



Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
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01-BLT-31

May 11, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert L. Williamson, Co-owner
Virginia Seafood LLC
11179 Hopson Road, Unit #4
Ashland, Virginia 23005

Mr. Robert Smith, Co-owner
Virginia Seafood LLC
11179 Hopson Road, Unit #4
Ashland, Virginia 23005

Dear Sirs:

The Food and Drug Administration (FDA) conducted an inspection of your vacuum packed smoked fish manufacturing facility located at 11179 Hopson Road, Unit #4, Ashland, Virginia, on May 1, 2001. The inspection revealed deviations from Fish and Fishery Products regulations (Seafood HACCP), Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). The deviations cause the seafood you process to be adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (FD&C Act). The deviations are as follows:

You must implement the monitoring procedures listed in your HACCP Plan, to comply with 21 CFR 123.6(b). However, during the inspection, the FDA investigator observed that you were not implementing the procedures (critical control points) listed in your HACCP Plan for smoked fish, including the following:

1. The HACCP Plan for smoked fish, which includes scombroid producing fish species, lists as a "Critical Limit" that fish, upon receipt, must be [REDACTED]. Two lots, received on 4/12/01 and 4/18/01, were at temperatures of 41⁰F and 42⁰F. The "Fish Receiving" form is checked as "Accept" for these lots.
2. The HACCP Plan for smoked fish requires, as a "Critical Limit", [REDACTED]. [REDACTED] Review of your smokehouse records revealed that this function is not consistently performed and/or recorded. For example, the smokehouse records dated 4/19/01, 4/2/01 and 3/26/01 were blank in the area where the internal temperature readings are recorded.
3. The HACCP Plan for smoked fish lists the brining time as [REDACTED]. Review of the smokehouse records revealed that the brine time is not always met. For example, the record dated 4/19/01 lists the actual brine time as 18 hours; the records dated 4/12 lists the actual brine time as 19 hours. Neither record is signed or dated by a reviewer.

4. Review of the smokehouse records revealed deviations from the "Critical Limits" listed in the HACCP Plan. For example:
 - The batch record dated 4/2/01 does not list the weight of the fish processed, but does list that 40 gallons of water and 30 pounds of salt were used. Your HACCP Plan lists as a "Critical Limit" the brine to fish ratio.
 - The batch records dated 4/12/01 and 4/19/01 list the fish weights as 143 and 129 pounds, respectively. Both batches were formulated using the same amount ([REDACTED]) of water, which differs from the amount of water used to produce a batch of unknown size on 4/2/01 ([REDACTED] of water).
 - The batch records do not contain all of the required process information, including the weight of the fish, initial brine temperatures, internal fish temperatures, salinometer readings, and/or reviewer's signature and date.
 - The salinometer used to measure the salt concentration was inoperable during the inspection. Your HACCP Plan includes the use of a salinometer to assure that the "Critical Limit" for brine concentration is met.
5. Sanitation monitoring records were not maintained in the years 2000 and 2001 (to date). Sanitation monitoring records must be maintained, in order to comply with 21 CFR 123.11(c).
6. The appropriate corrective action must be taken when deviations from critical limits occur, in order to comply with 21 CFR 123.7(a). However, during the inspection we observed deviations from the critical limits, for which no corrective action was taken. For example, batch records dated 4/12 and 4/19/01 list the brine times as 18 and 19 hours, respectively. The "Critical Limit" in your HACCP plan requires [REDACTED]. These records were not signed or dated by a reviewer nor was corrective action taken.

The above items are not an all-inclusive list of the objectionable conditions observed in your facility. However, some of the items are repeat violations that were observed during the previous FDA inspection and were listed in our letter to you dated June 27, 2000. You should take prompt action to correct all deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please 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 and to prevent recurrence. 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.

Mr. Robert L. Williamson and Mr. Robert Smith/Virginia Seafood LLC

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Your response should be sent to the Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Rosalie Bucey, Compliance Officer. Ms. Bucey can be contacted at telephone number 410/962-3591, extension 143.

Sincerely,



Lee Bowers
Director, Baltimore District

Cc: Virginia Department of Agriculture & Consumer Services
Division of Consumer Protection
Office of Dairy and Food
1100 Bank Street, Suite 510
Richmond, Virginia 23219