

APR - 4 1997

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Anthony L. Young, Esq.
Piper & Marbury L.L.P.
1200 Nineteenth Street, N.W.
Washington, D.C. 20036-2430

Dear Mr. Young:

This is in response to your letter of February 11, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), on behalf of Paracelsian, Inc., of Ithaca, New York. We also discussed your notification and information you provided to FDA's Buffalo District Office and Center for Drug Evaluation and Research (CDER) concerning the development and marketing of Androvir-DS and another dietary supplement called Androcar at a meeting on March 14, 1997. Your notification submitted on behalf of Paracelsian, Inc. states that the firm intends to make the following statement for the product Androvir-DS.

Helps to support normal immune function.

Section 403(r)(6) of the act 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 information you submitted with the notification state that Androvir will be marketed to HIV-positive persons and Androcar will be marketed to persons with cancer. Therefore, the information you submitted indicates that Paracelsian, Inc. intends to market these products in a way that constitutes a claim that the products are intended to treat or mitigate serious diseases, cancer and AIDS. Claims that a product is intended for use by specific patient populations with serious diseases do not meet the requirements of section 403(r)(6) of the act. Such claims suggest that these products are intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that they are 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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Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Buffalo District Office, Domestic Operations Branch, HFR-NE-350

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

VERIFICATION
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February 11, 1997

VIA FACSIMILE

Ms. Margaret Binzer
Office of Special Nutritionals
Food and Drug Administration
Center for Food Safety and Applied Nutrition
HFS-450
200 C Street, S.W.
Washington, DC 20204

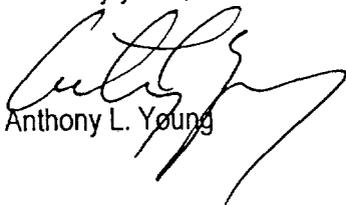
Re: DSHEA Section 6 Notification

Dear Ms. Binzer:

This letter will serve as a 30-day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that our client, Paracelsian, Inc., 222 Langmuir Laboratories, Cornell Technology Park, Ithaca, NY 14850 will utilize the following statement of nutritional support in the labeling of its AndroVir™-DS dietary supplement product containing an extract of the herb *Andrographis paniculata*:

Helps to support normal immune function.

Sincerely yours,



Anthony L. Young

ALY/bjw

cc: John G. Babish, Ph.D.
Chief Science Officer and
Vice President for Science
and Technology
Paracelsian, Inc.