



2758 '03 MAY 28 P2:34

MAY - 8 2003

Ms. Janet Sperry  
Compliance Coordinator, Labels & Packaging  
Flora, Inc.  
P. O. Box 73  
Lynden, Washington 98264

Dear Ms. Sperry:

This is in response to your letter of April 2, 2003 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 Flora, Inc. is making the following claims for the product **Flu Friend Tea**:

“Flu Friend’s traditional combination of herbs help support a healthy respiratory system, maintain normal airways and promote cleansing perspiration.\* Supports the respiratory system.\*”

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 use of the word “flu” in the name of your product is a claim that suggests that this product is intended to treat, prevent, or mitigate disease, namely, influenza<sup>1</sup>. 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

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<sup>1</sup>The term flu is an informal word for the viral disease influenza; see Webster’s II New Riverside University Dictionary (1994).

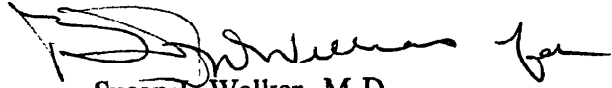
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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan J. Walker".

Susan J. Walker, M.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-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340



Quality Health From God's Pharmacy

April 2, 2003

APR 30 2003

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

Re: Structure/Function Label Claim

This letter is to notify the Food and Drug Administration that within the past 30 days our company has begun to market **Flu Friend Tea** Dietary Supplement, with the following statement(s) of nutritional support included on the label:

**Flu Friend's traditional combination of herbs help support a healthy respiratory system, maintain normal airways and promote cleansing perspiration.\* Supports the respiratory system.\***

The dietary ingredients of the product that are the subject of the above statement are:  
**Linden flower, rosehip husk, blackberry leaf, black elder berries, black currant leaf, calendula flower, everlasting herb.**

It is hereby certified that the information in this notification is complete and accurate, and that our company has substantiation that the above statement(s) is truthful and not misleading.

Very truly yours,

Flora, Inc.

Janet Sperry  
Compliance Coordinator  
Labels & Packaging

84268

**Flora, Inc.**

Head Office: P.O. Box 73, Lynden, WA 98264 (360) 354-2110 (800) 446-2110 FAX (360) 354-5355 [www.florahealth.com](http://www.florahealth.com)  
Eastern Branch: 62 Seaview Blvd., Port Washington, NY 11050

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