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10/27/97

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

October 6, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Bill Gay II
Chief Executive Officer
Nutraceutical
1104 Country Hills Drive, Suite 300
Ogden, Utah 84404

DEN-98-02

PURGED

Dear Mr. Gay:

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, Great Basin Botanical and Processing, Clearfield, Utah. This contamination is associated with plantain that Great Basin received directly from [X X X X X X X X X X], for custom milling into plantain powder for [X X X X X X X X X X].

The plantain leaves and plantain powder made from them 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 from you and from establishments which had received this material 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 processor, you are responsible for ensuring that ingredients that you process and distribute for use in foods 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. If you continue to process foods that are adulterated and misbranded as stated above, FDA may consider initiating regulatory action, such as seizure or injunction.

Please submit your written response to Compliance Officer Shelly L. Maifarth at the above address. You may contact Ms. Maifarth at (303) 236-3046 if you have any questions.

Sincerely,

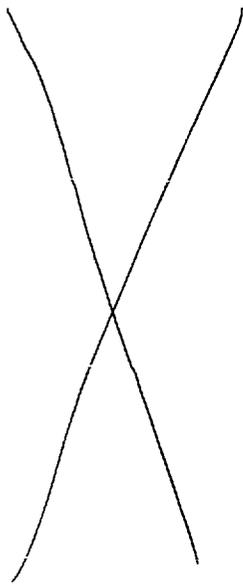


Gary C. Dean
District Director

cc: Mr. Daren Petersen
General Manager
Great Basin Botanical and Processing
Building E5, Freeport West
Clearfield, Utah 84016

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