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DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 22, 2005

Citi Pharmaceuticals Inc.
7340 SW 48 Street
Miami, Florida 33101

Dear Sir or Madam:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.citimiami.com and has determined that your products "IMMUNO-PFS" and "Hepacition" are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your web site [including your Spanish language site http://citimiami.com/compania.htm and 'French language version http://citimiami.com/entreprise.htm] establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

Examples of some of the claims observed on your web site include the following:

IMMUNO-PFS

- "Complimenting each other to improve the quality of life of the patient with CANCER or AIDS, reduces drastically the side effects of the chemotherapy and of the radiotherapy."
- "[S]ignificant decrease in the undesirable,side effects of the chemotherapy being administered to them as well as a purported increased antitumoral effect in conjunction with their conventional treatment."
- "IMMUNO-PFS was administered to a group of terminally ill patients with encouraging results in relation to the improvement in their quality of life and to tumor response,"
- "PF2: A New Tool in the Fight Against Cancer."

Hepacition

- "Complimenting each other to improve the quality of life of the patient with CANCER or AIDS,, reduces drastically the,side effects, of the chemotherapy and of the radiotherapy."
- "[W]e have confirmed the large possibilities that this product has in the treatment of hepatic disorders like Hepatitis A, B, & C, hepatic cirrhosis ...."
- "[I]t all indicates that it could be an antiviral agent."
- "[P]atients with diverse hepatic disorders that were treated with HP-57."

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the products are also "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. Your products are also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

FDA is aware that Internet distributors may not know that the products they offer are regulated as drugs or that these drugs are not in compliance with the law. Many of these products may be legally marketed as dietary supplements if claims about diagnosis, cure, mitigation, treatment, or prevention are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations.

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The intended use of a product may be established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at http://vm.cfsan.fda.gov/~lrd/fr000106.html (codified at 21 C.F.R. § 101.93(g)).

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, both disease and structure/function claims may cause them to be new drugs.

Certain over-the-counter drugs are not new drugs and may be legally marketed without prior approval from FDA. Additional information is available in Title 21 of the Code of Federal Regulations (21 C.F.R.) Parts 310 and 330-358, which contain FDA's regulations on over-the-counter drugs.

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. You may respond in writing to Shari Shambaugh, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

If you have any questions concerning this letter, please contact Ms. Sharnbaugh at 407-475-4730.

Sincerely,

Timothy J. Cowgill
for Jimmy L. Walthall
Director, Compliance Branch
Florida District

bcc:

HFA-224
HFI-35
HFC-210
HFD-013
HFS-022
HFS-811 (Moore)
HFS-600
HFS-605
HFS-607
HFS-615 (Angeles – Compliance Reference System)
GCF-1 (Bañuelos)

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