



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
FAX: 425-483-4996

July 16, 2001

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-72

Mr. Don Giles, President
Icicle Seafoods, Inc.
P.O. Box 79003
Seattle, Washington 98119

WARNING LETTER

Dear Mr. Giles:

We inspected your firm located at 500 W. Orchard Drive, Bellingham, Washington, on March 14, 2001, 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 Thomas S. Bailey, Operations Manager, at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your imitation crabmeat 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 that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan for vacuum-packaged imitation crab product does not list a critical limit(s) at the pasteurizing critical control point to adequately address the hazard of Clostridium botulinum in your refrigerated vacuum packaged product, and pathogen survival through pasteurization in your frozen vacuum packaged product.

Your HACCP plan lists critical limits for product pasteurization as follows:

- Products must attain a minimum core temperature of [REDACTED] degrees F for [REDACTED] seconds for frozen products.
- Refrigerated products must be heated to [REDACTED] degrees F for [REDACTED] minutes.

The internal core temperature of individual packages is not considered a suitable critical limit for pasteurization due to the variability of temperatures from package to package. Appropriate critical limits would include the speed of your belt (since your pasteurization is continuous) or residence time, the initial temperature of the product, the thickness of your

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packages, and the temperature of your cooker. Core temperatures can be used as a verification procedure to assure that your process is providing adequate heat penetration. Chapter 17 of the Fish & Fisheries Products Hazards and Controls Guide can provide guidance with regards to appropriate critical limits and monitoring procedures.

The validation study you provided from the National Food Processors Association, dated September 6, 1989, states that it is possible for you to reduce the product residence time in the pasteurizer, but that any reduction must be supported by thermal-death-time and heat penetration studies. Our review of your records indicates that you appear to have reduced the cook time of your pasteurization process. If your firm wishes to vary from the provided study, you must validate your new process and critical limits.

2. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). Your firm's HACCP plan for refrigerated vacuum-packed imitation crabmeat does not list the critical control points of container (package) sealing for controlling the food safety hazard of pathogen introduction after pasteurization and finished product refrigerated storage for controlling the food safety hazard of *Clostridium botulinum*.

You must be able to assure that your product containers are properly sealed according to the manufacturer's seal guidelines to ensure that your pasteurized products cannot be contaminated with pathogens after pasteurization. You must also be able to show that refrigerated vacuum packaged products are held at temperatures adequate to control the growth of *Clostridium botulinum* during their storage prior to shipment.

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 (21 CFR Part 110). 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 product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

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.

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Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

Sincerely,

A handwritten signature in black ink, appearing to read 'C. M. Breen', with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: WSDA with disclosure statement