



DEPARTMENT OF HEALTH & HUMAN SERVICES

9/7/01
New York District

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

WARNING LETTER NYK 2001-125

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 7, 2001

Mr. G. J. MacKnight
MacKnight Smoked Foods Inc.
15 Britain Drive
New Britain, Pennsylvania 18901-5186

Dear Mr. MacKnight:

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

On June 25, 2001 your firm imported [REDACTED] cases of frozen mackerel fillets into the United States under Entry Number 144-0161108-4. An investigation conducted by this office revealed the entry was not held intact for FDA sampling, and 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.

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. Failure to promptly correct these violations and prevent future violations may result in regulatory action without future notice.

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, including an explanation of each step being taken to prevent a recurrence of the violation. Your response should be directed to Michael Wirth, Compliance Officer.

If you require further information, you may contact Michael Wirth at (716) 551-4461, Extension 3144.

Sincerely,

A handwritten signature in black ink that reads "Robert L. Hart". The signature is written in a cursive style with a long horizontal flourish extending to the right.

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

Ms. Patty Davis
Norman G. Jensen Inc.
171 Cooper Avenue, Suite 110
Tonawanda, New York 14150