



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

December 23, 1998

WARNING LETTER NYK 1999-18

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

David M. Ginsberg, President
Ginsberg's Institutional Foods, Inc.
Route 66, P.O. Box 17
Hudson, New York 12534

Dear Mr. Ginsberg:

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 previous letters 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 seafood products, including vacuum packed smoked salmon fillets, deviates from the regulations contained in 21 CFR 123 as follows:

1. Failure to develop and implement written HACCP plans for all seafood products processed at your facility for which hazards such as *Clostridium botulinum* (*C. Bot*) or *histamines* have been determined to be reasonably likely to occur [21 CFR 123.6(b)]. At your facility these products include, but are not limited to, other smoked fish products such as Nova Bits, (*C. Bot* hazard), and mahi mahi, tuna loins, amberjack, and Boston Bluefish (histamine hazard). These products are not covered by your current HACCP plan.
2. 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.

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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 deficiencies and to prevent a recurrence of similar violations.

Other deficiencies which should be corrected at your facility include:

- Your HACCP plan continues to lack appropriate verification procedures for the Critical Control Points (CCPs) "Receiving" and "Storage" because it still does not include calibration of the thermometers used for temperature monitoring as a verification step, and does not specify the frequency at which the calibrations must be performed [21 CFR 123.6(c)(6)].

- Failure to have the HACCP plan for smoked salmon signed and dated either by the most responsible individual on site or by a higher level official of your firm [21 CFR 123.6(d)].

Your written response should be directed to James M. Kewley, Compliance Officer, at the above address. Mr. Kewley can be reached at (716) 551-4461, ext. 3128.

Sincerely,



Brenda J. Holman
District Director