



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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April 10, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-38

Tony Cheng, President
East Ocean Seafoods, Inc.
668 South Lane Street
Seattle, Washington 98104

WARNING LETTER

Dear Mr. Cheng:

We inspected your firm located at 668 South Lane Street, Seattle, Washington, on July 19, 1999, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to you at the conclusion of the inspection. These deviations cause your crab products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for live dungeness crab to control the food safety hazard(s) of natural toxins.
2. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b) and (c)(1). Your firm's HACCP plan for whole cooked crab does not list the food safety hazard of natural toxins.
3. You must implement a record keeping system as listed in your HACCP plan, to comply with 21 CFR 123.6(b). Your firm did not record monitoring observations at the cooking critical control point for cooked crabmeat and whole cooked crab, or at the storage critical points for whole cooked crab to control the hazard of biological pathogens.

Tony Cheng, President
East Ocean Seafoods, Inc., Seattle, Wa
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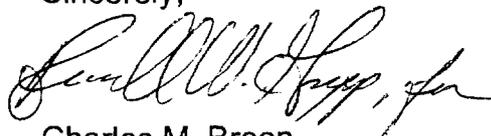
4. Since you have chosen to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, in order to comply with 123.7(b). Your corrective actions for the cooking and storage critical control points in your HACCP plans for cooked crabmeat and whole cooked crab do not address the cause of the deviation.
5. You must have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). Your firm was not maintaining sanitation monitoring records for seven of the eight areas of sanitation. These records should include monitoring the safety of processing water, prevention of cross contamination, maintenance of handwashing, hand sanitizing, and toilet facilities, protection from adulterants, proper labeling, storage, and use of toxic compounds, control of employees with adverse health conditions, and exclusion of pests. The sanitation monitoring record provided to our investigator was inadequate.

The above violations are not meant to be an all-inclusive list of deficiencies in your plant. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA, including the Seafood HACCP regulations and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations in 21 CFR 110. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating. Pertinent sections of the Act and regulations are enclosed for your review.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will 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, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

Sincerely,



Charles M. Breen
District Director