



MAY 17 2001

7905 '01 JUN 11 P2:05

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

Dear Mr. Hoover:

This is in response to your letters 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 making the following claims, among others, for the products below:

**Gymnema Sylvestre Extract**

“Balances blood sugar regulation.”

**Blueberry Extract**

“Balances blood sugar regulation.”

**Bugleweed Extract**

“Balances excess thyroid function.”

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 products suggest that they are intended to treat, prevent, cure, or mitigate diseases. 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.

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| OFFICE  | SURNAME       | DATE    | OFFICE  | SURNAME | DATE    | OFFICE | SURNAME | DATE |
|---------|---------------|---------|---------|---------|---------|--------|---------|------|
| HFS 811 | A. Pope       | 5/14/01 | HFS 800 | Lowell  | 5/16/01 |        |         |      |
| HFS 810 | MOOP          | 5/16/01 |         |         |         |        |         |      |
| HFS 811 | more for fact | 5/16/01 |         |         |         |        |         |      |
| HFS 800 | B. Adams      | 5/16/01 |         |         |         |        |         |      |

FILE COPY

Page 2 - Mr. William Hoover

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret  
Director  
Division of Compliance and Enforcement  
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

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-800 (r/f, file)  
HFS-811 (file)  
HFD-40 (Behrman)  
HFD-310  
HFD-314 (Aronson)  
HFS-605  
HFV-228 (Benz)  
GCF-1 (Nickerson)  
f/t:HFS-811:afp:05/07/01:docname74228:disc4

HERBALIST  
&  
ALCHEMIST  


RECEIVED  
1/29/01

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:

Gymnema sylvestre extract

bearing a structure/function claim of: Balances Blood Sugar Regulation

We have substantiation to support this claim.

Sincerely,



William Hoover

51 South Wandling Ave. Washington, NJ 07882

tel. (908) 689-9020

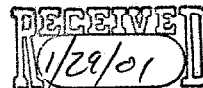
fax. (908) 689-9071

[www.herbalist-chemist.com](http://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,

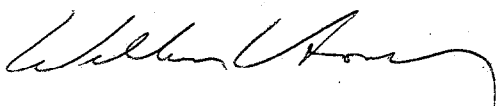
Herbalist & Alchemist, Inc., manufacturer, located at 51 South Wandling Ave., Washington, NJ 07882 is marketing the following product:

Blueberry extract

bearing a structure/function claim of: Balances Blood Sugar Regulation

We have substantiation to support this claim.

Sincerely,



William Hoover

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51 South Wandling Ave. Washington, NJ 07882

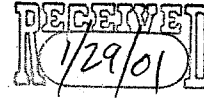
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HERBALIST  
&  
ALCHEMIST  


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:

Bugleweed extract

bearing a structure/function claim of: Balances Excess Thyroid Function

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](http://www.herbalist-chemist.com)

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