



NOV - 4 1997

0564 '98 MAR 24 P2:44

Mr. Leo Ehrlich
Immmu, Inc.
c/o Advanced Plant Pharmaceuticals, Inc.
17 John Street 3rd Floor
New York, New York 10038

Dear Mr. Ehrlich:

This is in response to your letter of October 21, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Immmu, Inc. is making claims for the product Alaskan Comfort:

“Natural cold relief for any season.”

You also submitted a notification pursuant to section 403(r)(6) of the act for a product named “Arthropain Glucosamine.”

Section 403(r)(6) of the act 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 statement that you are making for the product “Alaskan Comfort” suggests that it is intended to treat, mitigate, or cure a disease, namely the common cold. This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act.

The name of the product “Arthropain Glucosamine” is in itself a claim and suggests that the product is intended to treat, mitigate, prevent, or cure a disease, namely joint pain. The name of this product represents that the product is intended to be used for conditions of joint pain. As such, the claim constituted by the name of the product does not meet the requirements of section 403(r)(6) of the act and the claim suggests that the product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, 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.

975-0163

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Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
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 York District, Compliance Office, HFR-NE140

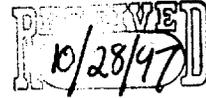
cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, JGordon)
HFS-456 (File)
HFS-450 (w/cpy incoming, #55436, r/f)
HFD-310 (Williams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
r/d:HFS-456:RMoore:10/29/97
Init:GCF-1:LNickerson:10/31/97
f/t:HFS-456:rjm:10/31/97:docname:55436.adv:disc23

Immmu Inc.

C/O Advanced Plant Pharmaceuticals, Inc
17 John Street 3rd Floor
New York, N.Y. 10038
212 964-5863

October 21, 1997



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

SECTION 403 (r) (6) NOTIFICATION

Dear Sir or Madam:

In accordance with the requirements of section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act, Immmu, Inc. notifies FDA that it has begun using the following statements:

Dietary Supplement- Natural cold relief for any season. Product statements assume use within context of good dietary practices. Consult your doctor before starting any dietary supplement program.

Ingredients: Zinc, Echinacea, Vitamin C

which contain the statutory statement, on the following products:

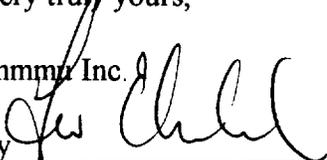
Alaskan Comfort

I certify that the foregoing is complete and accurate, and that Immmu Inc. has substantiation that the statements are truthful and not misleading.

Very truly yours,

Immmu Inc.

By



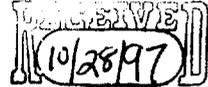
Leo Ehrlich

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Immmu Inc.

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17 John Street 3rd Floor
New York, N.Y. 10038
212 964-5863

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Washington, DC 20204

SECTION 403 (r) (6) NOTIFICATION

Dear Sir or Madam:

In accordance with the requirements of section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act, Immmu, Inc. notifies FDA that it has begun using the following statements:

Dietary Supplement- Nutritional support for healthy joints and bone mass, the #1 joint supporting supplement ingredient ; your "smart choice" for nourishment and support of cartilage, joints, tendons, ligaments, and bone mass. Product statements assume use with good dietary practices.

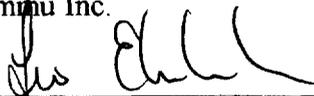
Ingredients: Glucosamine Sulfate, Calcium, Vitamin D, Boswellia , Turmeric which contain the statutory statement, on the following products:

Arthripain Glucosamine

I certify that the foregoing is complete and accurate, and that Immmu Inc. has substantiation that the statements are truthful and not misleading.

Very truly yours,

Immmu Inc.

By 

Leo Ehrlich

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