



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

94882d

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Arcadi Marcovich, President
Haifa Smoked Fish, Inc.
94-15 150th Street
Jamaica, NY 11435-4524

July 28, 2004

Ref: NYK-2004-26

Dear Mr. Marcovich:

On June 22, 23, and 24, 2004, we inspected your seafood processing facility, located at the above address. We found that you have serious deviations from the seafood Hazard Analysis Critical Control Point ("HACCP") regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR Part 123). Failure of a seafood processor to comply with the HACCP regulations renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 342(a)(4). Accordingly, your smoked fish products are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The observed deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for vacuum-packaged and air-packaged cold-smoked golden brook trout to control the food safety hazards of *Clostridium botulinum* toxin formation and/or pathogen growth and toxin formation as a result of time/temperature abuse.
2. You must have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(c)(2). A critical control point is defined in 21 CFR 123.3(b) as a "point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for cold-smoked mackerel and cold-smoked capelin does not list certain unrefrigerated and time-consuming processing steps (e.g.,

evisceration, packaging, and storage on the loading dock prior to shipment) as critical control points for controlling the food safety hazard of *Clostridium botulinum* toxin formation, pathogen growth and toxin formation, and/or histamine formation as a result of time/temperature abuse.

3. You must take corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). Sections 123.7(b) and (c) require that a corrective action ensures that no product enters commerce that is either injurious to health or otherwise adulterated as a result of the deviation and that the cause of the deviation is corrected. However, your firm did not take a corrective action to control the *Clostridium botulinum* toxin formation hazard when your process for cold-smoked mackerel and cold-smoked whitefish deviated from your critical limit of less than [REDACTED] F at the cold-smoking critical control point.
4. You must have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for vacuum-packaged cold-smoked fish does not list the food safety hazards of *Clostridium botulinum* at the brining, cold-smoking, and finished product storage critical control points and histamine formation (for scombrototoxin forming species of fish) at the finished product storage critical control point.
5. You must implement the monitoring procedures and record-keeping system that you have listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures for brining time/temperature at the brining critical control point and the continuous recording of the cold storage temperature at the finished product storage critical control point and did not record the monitoring observations at these critical control points to control the *Clostridium botulinum* toxin formation hazard listed in your HACCP plan for vacuum-packaged cold-smoked fish.
6. You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a). However, your firm did not verify the adequacy of the critical limits to achieve your required minimum of [REDACTED] water phase salt for vacuum-packaged hot and cold-smoked fish at the brining critical control point to control the *Clostridium botulinum* toxin formation hazard. Your test results dated February 27, 2004 for hot and cold-smoked fish show water phase salt results ranging from [REDACTED] to [REDACTED].
7. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm did not have product specifications for frozen herring and frozen mackerel imported from [REDACTED].

8. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for frozen herring and frozen mackerel manufactured by [REDACTED] in [REDACTED].
9. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the condition and cleanliness of food contact surfaces and the prevention of cross contamination with sufficient frequency to ensure control, as evidenced by the following observations:
 - a. Cutting boards in the evisceration room and packing/slicing room were gouged and had visible product residue in the gouges.
 - b. Knives used in the evisceration and packing/slicing room had wooden handles that were in direct contact with ready-to-eat products.
 - c. Processing aprons were stored on unclean equipment during breaks and at the end of the work day.
 - d. Plastic strip curtains between the eviscerating and main processing rooms were broken, gouged, and stained, and came in direct contact with raw fish to be processed as cold-smoked fish.
 - e. Product residues were observed underneath a cutting board and on a skinner, a slicer, and knives after cleaning and prior to processing.
 - f. An employee was observed dropping a side of salmon on the floor of the main processing area and then picking it up and placing it in the thaw tank.
 - g. Hoses with visible filth and product residues were dragged on the floor and then submerged in thaw tanks in direct contact with in-process product.
 - h. Employees were observed handling unclean and unsanitized equipment and other items (e.g., hoses and plastic bags previously on the floor, trash containers, faucet handles, cooler and freezer handles, and pallet jacks) and then handling in-process and finished product without washing and sanitizing their hands and/or gloves.
 - i. Ready-to eat smoked salmon was observed in direct contact with the door frame of a cooler.
 - j. The spray from high pressure water hoses used to rinse equipment and floors at the end of the day was observed hitting the floor and splashing onto equipment such as racks, brining totes, and thawing totes.
 - k. Flies were observed on food contact surfaces in the eviscerating, packing/slicing, and main processing rooms.

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, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Haifa Smoked Fish, Inc.

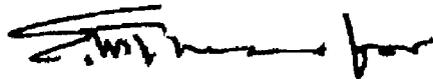
Page 4

We may take regulatory action without further notice if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation 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.

Please send your reply to the Food and Drug Administration, Attention: Bruce A. Goldwitz, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issue in this letter, please contact Mr. Goldwitz at 718-340-7000 ext. 5582.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Woysner".

Jerome G. Woysner
District Director

Enclosure: Form FDA 483 dated June 24, 2004