



OCT - 1 1999

18 5 07 - 21:52

Mr. Daniel Gagnon
President/Owner
Herbs, Etc., Inc.
1340 Rufina Circle
Santa Fe, New Mexico 87505

Dear Mr. Gagnon:

This is in response to your letter to the Food and Drug Administration (FDA) dated August 19, 1999, 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 Herbs, Etc., Inc. is making the following claim for the product "Allertonic™:"

"Support during Allergy/Hayfever 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 claim that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely allergies. 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-3 10, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET305

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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, Denver District Office, **Office** of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0 163)

HFS-22 (CCO)

HFS-456 (file, r/f)

HFS-450 (r/f, file)

HFD-3 10 (**B** Williams)

HFD-3 14 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

GCF- 1 (Dorsey, Bamett, Nickerson)

f/t:HFS-456:rjm:10/1/99:docname:67420.adv:disc41

FDA Notification Letter

Date: August 19, 1999

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 Sir:

This notification is on behalf of Herbs, Etc., Inc. 1340 Rufina Circle, Santa Fe, NM 87505.

We intend to include the following statement of nutritional support on our Allertonic™:

Support during **Allergy/Hayfever** Season**

This dietary supplement contains Nettle (Leaf).

Please be advised that the information contained herein is, to the best of our knowledge and information, accurate. Our firm has information substantiating that the above statement is truthful and not misleading.

Sincerely Yours,



Daniel Gagnon
President/Owner, Herbs, Etc., Inc.