



HFI-35
COPY 478
Public Health Service

October 6, 1997

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell, WA 98041-3012

Telephone: 206-486-8788
FAX: 206-483-4996

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 98-02

Dr. Michael Boumil
Naturopathic Physician
d.b.a. Physicians Botanicals
P.O. Box 1807
Bandon, Oregon 97411

WARNING LETTER

Dear Dr. Boumil:

The Food and Drug Administration (FDA) received a complaint regarding injuries sustained by a young woman who experienced an abnormal heart rate with complete heart block, a potentially life-threatening condition. The consumer's symptoms were consistent with an overdose of digitalis-like cardiac glycosides. The young woman experienced this condition after ingesting a regimen of dietary supplements. FDA's investigation determined that the problem was due to the ingredient plantain found in the dietary supplement "Chomper."

FDA's investigation indicates that you purchased contaminated plantain from [REDACTED] and caused it to be shipped to your custom miller [REDACTED]. You then sold these products to [REDACTED] for use in its Chomper products.

The plantain leaves and powder are adulterated and misbranded under the Federal Food, Drug and Cosmetic Act (the Act) as follows:

- within the meaning of Section 402(a)(1) in that they contain an added poisonous or deleterious substance, namely lanatosides (cardiac glycosides), which may render them injurious to health.
- within the meaning of section 403(a)(1) in that the labeling is false and misleading because it fails to reveal the material fact that the product contains lanatosides, e.g. cardiac glycosides, which, if ingested, can cause life-threatening heart reactions.

You further caused misbranding of the plantain leaves while in interstate commerce by falsely representing through your "Certificate of Analysis," provided to [REDACTED] for powdered plantain (lots 6C14-3 and 6H23-4), that the plant material was solely plantain powder made from wildcrafted plantain leaf.

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Dr. Michael Boumil
d.b.a. Physicians Botanicals

FDA collected multiple samples of plantain at establishments which had received this material from you. FDA also collected multiple samples of plantain "reserves" from you. FDA analyses of these samples showed that the plant material identified as "plantain" contained lanatosides (cardiac glycosides). The presence of lanatosides support that the plant material contains *Digitalis* glycosides. *Digitalis lanata* has been reported to contain these lanatosides. Plantain has not been reported to contain any cardiac glycosides.

FDA also conducted an analysis of a sample of plantain to determine whether the material identified as plantain actually contained plantain. The analysis found that the characteristic trichomes for plantain were low in concentration in the sample when compared to reference specimens. These analyses indicate that the plantain was contaminated with *Digitalis*.

As a shipper and distributor, you are responsible for ensuring that ingredients you distribute for use in food or dietary supplements are safe for human consumption. We are concerned that this type of situation does not occur again.

We request that you notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to preclude these violations from occurring in the future, including the steps you will pursue to preclude the issuance of false certificates of analyses. If you continue to distribute ingredients that are adulterated and misbranded as stated above, FDA may consider initiating regulatory action, such as seizure or injunction.

Your written correspondence should be sent to the Food and Drug Administration, Seattle District Office, P.O. Box 3012, Bothell, Washington 98041-3012, Attention: Robert L. Wesley, Compliance Officer.

Sincerely,



Roger L. Lowell
District Director