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MAR 22 2001

Shawn G. Hansen, Esq.
General Counsel
Advantage Marketing, Inc.
P.O. Box 27233
Salt Lake City, Utah 84127-0233

Dear Mr. Hansen:

This is in response to your letter of March 1, 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 Advantage Marketing, Inc. is making the following claim, among others, for the product Nutraceutica™ Noni Gold™:

"Noni Gold helps support your body's defenses against disease!"

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 statement that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate diseases caused by pathogenic microorganisms. 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. 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 – Shawn G. Hansen, Esq.

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

Page 3 - Mr. Shawn G. Hansen

cc:

Federal Trade Commission

HFA-224

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810 (Foret)

HFS-811 (Moore, w/original incoming)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson)

r/d:HFS-811:RMoore:3/14/01

f/t: __/__/01:docname:74898.adv:disc55

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ADVANTAGE MARKETING, INC.

ADVANTAGE MARKETING, INC.
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74898

March 1, 2001

VIA CERTIFIED MAIL

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, D.C. 20204-0002

**RE: Notice under 21 C.F.R. § 101.93
Nutraceutica™ Noni Gold™**

To Whom It May Concern:

Advantage Marketing, Inc., manufacturer of the dietary supplement sold under the name Nutraceutica™ Noni Gold™, hereby submits the following notice as required under 21 C.F.R. § 101.93:

§101.93(a)(2)(i) Advantage Marketing, Inc. (a Utah corporation)
2323 W. Directors Row, Suite 200
P.O. Box 27233
Salt Lake City, UT 84127-0233;

§101.93(a)(2)(ii) Statement #1: "Today, exciting medical research confirms that Noni juice contains active polysaccharide substances that help promote a healthy and strong immune system."

Statement #2: "Additionally, Noni Gold contains healthful phytonutrients and anti-oxidants to further support your health."

OFFICE OF SPECIAL NUTRITIONALS
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
FOOD AND DRUG ADMINISTRATION
MARCH 1, 2001
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Statement #3: "Noni Gold helps support your body's defenses against disease!";

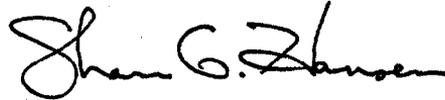
§101.93(a)(2)(iii) The above statements refer to a liquid dietary supplement containing the fruit of *Morinda citrifolia* (common name Noni);

§101.93(a)(2)(iv) The above statements appear on the label of a dietary supplement manufactured by Advantage Marketing, Inc., and sold under the name Nutraceutica™ Noni Gold™.

I hereby certify that the information contained in this notice is complete and accurate and that Advantage Marketing, Inc., has substantiation that the above statements are truthful and not misleading.

Very truly yours,

ADVANTAGE MARKETING, INC.



Shawn G. Hansen
General Counsel

Enclosures