



DEPARTMENT OF HEALTH AND HUMAN SERVICES

m34901

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

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

COPY

March 8, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-31

Scott A. Barton, Owner
Select Fish L.L.C.
5840 Airport Way South
Seattle, Washington 98108

WARNING LETTER

Dear Mr. Barton:

We inspected your firm located at 5840 Airport Way South, Seattle, Washington, on November 29 and 30, 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, some of which were previously brought to your attention, cause your fresh and frozen tuna loins and halibut steaks 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:

Your firm does not have an approved HACCP plan in place to control the hazard of scombrototoxin in scombroid fish species, including tuna loins and halibut steaks, which are processed and sold fresh and frozen by your firm. You must have an approved HACCP plan to control any food safety hazard that is reasonably likely to occur, in order to comply with 21 CFR 123.6(b). An approved HACCP plan is one that has been dated and signed by the most responsible individual of the firm indicating acceptance for implementation. Our most recent inspection found that your firm has a draft HACCP plan, but it has not been finalized. This deviation was previously brought to your attention during our June 1999 inspection and in our September 10, 1999 letter.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. 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.

Scott A. Barton, Owner
Select Fish L.L.C., Seattle, WA
Re: Warning Letter SEA 00-31
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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.

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 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations. Pertinent sections of the Act and regulations are enclosed for your review.

Please send your reply to the Food and Drug Administration, Attention: Robert L. Wesley, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Robert Wesley at (206) 553-7001, ext. 57.

Sincerely,



Charles M. Breen
District Director

Enclosures:

Form FDA 483
21 CFR Part 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: With Disclosure Statement
WSDA