



1020 701 APR 13 P3 21  
MAR 21 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 March 5, 2001 responding to our letter of February 22, 2001. In your letter, you present revised claims for the products "Infla-Profen," "Migra-Profen," and "Nettle Leaf" that you assert resolve the issues raised by us in our previous letter. You state that you believe that the revised claims are claims that may be made for dietary supplements pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The revised claims for the products "Infla-Profen" and "Migra-Profen" appear to be appropriate structure/function claims pursuant to 21 U.S.C. 343(r)(6). However, we disagree that the revised claim for the product "Nettle Leaf," namely that it is intended "for ultimate support in the Allergy Season" is a claim permitted to be made in the labeling of dietary supplements pursuant to 21 U.S.C. 343(r)(6).

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 the product "Nettle Leaf" suggests that it is intended to "support" persons during the allergy season; clearly, this is a claim that the product is intended for use by persons afflicted by allergies and to assist them in the treatment, prevention, or mitigation of allergies and/or their signs or symptoms. 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-310, 7520 Standish Place, Rockville, Maryland 20855.

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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

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cc:

Federal Trade Commission

HFA-224

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810 (Foret)

HFS-811 (Moore, w/original incoming)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson)

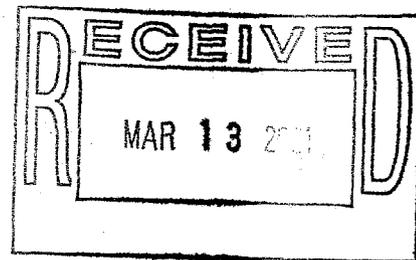
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# GAIA HERBS

Manufacturers of Fresh Botanical Extracts

748865



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

March 5, 2001

Dear Sir:

This letter is in response to your letter dated February 22, 2001. Based on your comments, we are changing these claims to read as follows:

**Infla-Profen**

"For ultimate support of back and joint mobility"

**Migra-Profen**

"For ultimate support during stress and tension"

**Nettle Leaf**

"For ultimate support in the Allergy Season"

We feel, however, that the name Migra-Profen is non-descriptive and used only to establish brand identity and does not convey or suggest a disease claim. Our legal council believes that this name is appropriate and legitimate and, with 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. Please call at 828-883-5938 if you have further questions or concerns about these products.

Cc: RS, EB, KD, KC

Sincerely,

A handwritten signature in cursive script that reads "James A. Grant".

James A. Grant  
Regulatory Compliance Officer