DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
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Maitland, Florida 32751

Telephone: 407-475-4700
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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-47

March 29, 2001

Stanley Markman, President
American Smoked Fish Co.
64 NE 73rd Street
Miami, FL 33138

Dear Mr. Markman:

We inspected your firm, located at 64 NE 73rd Street, Miami, FL on October 3, 6 and 10, 2000 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your hot and cold smoked fish and smoked fish dips to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in the FDA's home page at www.fda.gov.

The deviations were as follows:

> You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plans for vacuum packed hot smoked kippered salmon and cold smoked nova salmon fillets do not list the cool down step as a critical control point to control the food safety hazard of pathogens.
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> You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plans for vacuum packed cold smoked nova salmon and vacuum packed kippered salmon list critical limits that are not adequate to control the food safety hazard of botulism toxin formation. The critical limits at the Brining Critical Control Point do not include all the necessary values, such as actual thickness of product, actual time and actual salt concentration, to assure that the finished product contains adequate proportions of water phase salt in the loin muscle.

You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for smoked fish dip has an inadequate monitoring procedure at the Production Critical Control Point to control pathogen growth in that you are not monitoring either the processing room temperature or the product temperature.

You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures in some of your HACCP plans. For example: 1) at the Brining Critical Control Point for vacuum packed nova and kippered salmon to control the botulism toxin formation hazard, you did not include any requirement to check brine temperature, thickness of fillets or nitrite concentration; 2) at the Smoking Critical Control Point for vacuum packed kippered salmon to control the botulism toxin formation hazard, you did not record the internal temperature of the product in the smoker; 3) at the Finished Product Cooler Storage Critical Control Point for vacuum packed nova and kippered salmon to control the pathogen growth and toxin formation and the botulism toxin formation hazards, you did not record the temperature using a continuous recording device with periodic checks of the refrigerator and product; and 4) at the Production Critical Control Point for smoked fish dip to control the pathogen growth and toxin formation hazard, you did not monitor the product temperature, production room temperature or product exposure time.

You must take an appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). However, on May 22, 2000 your firm did not take a corrective action to control the botulism toxin formation hazard when your process for vacuum packed nova and kippered salmon deviated from your critical limit at the Smoking Critical Control Point in that the actual smoke times deviated significantly from the smoke schedule. Similar deviations without appropriate corrective action occurred on September 19 and October 2, 2000.

Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, the corrective action plans for smoked fish dip, vacuum packed nova salmon, and vacuum packed kippered salmon are not appropriate in that the plans do not always describe the steps to be taken to ensure the food safety of the affected product and the steps taken to correct the cause of the deviation at each critical control point. For example, the Brining Critical Control Point for vacuum packed nova salmon and vacuum packed kippered salmon to control the botulism toxin formation hazard does not describe the steps to be taken to ensure the food safety of the product when the critical limits are not achieved. In addition, the Processing Critical Control Point for smoked fish dip does not address the actions taken to correct the cause of the time/temperature abuse of the product.

You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control records.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. 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 respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as revised HACCP plans, completed monitoring and sanitation control records 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 the 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 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 Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4730.

Sincerely,

Emma R. Singleton
Director, Florida District

bcc: HFR-SE240/ KWH /LGL JKT/WL FILE
HFR-SE250/DJG/EI JKT
MIA -RP/KMS/MAE
HFA-224
HFI-35 (PURGED)
HFC-210
HFS-607

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