



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

Food and Drug Administration
St. Louis Branch
12 Sunnen Drive, Suite 122
St. Louis, Missouri 63143-3800

voice: (314) 645-1167
fax: (314) 645-2969

October 6, 1997

WARNING LETTER

Re: STL-98-1

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. LeRoy J. Ballard
President
Nature's Cathedral, Inc.
1995 78th Street
Blainstown, Iowa 52209

Dear Mr. Ballard:

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 traced this contaminated plantain to your firm. This contamination is associated with plantain that you purchased from Herbarium, Inc., Kenosha, Wisconsin, and widely distributed throughout the United States between July 1995 and May 1997.

The cut plantain leaves and plantain leaves which you repacked and distributed or distributed as such 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.

FDA collected multiple samples of plantain at various establishments nationwide which had received this material either directly or indirectly from you. The plantain was being sold as such or used or destined for use in the manufacture of dietary supplements, foods, and other products. 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.

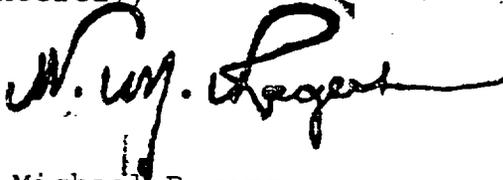
FDA also conducted an analysis of a sample of plantain to determine whether the material labeled as plantain actually contained plantain. The analysis found that the characteristic trichomes for plantain were low in concentration in the sample when compared to reference specimens. These analyses indicate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

As a repacker and distributor, you are responsible for ensuring that foods that you repack or distribute are safe for human consumption. We note that you have voluntarily recalled the adulterated plantain leaves, cut or powdered, that you distributed. However, 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 this violation from occurring in the future. If you continue to distribute foods that are adulterated and misbranded as stated above, FDA may consider initiating regulatory action, such as seizure or injunction.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Michael Rogers". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

W. Michael Rogers
District Director
Kansas City District