



DEPARTMENT OF HEALTH & HUMAN SERVICES

g1381d
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

WARNING LETTER NYK 2001-86

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

June 13, 2001

Mr. Robert E. Rich, Chairman
Rich Products Corporation
P.O. Box 245
Buffalo, New York 14240

Dear Mr. Rich:

The Food and Drug Administration (FDA) has information which shows your firm violated the Federal Food, Drug, and Cosmetic Act.

On May 16, 2001 your firm imported various baked goods into the United States under Entry No. 310-5501376-2. An investigation conducted by this office revealed the entire entry was not held intact, and part of the entry has been distributed.

We have requested U.S. Customs to order redelivery of the entry.

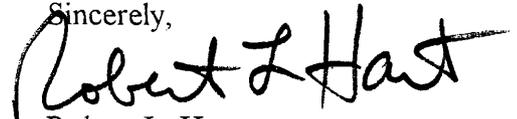
This action taken by your firm is in violation of 21 CFR 1.90, which requires an importer to hold an entry intact pending receipt of a "May Proceed" or "Release Notice" from the FDA. A "Release" by the U.S. Customs Service is a conditional release, which merely permits you to take possession of the shipment. When other Federal Agencies, such as the FDA, also exercise jurisdiction over a product offered for importation, their release must be obtained before a product may be legally distributed.

Failure to promptly correct these violations and prevent future violations may result in regulatory action without future notice, such as seizure or automatic detention, to ensure that imported products are held intact until released by FDA. It is your responsibility, as the owner/importer, to ensure imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

Within fifteen (15) working days of the receipt of this letter, please notify our office in writing of the specific steps you have taken to correct the violation(s), including an explanation of each step being taken to prevent a recurrence of the violation(s). Your response should be directed to Mark P. Prusak, Supervisory Investigator.

If you require further information, you may contact Mark P. Prusak at (716) 551-4461, Extension 3153.

Sincerely,

A handwritten signature in black ink that reads "Robert L. Hart". The signature is written in a cursive style with a large, prominent "R" and "H".

Robert L. Hart
Acting District Director

cc: Ms. Ann Marie Paul, Field National Import Specialist
United States Customs Service
111 West Huron Street
Buffalo, New York 14202

Mr. James Wisner, Owner
PBB USA, Inc.
434 Delaware Avenue
Buffalo, New York 14202