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JUN 17 2002

Ms. Laura Quintano
Senior 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 May 21, 2002 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 the following claims for the product **VitAdvance Cold Season**:

“...supports your body’s natural defenses against colds and flu”

“...support the body’s natural resistance during cold and flu season.”

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 statements that you are making for this product, along with the name of the product (i.e., VitAdvance Cold Season), suggest that it is intended to treat, prevent, cure, or mitigate a disease, namely the common cold. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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.

975-0163

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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, Atlanta District Office, Office of Compliance, HFR-SE140



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BY:

May 14, 2002

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

Dear Sir or Madam:

This letter will serve as notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that Physicians Laboratories is using the following statements on our herbal supplements under the following brand names: Revival Fresh Herbals.

Better memory & concentration

A positive, happy outlook

Better calmness/relaxation

More restful, peaceful sleep

Relief of allergy symptoms

Improved energy/stamina

Healthier immune function

Healthier liver function

Better prostate function

The above statements are accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act.

Sincerely,

Aaron Tabor, MD
President, Physicians Laboratories



PHYSICIANS LABORATORIES
Serving you through good nutrition,
education and research

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