



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

November 8, 2000

WARNING LETTER
CHI-3-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Sean J. O'Scannlain, President
The Plitt Company
1455 West Willow Street
Chicago, IL 60622

Dear Mr. O'Scannlain:

On October 13, 2000, the Food and Drug Administration (FDA) provided, by mail, a Notice of Sampling to your firm and your filer, [REDACTED], for an entry of fresh Alaskan halibut/returned goods, #120-0157957-7. On October 18, 2000, your firm 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 an importer to hold an entry intact pending receipt of a "May Proceed" or "Release" Notice from FDA.

Failure to 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 the imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder.

Please notify this office within 15 working days of receipt of this letter, as to the specific steps you have taken to prevent future violations, including an explanation of each step being taken to prevent the recurrence of the violations.

Your reply should be sent to the attention of Robert A. Sittig, Compliance Officer.

Sincerely,

\s\
Raymond V. Mlecko
District Director