



DEPARTMENT OF HEALTH AND HUMAN SERVICES

11213711

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: Customs Entry No: AT0-0029138-8
Products: Milk-Based Baby Formula
Instant Coffee
Mixed Ready-to-Eat Cereal
Potato Chips

WARNING LETTER

FLA-98-78

September 23, 1998

Mr. William Janco
Wetter E. D., Inc.
11063 S.W. 37th Manor
Davie, Florida 33328-1320

Dear Mr. Janco:

The Food and Drug Administration (FDA) attempted to examine a shipment of food products referenced above, offered for entry into the United States by your firm on or about June 12, 1998, under the above referenced entry numbers and determined that these shipments were not available for FDA examination. Title 21, Code of Federal Regulations (21 CFR) Part 1.90, requires the importer to hold an entry intact pending receipt of a "May Proceed" notice or "Notice of Release" from FDA. We have requested the U. S. Customs Service (Customs) to order redelivery of these shipments (copy enclosed).

Failure to promptly correct this violation and prevent future violations 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 regulations promulgated thereunder.

Mr. William Janco
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We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, 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.

Your written reply should be addressed to the Food and Drug Administration, Attention: Benjamin L. England, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a large, sweeping initial 'D'.

Douglas D. Tolen
Director, Florida District

Enclosure