



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Cho Kyung, President
Seacome Foods Inc.
970 Longfellow Avenue
Bronx, New York 10474

April 6, 1999

re: NYK 1999-39

Dear Mr. Kyung:

An inspection of your facility at 970 Longfellow Avenue, Bronx, New York, was conducted on October 22, 28 and November 2, 1998 by U.S. Food and Drug Administration (FDA) Investigator Andrew Cohen. The inspection revealed seafood products, including cooked fish cakes and fish balls, 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 Title 21 Code of Federal Regulations (CFR), Part 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 fish cakes and fish balls deviates from the regulations contained in 21 CFR 123 as follows:

1. Failure to have and implement a HACCP plan for your cooked fish cakes as required by 21 CFR 123.6 (b). We observed that you have not established time and temperature control parameters to verify the cook process or establish a cooling schedule for cooked product.
2. Failure to establish and monitor manufacturing practices. We observed that you have not conducted monitoring of the time and temperature of cooking or of cooling to reach a safe temperature.

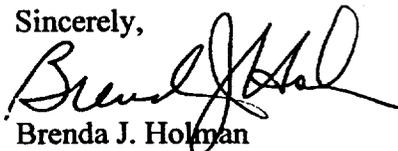
3. Failure to monitor sanitation conditions and practices as required by 21 CFR 123.11(b). Insanitary practices were observed during the inspection and the following are examples that relate to your plant and the food being processed:
 - 3.1. With regard to exclusion of pests from the food plant, a cat was observed in the plant during production, including the production area.
 - 3.2. With regard to prevention of cross-contamination from insanitary objects to the food or food-contact surfaces, the FDA sample consisting of a swab taken from the surface of the boning table during the inspection revealed the presence of *Listeria monocytogenes* organisms.
 - 3.3. Also with regard to prevention of cross-contamination, there was inadequate sanitary design, construction, and maintenance. For example, plastic crates containing fish were placed directly on the floor and the same crates were stacked directly on top of one another. Encrusted product was observed throughout the plant on walls, ceilings, floors, equipment, and reused cartons for holding finished product. Refrigerator lights lacked covers, and covers when present had dead insects within. An excessive amount of standing water was observed on the floor near the freezer entrance.
4. Failure to maintain sanitation control records required by 21 CFR 123.11(c) that document the monitoring and correction of sanitary conditions and practices during processing.

The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your facility is in compliance with all requirements of the federal regulations. 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 violations and to prevent a recurrence of similar violations. 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.

Your response should be sent to the Food and Drug Administration, 850 Third Avenue, Brooklyn NY 11232, Attention: William Friedrich, Compliance Officer. Mr. Friedrich can be telephoned at 718/340-7000 ext. 5532.

Sincerely,



Brenda J. Holman
District Director