



DEPARTMENT OF HEALTH & HUMAN SERVICES

m3049n

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

October 7, 1999

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

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-01

Donald D. Elder, President
Reel Food Service, Inc.
304 Americana Boulevard
Boise, Idaho 83702

WARNING LETTER

Dear Mr. Elder:

On May 10, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 304 Americana Boulevard, Boise, Idaho. At the conclusion of the inspection, you were presented with a Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (HACCP Regulation). A copy of the Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the tuna, mahi mahi, and refrigerated vacuum packaged products processed or stored by your firm are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

The observations of concern to us are listed below:

1. Your firm did not have and implement a written HACCP plan to control one or more food safety hazards that are reasonably likely to occur as required by 21 CFR 123.6(b). Specifically:

Your firm did not address the food safety hazard of histamine formation in tuna and mahi mahi. Your firm needs to monitor product temperature at receipt and during product storage.

Your firm did not address the food safety hazard of *C. botulinum* growth and toxin formation in vacuum packaged smoked fish. Your firm needs to monitor temperature during finished product storage.

Your firm did not address the food safety hazard of *C. botulinum* growth and toxin formation in vacuum packaged raw fish. FDA is unaware of appropriate controls for this type of product other than maintaining the product in a frozen state, or maintaining the product at or below 38 degrees F if the vacuum seal is broken before the product leaves the processor's control.

2. Your firm failed to monitor the conditions and practices related to eight elements of sanitation as required by 21 CFR 123.11(b). The areas of sanitation which are not monitored include:
 - a. safety of water;
 - b. condition and cleanliness of food contact surfaces;
 - c. prevention of cross contamination;
 - d. maintenance of handwashing and toilet facilities;
 - e. protection from adulterants;
 - f. proper labeling, storage and use of toxic compounds; and
 - g. control of employees with adverse health conditions.

21 CFR Part 123.11(b) and (c) require seafood processors to monitor eight points of sanitation and to maintain records documenting the monitoring of these aspects of sanitation.

During the previous inspection, on July 22, 1998, and in a letter from the FDA, dated April 13, 1999, you were notified of many of the same deficiencies described in this letter. During the inspection and in a letter dated April 13, 1999, the FDA explained that you would need to take steps to correct those deficiencies. The FDA is concerned that in ten months' time, your firm has not taken action to correct these deficiencies.

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. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act

Donald D. Elder
Reel Food Service, Inc.
Page 3

and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Lisa M. Elrand, Acting Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

A handwritten signature in black ink, appearing to read 'A. Long', written in a cursive style.

Austin R. Long, Ph.D.
Acting District Director

Enclosures:

FORM FDA 483

21 CFR PART 123

Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: ISDH with disclosure statement