



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

g/06/d

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6009

September 19, 2001

WARNING LETTER

CERTIFIED MAIL-
RETURN RECEIPT REQUESTED

Mr. Nash Cohen
President/Owner
Herb's Seafood, Inc.
112 Schoolhouse Road
Mt. Holly, New Jersey 08060

File No.: 01-NWJ-37

Dear Mr. Cohen:

We inspected your seafood processing facility located at 112 Schoolhouse Road, Mt. Holly, New Jersey, from August 7-17, 2001, and found serious deviations from the Seafood Hazard Analysis and Critical Control Point (HACCP) regulations in Title 21, Code of Federal Regulations (CFR), Part 123. These deviations cause your deviled crab cake, tuna burger and breaded stuffed shrimp products to be in violation of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). You can find the Act and seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations included the following:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR, Part 123.6(c)(1). However, your HACCP plans for deviled crab cakes, tuna burgers and breaded stuffed shrimp products do not identify, nor require monitoring of food safety hazards for natural toxins and bacterial contamination. For example, your practice of initially thawing frozen vacuum packaged surimi and other raw materials at ambient temperatures for an undetermined amount of time, without monitoring this process, is unacceptable. During the inspection, investigators observed raw materials, to be later used in deviled crab cakes, thawing at dock-side, when outdoor temperatures were near 100° F, prior to staging in cooler storage.
2. 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 plan for deviled crab cakes and breaded stuffed shrimp products, does not identify critical control points during the receiving, thawing, cooler storage and battering steps of production. For example, battering temperatures and cooler storage temperatures are not routinely monitored.

Also, your HACCP plan for tuna burger processing does not include critical limits or monitoring procedures for the critical control points of tuna patty blending, forming, packaging and metal inclusion. The investigators observed raw tuna processed and packaged in ambient temperatures. Metal detection and equipment examination was not performed nor identified in the HACCP plan.

3. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR Part 123.6(b). However, during the inspection, the following was observed:
 - There were no monitoring records maintained for the processing of deviled crab cake products at the mixer or battering stages on January 16, 23, February 14, March 1 and April 10, 2001.
4. You must implement corrective actions when deviations from critical limits are identified at critical control points, to comply with 21 CFR Part 123.7(a). Examples of deficiencies in meeting this requirement include:
 - Monitoring records for coolers used to store vacuum packaged surimi and crabmeat, tuna and tuna burgers, were reviewed from April through August 2001. Temperatures were found to range from 41° to 51° F, however no corrective actions were taken.
 - Temperature of shrimp, during processing for breaded stuffed shrimp, were found to be 61.5° F. Battering temperatures were found between 66° and 69° F. Temperatures are not routinely monitored. No corrective action was taken.
 - Metal detector test records for deviled crab cake products indicated "y" for reject. However, no assessment was made to determine whether the detection was ferrous or non-ferrous material or the level of metal detection and no corrective actions were taken.
5. You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a). However, your firm did not verify the adequacy of the critical control limits for cooler monitoring. For example, the HACCP plan indicates that cooler temperatures are monitored four times daily, however records indicate that temperatures are taken three times daily, only on production days. Additionally, verification procedures were inadequate, which states that cooler thermometers are calibrated with boiling water rather than in an ice water bath.
6. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, there is no documentation to support that the following eight key sanitation areas are evaluated and monitored: safety of water, condition and cleanliness of all food contact surfaces, prevention of cross contamination, handwashing facilities, protection of food, food packaging, storage of toxic compounds and exclusion of pests. For example, there are no backflow protection valves on the water lines to the patty forming machine, [REDACTED] machine or the batter mixer. This item was previously cited during a February 1999 inspection and has not yet been corrected.

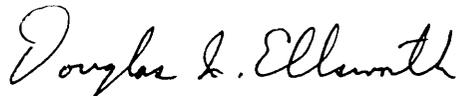
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within 3 weeks from your receipt of this letter. Your response should outline the specific steps you have taken to correct these deviations. You may wish to include in your response documentation such as a revised HACCP plan, revised monitoring procedures, or other useful information that would assist us in evaluating your corrections. If you cannot complete the corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, New Jersey District, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes B. Mota, Compliance Officer.

Sincerely,



Douglas I. Ellsworth
District Director