



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
m3144n

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 10, 1999

James L. Miller, President/CEO
U.S. Food Service
9755 Patuxent Woods Drive
Columbia, MD 21046

Dear Mr. Miller:

A seafood HACCP inspection of your multiple food storage warehouse, Illinois Fruit and Produce, Inc., located at 1200 Hoover Avenue, Allentown, PA was conducted by Investigator Colleen M. Damon of the Food and Drug Administration (FDA) on August 31 – September 2, 1999. The product covered during the inspection was refrigerated fresh tuna loin. At the conclusion of the inspection John Kowalski, Vice President of Operations was presented with a form FDA-483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR), Part 123. This section covers the Good Manufacturing Practices for Fish and Fishery Products. By virtue of these deficiencies, the fresh refrigerated tuna loins stored at your facility are adulterated within the meaning of section 402(a)(4) of the Food, Drug and Cosmetic Act (the Act), since they have been prepared, packed or held under conditions whereby they may have become injurious to health.

Specifically the investigator found:

- 1) Your HACCP plan addressed the hazard of histamine, but is inadequate for its control in that you are not monitoring and recording items as stated in your HACCP plan as required by 21 CFR 123.6(b). For example,
 - (a) The temperature of raw tuna is not taken and recorded upon receipt.
 - (b) The dock refrigerator temperature is not always recorded as required by your HACCP plan. For example, on January 29, 1999, March 30, 1999 and June 5, 1999 no temperatures were recorded.

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- 2) Failure to take corrective action when the critical limit of 40 degrees F for histamine producers (fresh refrigerated tuna loin) were exceeded on October 19-23, 1998, June 6–July 2, 1999 and July 5-9, 1999 [21 CFR 123.7(a)].

The above is not intended to be an all-inclusive list of deficiencies at your firm. As top management it is your responsibility to assure that all of your company's operations are in compliance with the Act and its implementing regulations.

We acknowledge management's promise to Investigator Damon that your firm will correct all deficiencies observed, however, you should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days after the receipt of this letter of the specific action you have taken to correct the violation. Your response should include each step that has or will be taken to completely correct the violation. If corrective action cannot be completed within 15 working days, please state the reason for the delay, the time within which the corrections will be completed and any documentation necessary to indicate correction has been achieved.

Your reply should be sent to the attention of Lynn S. Bonner, Compliance Officer, at the address noted above.

Sincerely,



Thomas D. Gardine
District Director
Philadelphia District

lsb