



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

AUG - 4 2004

Ms. Laura Quintano  
Assistant General Counsel  
Avon Products, Inc.  
1251 Avenue of the Americas  
New York, New York 10020-1196

Dear Ms. Quintano:

This is in response to your letter of June 18, 2004 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 Avon Products, Inc. is making various "natural defense" and immune system maintenance claims for a product named "Vitadvance Cold Season Liquid."

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. In the context of the statements being made for this product, the use of the term "Cold Season" in the product name is an implied disease claim that the product is intended to treat, prevent, mitigate, or cure a disease, namely, the common cold. 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.

975-0163

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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 'SJK', with a long horizontal stroke extending to the left.

Susan J. Walker, M.D.  
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, New York District Office, Office of Compliance, HFR-NE140

**AVON**

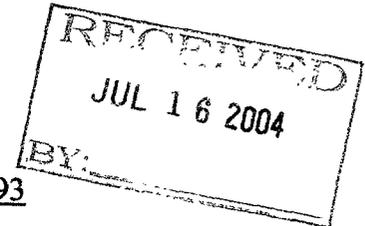
the company for women

June 18, 2004

AVON PRODUCTS, INC.  
1251 AVENUE OF THE AMERICAS  
NEW YORK, NY 10020-1196

212 282 7000 TEL

Office of Nutritional Products,  
Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St., SW  
Washington, DC 20204



Re: Dietary Supplement Notification; 21 CFR § 101.93

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act and Food and Drug Administration regulation 21 CFR § 101.93, this letter is submitted by Avon Products, Inc. as notification to FDA of the below statements made on the labeling of the following dietary supplement product:

Product Name: Vitadvance Cold Season Liquid

Statements:

- Helps promote the body's natural defense system.
- Protect your family with the natural strength of Echinacea, an herbal supplement that works to help maintain a healthy immune system.

The undersigned certifies that the information contained in this notice is complete and accurate and that Avon Products, Inc. has substantiation that the statements are truthful and not misleading.

Sincerely,

A handwritten signature in cursive script that reads "Laura Quintano".

Laura Quintano  
Assistant General Counsel

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