



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JAN 19 2007

Dr. Marco Sedelis
Vice President
Hillestad Pharmaceuticals USA, Inc.
178 U.S. Highway 51 North
PO Box 1700
Woodruff, Wisconsin 54568-1700

Dear Dr. Sedelis:

This is in response to your letter of January 8, 2007 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)) for the product Aloe Vera Drink with Citriplex.

21 U.S.C. 321(ff) defines the term "dietary supplement." As defined by the Act, a dietary supplement does not include a product represented for use as a conventional food or as a sole item of a meal or the diet (21 U.S.C. 321(ff)(2)(B)). The product identified above appears to be represented for use as a conventional food (i.e., it is identity labeled as a "Drink"). Therefore, in that it appears to be represented for use as a conventional food (i.e., a drink or beverage), it does not appear to be a dietary supplement within the meaning of 21 U.S.C. 321(ff) and claims made for it are not subject to 21 U.S.C. 343(r)(6). Instead, this product appears to be a conventional food that must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, it must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the product in its labeling if they are claims defined by 21 U.S.C. 343(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. Use of a food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to market this product as a conventional food and you have any questions about the status of any of its ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

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Please contact us if you require further assistance.

Sincerely yours,

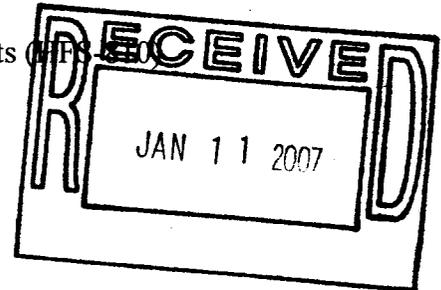
A handwritten signature in black ink that reads "Vasilios Frankos". The signature is written in a cursive style with a large, prominent "V" at the beginning.

Vasilios H. Frankos, Ph..D.
Acting Director
Division of Dietary Supplement Programs
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-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Minneapolis District Compliance, HFR-CE840

Food and Drug Administration
Office of Nutritional Products, Labeling & Dietary Supplements (OPFS-500)
5100 Paint Branch Parkway
College Park, MD 20740



January 08, 2007

RE: Dietary Supplement Claims Notification

Dear Sir/Madam:

This letter is to notify the Food and Drug Administration (FDA) that the following product is manufactured, packed and/or distributed by Hillestad Pharmaceuticals at 178 US Highway 51N, Woodruff, WI 54568.

This notification is being provided pursuant to 21 U.S.C. 343(r)(6) and 21 CFR 101.93(a).

Product Names: **Aloe Vera Drink with Citriplex**
Aloe Vera Concentrate
Aloe Jewel

Dietary ingredients: Aloe vera Gel Concentrate

The following statement(s) are or may be used on the labels and in the labeling of the product:

- "may help support digestive health"

I certify that the information in this notice is complete and accurate and that Hillestad Pharmaceuticals has substantiation that the statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read "Marco Sedelis".

Dr. Marco Sedelis
Vice President

First in Quality for Almost Fifty Years •

Hillestad Pharmaceuticals USA, Inc.

178 U.S. Highway 51 North • P.O. Box 1700 • Woodruff, Wisconsin 54568-1700

(715) 358-2113 • (800) 535-7742 • Fax (715) 358-7812 • E-mail info@hillestadlabs.com • www.hillestadlabs.com

Winnipeg, Manitoba, Canada

Dialyvite Division

P.O. Box 1010 • Woodruff, Wisconsin 54568-1010 • (715) 358-9773 • (866) 358-9773 • Fax (715) 358-9778 • www.dialyvite.net • E-mail info@dialyvite.net

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