



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

m2862n

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

Telephone: 215-597-4390

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 16, 1999

Mr. Fred Imler, Jr., Partner
Imlers Poultry
3421 Beale Avenue
Altoona, PA 16601

Dear Mr. Imler:

A seafood HACCP inspection of your multiple food storage warehouse was conducted by Investigator Tammy Phillips of the Food and Drug Administration (FDA) on June 30, 1999. The product covered during the inspection was ready-to-eat (RTE) tuna salad. At the conclusion of the inspection Clyde H. Munahan, National Accounts Manager 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 RTE tuna salad stored at your facility is adulterated within the meaning of Section 402(a)(4) of the Food Drug and Cosmetic Act (the Act), in that the products are adulterated by being prepared, packed or held under conditions whereby they may have become injurious to health.

Specifically the investigator found:

- 1) Failure to develop and implement a written HACCP plan to control food safety hazards that are reasonably likely to occur, as required by 21 CFR Part 123.6(b). Specifically, you have not implemented a HACCP plan to control pathogen growth due to time/temperature abuse in the ready-to-eat tuna salad that you hold and store.

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 FD&C Act and its implementing regulations.

Page 2
Fred Imler, Jr.
August 16, 1999

We acknowledge management's promise to Investigator Phillips 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, the reason for the delay and 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

cc: Pennsylvania State Department of Agriculture
Bureau of Food Safety and Laboratory Services
2301 North Cameron Street
Harrisburg, PA 17110-9408
Attention: Lenchen H. Radle, Chief
Food Safety Division