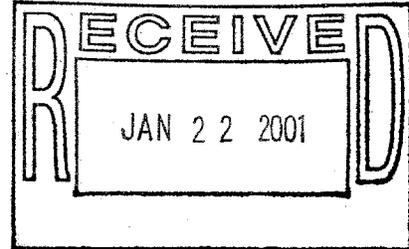
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Cholesterlo – Maintain healthy cholesterol levels

The undersigned certifies that the information contained in this notice is complete and accurate and that WMDS, Inc. has substantiation that this statement is truthful and not misleading.

Sincerely,


Christian Rochon
President

74120