DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

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MAY 15 2001

Mr. James A. Grant
Regulatory Compliance Officer
Gaia Herbs
108 Island Ford Road
Brevard, North Carolina 28712

Dear Mr. Grant:

This is in response to your letter to the Food and Drug Administration (FDA) dated April 20, 2001 pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter notified the agency of a claim that you intend to make for the product Nettle Leaf. In previous letters to you dated February 22, 2001 and March 21, 2001 we informed you that certain claims that you intended to make for this product were not claims that may be made for a dietary supplement under 21 U.S.C. 343(r)(6), but instead were disease claims under the Act and 21 CFR 101.93(g).

We have carefully reviewed the revised claim in your April 20, 2001 letter and continue to believe that the statement you intend to make, namely "For ultimate relief of environmental sensitivity," is not a claim under 21 U.S.C. 343(r)(6), but instead is a disease claim under the Act and 21 CFR 101.93(g):

For purposes of 21 U.S.C. 343(r)(6), FDA defined the term "disease" to mean, in part, "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension) (see generally 21 CFR 101.93(g)(1)). In the final rule that established this definition of disease, FDA stated that the requirement of "damage to an organ, part, structure, or system of the body such that it does not function properly" included conditions where there is "direct evidence of structural damage" as well as conditions where there is "indirect evidence of damage, indicated by the failure of the organ, part, structure, or system of the body to function properly." We further stated that the reference to "a state of health leading to such dysfunctioning" also permits the agency to look at evidence other than actual damage to an organ, part, structure, or system of the body." (65 FR 1000 at 1010).

In our previous letter to you, we stated that the claim "for ultimate support in the allergy season" was within the scope of the definition of disease in 21 CFR 101.93(g)(1). The claim "for ultimate relief of environmental sensitivity" is also a disease claim because it is simply another means of describing allergies, which are abnormal or pathological reactions to

environmental substances. In that the claim implicitly represents that the intended use of the product is for the relief of allergies, it is a claim that fits squarely within the scope of the definition of disease in 21 CFR 101.93(g)(1) and is not a structure/function claim under 21 U.S.C. 343(r)(6).

Therefore, we believe that the claim you are making for this product subjects it to regulation as a drug and we stand by our position stated in our February 22 and March 21, 2001 letters.

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

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:rjm:5/3/01:docname:75646.adv:disc57

75646

GAIA HERBS

Manufacturers of Fresh Botanical Extracts

Mr. John B. Foret, Director
Division of Compliance and Enforcement/ONPLDS
Center for Food Safety and Applied Nutrition
Food and Drug Administration
HFS-810
200 C Street, SW
Washington, DC 20204

April 20, 2001

Dear Sir:

This letter is in response to your letter dated March 21, 2001. Based on your comments, we are changing the following claim to read as follows:

Nettle Leaf
"For Ultimate Relief of Environmental Sensitivity"

We feel that this structure function claim meets the requirements of 21 U.S.C. 343 (r)(6).

It is our intention to comply completely with this requirement and to only use names and structure function claims that are appropriate for dietary supplements. Please call at 828-883-5938 if you have further questions or concerns about these products.

Cc: RS, EB, KD, KC

Sincerely,

James A Grant

James A. Grant
Regulatory Compliance Officer

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