



0580 '03 FEB 12 P1:49

FEB 10 2003

Mr. William Hoover
Herbalist & Alchemist, Inc.
51 South Wandling Avenue
Washington, New Jersey 07882

Dear Mr. Hoover:

This is in response to your letter of January 10, 2001 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 Herbalist & Alchemist, Inc. is using the statements "Anti-Fungal Compound" and "Anti-Parasite Compound" as the names for two products you are marketing as dietary supplements.

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 these two products (i.e., the product names "Anti-Fungal Compound" and "Anti-Parasite Compound") suggest that they are intended to treat, prevent, or mitigate diseases, namely diseases caused by pathogenic fungi or by parasitic organisms¹. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), 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.

¹In the preamble to the January 6, 2000 final rule on structure/function claims (65 FR 1000 at 1028; see discussion for section Q), FDA discussed when a claim about the role of a dietary supplement or dietary ingredient in the body's response to disease or disease vector would be a disease claim.

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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 'S Walker', with a long horizontal flourish extending to the right.

Susan 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

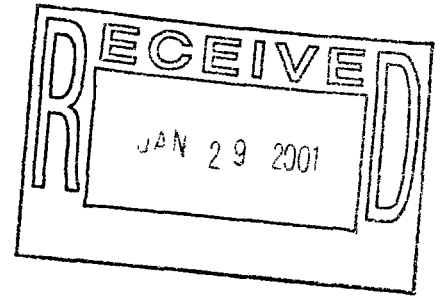
Copies:

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, New Jersey District Office, Office of Compliance, HFR-MA340

HERBALIST
&
ALCHEMIST

January 10, 2001

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

Dear Food and Drug Administration,

Herbalist & Alchemist, Inc., manufacturer, located at 51 South Wandling Ave., Washington, NJ 07882 is marketing the following product:

Anti-Fungal Compound

containing: black walnut
yellowroot
spilanthes
usnea
myrrh
cardamom

bearing a structure/function claim of: Supports Normal Systemic Flora

We have substantiation to support this claim.

Sincerely,

William Hoover

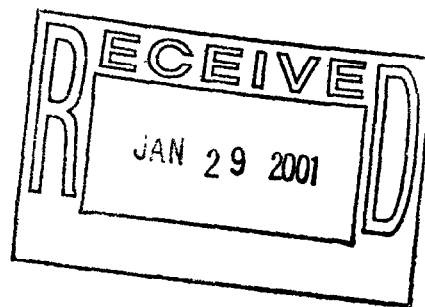
51 South Wandling Ave. Washington, NJ 07882

tel. (908) 689-9020
fax. (908) 689-9071
www.herbalist-chemist.com

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HERBALIST
&
ALCHEMIST

January 10, 2001

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

Dear Food and Drug Administration,

Herbalist & Alchemist, Inc., manufacturer, located at 51 South Wandling Ave., Washington, NJ 07882 is marketing the following product:

Anti-Parasite Compound

containing: elecampane
black walnut
sweet annie
quassia

bearing a structure/function claim of: Traditionally Balances Intestinal
Flora And Organisms

We have substantiation to support this claim.

Sincerely,

William Hoover

51 South Wandling Ave. Washington, NJ 07882

tel. (908) 689-9020
fax. (908) 689-9071
www.herbalist-chemist.com

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