



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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June 28, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-54

Ryan K. Mackey, President
Orca Bay Foods, Inc.
900 Powell Avenue SW
Renton, Washington 98055

WARNING LETTER

Dear Mr. Mackey:

We inspected the Cuizina Italia Division of Orca Bay Foods located at 18744-142nd NE, Woodinville, Washington on January 6 and 7, 2000, 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 Pat A. Flin, Operations Manager, at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your frozen, fully cooked, non-shelf stable Cioppino 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 home page at www.fda.gov.

The deviations were as follows:

1. 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(c)(1). Your firm's HACCP plan for frozen, fully cooked, non-shelf stable Cioppino, a seafood soup product, does not list the food safety hazard of allergens. The Cioppino soup product contains several allergens including shrimp, shrimp base, clams and clam base.
2. You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan for frozen, fully cooked, non-shelf stable Cioppino lists an internal temperature of 165°F. (center of kettle) as a critical limit at the cooking critical control point. This alone is not adequate to control the bacteriological hazard. This deviation was previously brought to your attention in our letter of October 20, 1999.

Ryan K. Mackey, President
Orca Bay Foods, Cuizina Italia Division
Woodinville, WA
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3. You must implement the monitoring procedures and frequency listed in your HACCP plan, in order to comply with 21 CFR 123.6(b). Your firm did not follow the monitoring procedures or frequency listed in your HACCP plan for frozen, fully cooked, non-shelf stable Cioppino at the cooling critical control point to control pathogens. The temperature of the product is not being monitored every two hours, as listed in the HACCP plan, to ensure it reaches 40° F within 5 hours, nor is every batch being monitored as listed in the HACCP plan. This deviation was previously brought to your attention in our letter of October 20, 1999.

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 three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response the following: a copy of your revised HACCP plan, scientific documentation supporting the adequacy of the cook process, and any other useful information that would assist us in evaluating your corrections to the deviations listed on the Form FDA 483. 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.

This letter may not list all the deviations at your facility. You are responsible for ensuring that each of your processing plants operate in compliance with the Act, the Seafood HACCP regulations and 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 applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Robert L. Wesley, Compliance Officer, 1000 2nd Avenue, Suite 200, Seattle, Washington, 98104. If you have any questions regarding any issue in this letter, please contact Robert L. Wesley at 206/553-7001, extension 57.

Sincerely,



Charles M. Breen
District Director

Enclosures:

Form FDA 483

cc: WSDA with disclosure statement