



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

M2391N

WARNING LETTER

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

Telephone: 215-597-4390

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

99-PHI-13

January 29, 1999

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SPEC.

RELEASE

F# _____ DATE 7/2/99

Reviewed by: *Wm. W. Krupke*

Richard M. Cox, President
Specialty Seafood, Inc.
7303 Kernsville Road
Orefield, PA 18069

Dear Mr. Cox:

On November 17, 1998, Colleen Damon, an Investigator for the U. S. Food & Drug Administration (FDA), conducted a HACCP inspection of your seafood processing firm. At the conclusion of the inspection she issued you a form FDA-483 which described a number of serious deficiencies in HACCP and sanitation procedures in your seafood processing facility. These deficiencies cause foods processed in your facility to be adulterated within the meaning of Section 402 (a)(4) of the Food, Drug and Cosmetic Act (the Act), in that products are adulterated by being prepared, packed or held under conditions whereby they may have become injurious to health.

- 1) Your firm failed to address the hazard of histamine formation in amberjack and other scombroid species and to implement appropriate preventive measures. This is a violation of 21 CFR 123.6 (b) and (c) that requires a written HACCP plan that addresses each potential hazard and implements specific controls to prevent its occurrence.
- 2) Your firm has failed to document properly sanitation monitoring and corrective action in accordance with 212 CFR 123.11 (b) and (c). For example:
 - A) Food build-up was observed on walls, utensils, and utensil racks in the processing area.
 - B) There are potential avenues of cross contamination between fish species. For example, whole tuna were observed in physical contact with other species of fish at several locations in the preparation area.
 - C) You are not monitoring the strength of your sanitizing solution
 - D) Mold like material was observed in the bin of the ice-maker. This ice is used on your seafood products. .

We also note that you have no records of thermometer calibration.

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 associated regulations.

Richard M. Cox, President
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We acknowledge your firm's promise to the Investigator that you will correct all deficiencies observed. However, you should take prompt action to correct these deficiencies. Failure to correct them promptly may result in enforcement action without further notice, such as seizure and/or injunction. You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the attention of William W. Knipe, Compliance Officer, at the address noted above.

Sincerely,



Thomas D. Gardine
District Director

cc: PENNSYLVANIA STATE DEPARTMENT OF AGRICULTURE
Bureau of Foods and Chemistry
2301 North Cameron Street
Harrisburg, PA 17120-9408
Attn: Division of Food Control
Leroy C. Corbin, Jr., Director