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DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

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

Telephone: 215-597-4390

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

00-PHI-12

March 9, 2000

Harvey Oxenberg, President
Florida Smoked Fish, Co.
1111 Northwest 159th Drive
Miami, Florida 33169

Dear Mr. Oxenberg:

A seafood HACCP inspection of your manufacturer of hot and cold smoked fish, Premier Smoked Fish, Inc., located at 3185 Tucker Road, Bensalem, PA was conducted by Investigator Magda M. Karlsen of the Food and Drug Administration (FDA) between September 20, 1999 and October 12, 1999. During the inspection, serious deviations from Title 21 of the Code of Federal Regulations (21 CFR), Part 123, Fish and Fishery Products were documented. These deviations cause vacuum packaged hot and cold smoked salmon and smoked whitefish salad manufactured by your firm to be adulterated within the meaning of section 402(a)(4) of the Food Drug and Cosmetic Act (the Act), in that they have been prepared, packed or held under conditions whereby they may have become injurious to health, as follows:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your HACCP plan for Hot and Cold Smoked Finfish, Air and Modified Air Pack, and Hot Smoked White Fish Salad does not list *Clostridium botulinum* as a specific hazard. The term you used as the food safety hazard "bacterial pathogens" represents a range of bacterial organisms. As a hazard that is reasonably likely to occur in your processes, *Clostridium botulinum* requires specific controls.
2. You must have a HACCP plan that lists each critical limit (CL) that must be met at each critical control point (CCP) to comply with 21 CFR 123.6(c)(3). However, you have established an inappropriate CL for water phase salt (WPS) in vacuum packaged smoked fish for controlling the formation of toxin

by *Clostridium botulinum* during the shelf life of the product under normal and moderate abuse conditions. Although not stated in your HACCP plan, we clarified during discussion with management (Mr. Donahue) at the close of the inspection that your brining process was designed to achieve [REDACTED] WPS in smoked fish. Current scientific data supports a need for a 3.5% WPS level in vacuum packaged smoked fish, or a minimum 3.0% WPS for vacuum packaged smoked salmon with 100 to 200 ppm-added nitrites in the loin muscle. Also, critical to the brining process are the brine-to-fish ratio, and thickness of the fish portions. Your firm should either follow the Fish & Fisheries Products Hazards & Controls Guide (Second Edition) or take measures, which provide equivalent assurances of safety. Lot-by-lot testing of the final product would assure the adequacy of a brining process to achieve the desired WPS level in the products. Alternatively, you could establish and document a well-controlled brining process that would consistently achieve the desired WPS.

3. You must take an appropriate corrective action when a deviation from a CL occurs, to comply with 21 CFR 123.7(a). However, your firm did not take an appropriate corrective action for the following: 1. Vacuum packaged smoked salmon lot # [REDACTED] (WPS level of [REDACTED]); 2. Nova (Belly) lot # [REDACTED] (internal temperature - [REDACTED] F); 3. Kipperd Salmon lot # [REDACTED] (internal temperature - [REDACTED] F); 4. Whitefish salad lot # [REDACTED] (internal temperature - [REDACTED]); and 5. Whitefish salad lot # [REDACTED] (internal temperature - [REDACTED] F). [For 2 & 3, the HACCP plan requires a minimum internal temperature of [REDACTED] F, and for 4 & 5, a minimum internal temperature of [REDACTED] F.]
4. You must create documentary evidence of your corrective actions, to comply with 21 CFR 123.7(d). However, your firm did not document the corrective action when a CL was not met for kippered salmon lot #s [REDACTED] and [REDACTED] ([REDACTED] and [REDACTED] WPS, respectively), and for Norwegian salmon lot # [REDACTED] ([REDACTED] WPS and [REDACTED] parts ppm sodium nitrite).
5. You must implement the record-keeping system listed in your HACCP plan that documents the monitoring procedures, to comply with 21 CFR 123.6(b). However, your firm did not record [on a temperature chart] the monitoring of CL temperatures for Kipperd salmon lot #s [REDACTED], [REDACTED], and [REDACTED], Nova (Belly) Salmon lot # [REDACTED], and whitefish salad lot # [REDACTED]. Also, HACCP plan records, i.e., internal temperature chart and ambient temperature chart, were missing for whitefish salad lot #s [REDACTED], [REDACTED], and [REDACTED], and kippered salmon lot # [REDACTED]. Additionally, the salimeter concentration was not recorded for kippered salmon lot # [REDACTED].

At the conclusion of the inspection, David J. Donahue, Director of Operations was presented with a form FDA-483 listing serious deviations from the regulation.

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A copy of the Form FDA-483, Inspectional Observations is enclosed for your review.

During the inspection, FDA collected a sample of hot smoked vacuum packaged kippered salmon. Results of the FDA analysis revealed water phase salt levels in the range of [REDACTED] to [REDACTED], and upon check analysis, water phase salt levels in the range of [REDACTED] to [REDACTED]. Water phase salt levels in this range would not provide preventive control for *C. botulinum* toxin formation in a refrigerated, vacuum packaged smoked fish. We acknowledge that your firm voluntarily destroyed the remaining portion of this lot on November 12, 1999, however the sample test results noted above, demonstrate to us that your firm has not adequately established a process that will consistently provide a finished product of hot smoked vacuum packaged salmon with the desired water phase salt (21 CFR 123.16).

We acknowledge your October 21, 1999 response to correct these deviations which addressed some, but not all of our concerns. In addition, during the previous inspection, on January 6-9, 1998 and in a letter from FDA, dated March 17, 1998, you were notified of similar deficiencies described in points numbered two, four and five. During the inspection, and in the letter noted above, the FDA explained that you would need to take steps to correct those deficiencies. The FDA is concerned that in twenty months time, your firm has not taken action to correct these deficiencies.

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. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please notify this office in writing within fifteen (15) working days from your receipt of this letter of the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as data to support established WPS critical limits, copies of corrective action records, copies of monitoring records, etc. or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations (21 CFR Part 123) and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug and Cosmetic

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Act and all applicable regulations.

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

Sincerely,

for W. Charles Beant
Thomas D. Gardine
District Director
Philadelphia District

Enclosure
FDA-483

lsb

cc: George Wenger, Vice President
Premier Smoked Fish, Inc.
3185 Tucker Road
Bensalem, PA 19020

Michael Roth, Director of Operations
Premier Smoked Fish, Inc.
3185 Tucker Road
Bensalem, PA 19020

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