



MAR 21 2001 APR 13 P3 21

Ms. Kathleen Kelly  
Assistant General Manager  
World Marketing Direct Selling, Inc.  
101 Federal Street  
Suite 1900  
Boston, Massachusetts 02 110

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 20855.

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 1017-18) 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:

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 973-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-8 10 (Foret)

HFS-811 (Moore, w/original incomingfile)

HFD-3 10

HFD-3 14 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson)

r/d:HFS-81 1:RMoore:3/14/01

f/t: / /01:docname:74897.adv:disc55

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

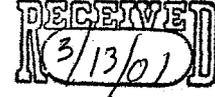
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March 1, 2001

74897



John B. Foret c/o  
Food and Drug Administration  
Washington, DC 20204

Dear Mr. Foret:

Pursuant to the letter dated February 22, 2001, regarding the claims for the following products **MealAid** and **Cholesterlo**. We understand that they do not meet the requirements of 21 U.S.C. 343(r) (6).

These claims are only mentioned in the draft copy of our catalog and not on our bottles. I have changed the statements in our catalog to 'read as follows.

**MealAid** "Help for acid indigestion – gas – stomach pain."

**Cholesterlo** "Aids in maintaining healthy cholesterol levels."

I hope this resolves the problem to the FDA's satisfaction. Please do not hesitate to contact me, if you should have any questions.

Sincerely,

Kathleen Kelly  
Assistant General Manager