



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
M2448N

WARNING LETTER

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

Telephone: 215-597-4390

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 9, 1999

Jonathan Brown, President
MacKnight Smoked Foods, Inc.
550 NE 185th Street
Miami, FL 33179

| | |
|---------------------------------|--------------------|
| GEN. | SPEC. |
| RELEASE | |
| F# _____ | DATE <u>3/9/99</u> |
| Reviewed by: <u>Wm W. Knipe</u> | |

Dear Mr. Brown:

During the period November 3-4, 1998, Colleen Damon, an Investigator for the U. S. Food & Drug Administration (FDA), conducted an inspection of your seafood processing firm located at 15 Britain Drive, New Britain, PA. At the conclusion of the inspection she issued a form FDA-483 to Paul Agnew, Vice President, (copy enclosed) which delineated a number of serious deficiencies in HACCP and sanitation procedures in your seafood processing facility. These deficiencies cause hot and cold smoked salmon and trout 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) You have not assessed the parameters necessary to assure a water phase salt (wps) concentration of at least 3.5% in finished vacuum packed cold smoked salmon and trout. This is required by 21 CFR 123.16 to control the food safety hazard of *clostridium botulinum* toxin formation, a hazard that is reasonably likely to occur in vacuum packaged smoked salmon.
- 2) You are not continuously monitoring and recording data as stated in your HACCP plan [21 CFR 123.6(b)].
 - The temperature of raw fish is not taken and recorded upon receipt.
 - The temperature of processing rooms is not always taken and recorded.
 - Sanitation SOP's (SSOP's) are not monitored as required by your plan.
- 3) Appropriate Critical Limits (CL) are not listed in the plan [21 CFR 123.6 (c)(3)].
 - A maximum product temperature of 20° C is listed as the critical limit for cold smoking, however, according to the plan, the maximum cooker temperature, not the maximum product temperature is monitored..
 - The time limit for cooling the smoked product to 38° F should be twelve hours total. A two step process is recommended in which the product is cooled to 50° F in no more than 3 hours and then to 38° F in the remaining time.

Jonathan Brown, President
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We also note the following:

Your HACCP plan incorrectly lists "improper temperature" and "time/temperature abuse" as hazards. The plan should list *C. Botulinum* formation as the hazard.

We recommend that you determine water phase salt levels on every batch until consistent salt levels are obtained. After which, the level may be determined quarterly

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.

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 Rhonda J. Walley, Compliance Officer, at the address noted above.

Sincerely,



Thomas D. Gardine
District Director
Philadelphia District

Enclosure

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

cc: Paul G. J. Agnew, Vice President
MacKnight Smoked Food, Inc.
15 Britain Drive
New Britain, PA 18901