



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-97-11

December 13, 1996

Mr. Ricardo J. Poirier
Vice President
Amazonic Herbals, Inc.
7424 S.W. 42nd Street
Miami, Florida 33155

Dear Mr. Poirier:

This letter is in reference to your firm's marketing and distribution of Cat's Claw (Una de Gato), an herbal product which is promoted to treat disease conditions. Your 1996 Internet promotional home page describes Cat's Claw as an herb used to treat arthritis, gastritis, cancer, asthma, dermal and genito-urinary tract infections, and female hormone imbalances, as well as for other indications. Further, your brochure contains additional drug claims for the treatment of rheumatism, genital herpes, ulcers, systemic candidiasis, organic depression, and HIV virus.

We regard both your promotional brochure and your internet home page as labeling which makes therapeutic claims for Cat's Claw. These claims cause this product to be a drug [Section 201(g)] of the Federal Food, Drug, and Cosmetic Act (the Act) and also a "new drug" [Section 201(p)] because there is no evidence that this product is generally recognized as safe and effective for its intended uses. Therefore, it may not be introduced or delivered for introduction into interstate commerce without an approved new drug application [Section 505].

This drug is misbranded [Section 502(f)(1)] because its labeling fails to bear adequate directions for use for the conditions for which it is offered. Cat's Claw is further misbranded [Section 502(a)] in that its labeling is false and misleading as it suggests that there is evidence that the product is safe and effective for its intended uses.

This letter is not intended to be an all inclusive list review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

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We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be directed to Martin E. Katz, Compliance Officer, Food and Drug Administration, 7200 Lake Ellenor Drive, Ste. 120, Orlando, Florida 32809, telephone no. (407) 648-6823, ext. 262.

Sincerely,



Douglas D. Tolen
Director, Florida District