

MAY - 5 2001
4 35 4 '01 MAY 15 P2:30

Ms. Kathleen Kelly
Assistant General Manager
World Marketing Direct Selling, Inc.
101 Federal Street
Suite 1900
Boston, Massachusetts 02110

Dear Ms. Kelly:

This is in response to your letter of April 4, 2001 to the Food and Drug Administration (FDA). Your letter responded to a letter from FDA dated March 21, 2001 in which we stated that claims being made for the products "MealAid" and "Cholesterlo" were not claims that may be made for dietary supplements pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

In your letter, you state that World Marketing Direct Selling, Inc. is using the claim "Aids in maintaining healthy cholesterol levels" for its product Cholesterlo only in its product catalog, and not on the product label itself. The requirements of 21 U.S.C. 343(r)(6) and 21 CFR 101.93(g) apply to statements made both on the label and in the labeling of the product. Labeling, as defined in 21 U.S.C. 321(m) means "all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article." The product catalog may constitute labeling under the Act, and, therefore, as we have previously stated, the claim identified above 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.

You also state that the label of the product MealAid, which bears the claim "Help for acid indigestion - gas- stomach pain," also contains the disclaimer required under 21 U.S.C. 343(r)(6) and 21 CFR 101.93(b)(- (e). The Act requires that any claim made under 21 U.S.C. 343(r)(6) include the disclaimer mandated in that section. However, 21 U.S.C. 343(r)(6) further states that a "statement made under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." Consequently, the use of the required disclaimer does not sanction the use of a disease claim on the label of a product. Therefore, the statement that you are making for this product suggests that it is intended to treat, prevent, cure 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.

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

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cc:

Federal Trade Commission

HFA-224

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-8 10 (Foret)

HFS-811 (Moore, w/original incomingfile)

HFD-40 (Behrman)

HFD-3 10

HFD-3 14 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson)

r/d:HFS-81 1:RMoore:4/13/01

docname:75362.adv:disc56

F/T:LBarr:HFS-810:4/17/01

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

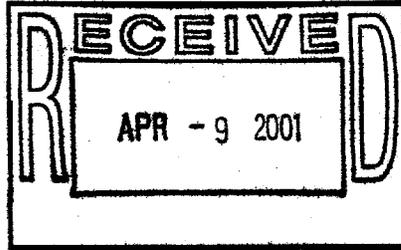
Mailing Address:
101 Federal Street
Suite 1900
Boston, MA 02110

www.wmds.net

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

75362

April 4, 2001



Mr. John B. Foret, Director
Division of Compliance and Enforcement
Department of Health & Human Service I-IFS-8 10
Food and Drug Administration
200 C Street SW
Washington, DC 20204

Dear Mr. Foret:

In response to the attached letter, please be advised that the actual Cholesterlo label makes absolutely no claims regarding treatment, **cure**, diagnosis, mitigation or prevention of any disease or class of disease. We only use the words "aids in maintaining..." in our product catalog.

The **MealAid** label does state "help for acid indigestion"; however, there is a notice on the bottle that states: *This product has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease*". Additionally, every product we sell has the same "Food and Drug" statement listed clearly on the front of the bottle.

Please advise if this meets FDA approval.

Sincerely,

Kathleen A. Kelly
Assistant General Manager



MAR 21 2001

Ms. Kathleen Kelly
Assistant General Manager
World Marketing Direct Selling, Inc.
101 Federal Street
Suite 1900
Boston, Massachusetts 02110

Dear Ms. Kelly:

This is in response to your letter of March 1, 2001 to the Food and Drug Administration (FDA). Your letter responded to a letter from FDA dated February 22, 2001 in which we identified claims being made for the products "MealAid" and "Cholesterlo" that we identified as not being claims permitted to be made in the labeling of dietary supplements pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

In your letter, you state that World Marketing Direct Selling, Inc. is using the following revised claims for the two aforementioned products:

MealAid

"Help for acid indigestion - gas- stomach pain"

Cholesterlo

"Aids in maintaining 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. We believe that the statements that you are making for these products continue to 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-3 10, 7520 Standish Place, Rockville, Maryland 2085 5.

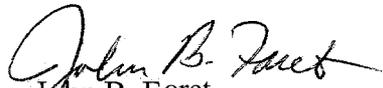
In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1 000), FDA discussed the context of certain claims describing the effect of a product on blood cholesterol or on acid indigestion that may result in such claims being structure/function claims under 21 U.S.C. 343(r)(6).

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You may find it useful to consult the discussion in the January 6, 2000 Federal Register cited above that addresses claims about blood cholesterol level (see discussion for comment 45 in 65 FR 1000 at 1017-1 8) and acid digestion (see discussion for comment 86 in 65 FR 1000 at 1030-1031).

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:

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Enforcement, HIT-200

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