



May 24, 2001

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

WARNING LETTER  
CHI-32-01

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Yoshio Takeda, President  
Daiei Trading  
14-50 128<sup>th</sup> Street  
College Point, NY 11356

Dear Mr. Takeda:

Your facility at 975 Bryn Mawr Avenue, Bensenville, Illinois, imported entry K94-0826463-3 on February 5, 2001. On March 2, 2001, the Federal Food and Drug Administration (FDA) detained frozen flounder and frozen sardines, lines 007/001 and 011/001, for lack of the required label statement, "KEEP FROZEN." On April 17, 2001, a proposal to relabel the articles was approved by FDA. FDA was notified the relabeling was complete on April 19, 2001. When our Inspector, John Verbeten, visited your facility, he found the detained articles had been distributed without an FDA release.

This is a violation of Title 21, Code of Federal Regulations, Part 1.90 (21 CFR 1.90), which requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or a "Release Notice" from FDA (copy enclosed).

Additionally, all of the products had not been relabeled. Since the articles were not held and there was an attempt to evade regulation, the FDA and U.S. Customs Service have issued a Refusal Request for Redelivery Notice for the articles in question.

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.

We wish to remind you that making fraudulent misrepresentations or false statements to federal officials are criminal offenses under Title 18, United States Code (18 USC), 542 and 1001. When evidence demonstrates the article presented to FDA for examination is not from the entry, but was substituted for the entry, the article may be seized. Liquidated damages may be assessed for articles not redelivered. Criminal charges of entry contrary to law (18 USC 545) may result in addition to the charges mentioned above. Criminal offenses can result in imprisonment or fines or both. Copies are included for your information.

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Please notify this office in writing within 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 Food and Drug Administration, attention: Robert A. Sittig, Compliance Officer.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director

Enclosures:

21 CFR 1.90  
18 USC 542, 545 & 1001,

cc: Mr. Hong In-Young, Manager  
Daiei Trading  
975 Bryn Mawr Avenue  
Bensenville, IL 60106