



DEPARTMENT OF HEALTH & HUMAN SERVICES

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San Francisco District  
1431 Harbor Bay Parkway  
Alameda, California 94502-7070  
Telephone: (510) 337-6700

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

October 7, 1997

Our Reference: 2917665

Alan Baron, President  
ABCO Laboratories, Inc.  
2377 Stanwell Dr.  
Concord, CA 94520

**WARNING LETTER**

Dear Mr. Baron:

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."

Our investigation found that your firm received contaminated plantain powder from one or more lots and used this plant material in the manufacture of Chomper tablets and Chomper bulk powder for [REDACTED]

The Chomper tablets and bulk Chomper powder that you produced with the contaminated plantain are adulterated and misbranded under the provisions of 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 402(f)(1)(A) of the Act in that they are dietary supplements, which contain lanatosides, e.g. cardiac glycosides, that present a significant or unreasonable risk of illness under conditions of use recommended or suggested in the product's labeling.
- 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 samples of plantain, identified as lot numbers "[REDACTED]" which were either used or destined for use in the manufacture of Chomper products for [REDACTED]. 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 the plantain was contaminated with *Digitalis*.

As a manufacturer, you are responsible for ensuring that ingredients which you use in manufacturing dietary supplements are safe for human consumption. We note that [REDACTED] voluntarily recalled the adulterated Chomper products that you manufactured and distributed to [REDACTED]. 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 manufacture dietary supplements that are adulterated and misbranded as stated above, FDA may consider initiating regulatory action, such as seizure or injunction.

Your reply should be addressed to:

Sam M. Ali  
Recall and Emergency Coordinator  
U.S. Food and Drug Administration  
San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502

Telephone (510) 337-6869  
FAX (510) 337-6705

Sincerely,

A handwritten signature in cursive script that reads "Charlie D. Moss". The signature is written in black ink and is positioned above the printed name and title.

Charlie D. Moss  
Acting District Director  
San Francisco District