



March 8, 2000

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-13-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Martin Hencz
Back To Nature, Inc.
5627 Milwaukee Avenue
Chicago, IL 60646

Dear Mr. Hencz:

On December 2, 1999, the Food and Drug Administration requested, by mail from your firm (Back To Nature, Inc.) and from your filer ([REDACTED]), documents related to an entry of dietary supplements, J88-0150576-1. These documents, which were never provided to our office, were required to supply information lacking in the electronic entry for this shipment. On January 4, 2000, your broker informed FDA that the shipment was not held intact, and you had already distributed the merchandise without a FDA release. This is a violation of Title 21, Code of Federal Regulations, Section 1.90, which requires the importer to hold an entry pending receipt of a "May Proceed" or "Release" Notice from FDA.

Failure to prevent future violation may result in regulatory action without further notice, such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug and Cosmetic Act, and the regulation promulgated thereunder.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to prevent future violations, including an explanation of each step being taken to prevent the recurrence of the violation. In addition, you should inform Customs and FDA if and when redelivery is accomplished.

You should return your written reply to the Food and Drug Administration at the above address, and mark it to the attention of James T. Karpus, Acting Compliance Officer.

Sincerely,

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Raymond V. Mlecko
District Director