



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94791d
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

June 15, 2004

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-34

Mr. C.T.(Chi-Tai) Kuo, President
Barclay Seafoods & Meat Corporation
703 South King Street
Seattle, Washington 98104

WARNING LETTER

Dear Mr. Kuo:

On May 5-6, 2004, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 19115 84th Avenue South, Kent, Washington. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations (21 FR 123).

During our inspection, the FDA investigator observed deviations from the seafood processing regulations. The FDA investigator also provided you with a copy of the Import Seafood HACCP Report (form FDA 3502), which presents her evaluation of your firm regarding various aspects of the HACCP requirements. The observations of concern to us are as follows:

1. You must have product specifications that are designed to ensure that the fish and fisher products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have a product specification for live dungeness crab imported from Canada.
2. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for live dungeness crab imported from Canada.

Note that purchasing from foreign processors approved by their government inspection authority and listed in good standing on the foreign government's posted list meets the requirements of an affirmative step. You must, however, document in your written verification procedures that you have chosen this affirmative step.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

C.T. (Chi-Tai) Kuo, President
Barclay Seafoods & Meat Corporation, Kent, WA
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You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificate for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct this (these) violation(s), including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within fifteen working days, state the reason for your delay and time frame within which the corrections will be completed.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding the implementation of the HACCP Regulations, you may contact Ms. Elrand at (425) 483-4913.

We look forward to working with you to achieve a successful HACCP program.

Sincerely,



Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: WSDA with disclosure statement