



DEPARTMENT OF HEALTH & HUMAN SERVICES

M3355m
New York District

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

WARNING LETTER NYK 2000-13

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 29, 1999

Mr. Peter Dunn
President
Borden Foods Corporation
180 E. Broad Street
Columbus, Ohio 43215

Dear Mr. Dunn:

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

On October 25, 1999, your firm imported assorted macaroni products into the United States under Entry No. 112-5975908-0. Since the necessary documentation was not presented at the time of entry, FDA issued a request for documents to the customhouse broker (Tower Group International, Champlain, New York) on October 29, 1999. This office received the documents on November 16, 1999.

An investigation conducted by this office revealed distribution of the referenced products on this entry as follows:

Gioia Jumbo Shells
Original Count-450 cases
Amount Distributed-390 cases
Amount Remaining-60 cases

Gioia Ziti
Original Count-840 cases
Amount Distributed-478 cases
Amount Remaining-362 cases

Gioia Spaghetti

Original Count-720 cases

Amount Distributed-180 cases

Amount Remaining-540 cases

New Milk Kluski Noodles

Original Count-63 cases

Amount Distributed-63 cases

Amount Remaining-0 cases

We are hereby requesting U.S. Customs to order redelivery of the products which have been distributed (copy enclosed).

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.

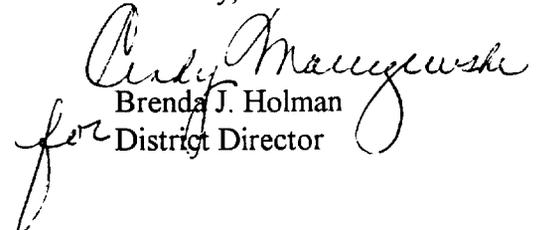
Failure to promptly correct these violations and prevent future violations may result in regulatory action without future notice, such as seizure or automatic detention, to ensure that imported products are held intact until released by FDA. It is your responsibility, as the owner/importer, to ensure 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.

A copy of this letter, except for any confidential, personal, or commercial information will be placed on public display no earlier than fifteen (15) days after the date of this letter. Your response will be on public display with any confidential, personal, or commercial information purged.

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

Sincerely,


Brenda J. Holman
District Director

Enclosure

cc:

Mr. Robert Kidder, Chief Executive Officer
Borden Foods Corporation
180 E. Broad Street
Columbus, Ohio 43215

Mr. Stephen Odland
President & Chief Executive Officer
TOPS Markets, Inc.
6363 Main Street
Williamsville, New York 14221

Mr. Jon Kitts, Director of Warehousing
TOPS Distribution Center
5873 Genesee Street
Lancaster, New York 14086

Mr. Thomas W. Facey, Supervisor
Tower Group International
205 West Service Road
Champlain, New York 12919