

HEP-35



DEPARTMENT OF HEALTH & HUMAN SERVICES

M2150N

New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

October 28, 1998

**WARNING LETTER NYK 1999-4**

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Joseph R. Messina, President  
Specialty World Foods, Inc.  
84 Montgomery Street  
Albany, New York 12207

Dear Mr. Messina:

An inspection of your facility was performed August 19-20, 1998 by U.S. Food and Drug Administration (FDA) Investigator Denise L. Terzian. The inspection revealed various seafood products, including vacuum packed smoked salmon fillets, processed at, and distributed from, your facility, are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act. They are adulterated because they were processed and held under conditions contrary to 21 CFR 123 which constitute insanitary conditions whereby they may have been rendered injurious to health.

As we explained in a previous letter to you, the seafood processing regulations, which became effective December 18, 1997, require implementation of a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: **(1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.**

Our inspection revealed your processing of vacuum packed smoked salmon fillets deviates from the regulations contained in 21 CFR 123 as follows:

- Failure to include the hazard Clostridium botulinum in the HACCP plan [21 CFR 123.6 (c)(1)]. This hazard has been determined to be reasonably likely to occur in vacuum packed smoked salmon fillets.

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- Records required by 21 CFR 123 must be made available for official review [21 CFR 123.9(c)]. However, at the time of our inspection, there were no records of the temperature of the interior of the styrofoam cartons in which smoked salmon fillets were received.
- Your plan states that product temperature be monitored when, in practice, the temperature readings are taken on the interior of the styrofoam container upon receipt. The plan should be modified to reflect what is actually done. The thermometer used to take these temperature readings is required to be calibrated on an ongoing basis [21 CFR 123.8]. Your HACCP plan is incomplete because it does not provide for this verification procedure [21 CFR 123.6(c)(6)].
- Failure to maintain calibration records for the thermometer used to monitor the temperature inside the styrofoam containers at the time the vacuum packed smoked salmon fillets are received [21 CFR 123.8(a)(2)(ii) and 123.8(a)(3)(iii)].
- Failure to maintain sanitation control records required by 21 CFR 123.11(c) that document the monitoring and corrections of sanitary conditions and practices during processing.

In addition, the following deficiency was noted related to the products *herring fillets in wine* and *herring fillets in cream sauce* processed by your firm:

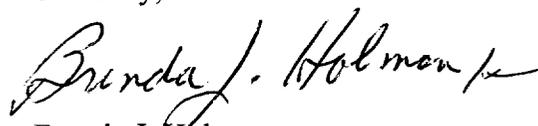
- Failure to develop and implement a written HACCP plan to address potential food safety hazards [21 CFR 123.6(b)].

You should take prompt action to correct these and all violations at your firm. Failure to achieve prompt corrective action may result in further regulatory action - without further notice. These actions include seizure and/or injunction.

Please notify this office in writing, within 15 days, of the specific steps you have taken to correct the noted violation and to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Compliance Officer, at the above address. Mr. Kewley may be reached by telephone at (716) 551-4461 ext. 3128.

Please note, under separate cover, you will be receiving copies of the establishment inspection reports covering inspections of your facility performed 2/18-19/98 and 8/19-20/98. These are provided to further assist you in bringing your firm's operations into compliance.

Sincerely,



Brenda J. Holman  
District Director