



NUTRACEUTICA™

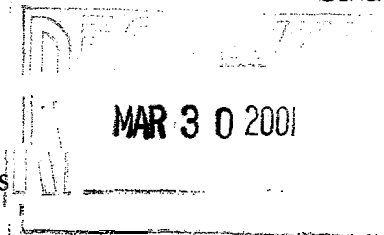
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SHAWN G. HANSEN
GENERAL COUNSEL

March 26, 2001

Mr. John B. Foret
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Washington, DC 20204-0001



Dear Mr. Foret:

Thank you for your correspondence dated March 22, 2001, regarding statements being made by Advantage Marketing, Inc. ("AMI") for the product **Nutraceutica™ Noni Gold™**. Your letter advises that the statement: **"Noni Gold helps support your body's defenses against disease!"** is subject to regulation under the drug provisions of the Federal Food, Drug, and Cosmetic Act ("Act"). AMI used the above statement in the good faith belief that it was a permitted "structure-function" claim under 21 U.S.C. § 343(r)(6) and its implementing regulations.

AMI will discontinue use of the above-described statement in order to avoid regulation under the drug provisions of the Act. In its place, AMI intends to use the following statement: **"Noni Gold supports the healthy performance of your body's immune system!"** Please advise me immediately whether this statement is permitted under 21 U.S.C. § 343(r)(6).

Thank you for your attention to this matter.

Very truly yours,

Shawn G. Hansen
General Counsel
Advantage Marketing, inc.

Enclosure: 3/22/01 letter

c c : 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).

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