



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

February 15, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-26

Diane L. Zollinger, Owner
Felix Custom Smoking
17461 147th Street SE, 2A
Monroe, Washington 98272

WARNING LETTER

Dear Ms. Zollinger:

We inspected your firm located at 17461 147th Street SE, 2A, Monroe, Washington, on October 5, 6, 10, 11, 12 and 13, 2000, and found 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 tuna jerky and hot smoked vacuum packaged tuna 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 food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for tuna jerky (titled Salmon Jerky) does not list the food safety hazard of scombrototoxin (histamine) formation. There is a reasonable likelihood of scombrototoxin (histamine) formation any time scombrototoxin-forming fish are exposed to temperatures above 40°F. Our investigator observed cooler temperatures ranging from 43-46°F throughout the inspection. Our investigator checked the temperature of the tuna during butchering and recorded a temperature of 48°F. Therefore, scombrototoxin (histamine) formation should be identified as a food safety hazard and as such, should include monitoring of cumulative exposure time.
2. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for hot smoked vacuum packaged tuna does not list the critical control point of cooling for controlling the food safety hazard of *Clostridium botulinum*.

3. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Brine critical control point to control *Clostridium botulinum* listed in your HACCP plan for tuna jerky (titled Salmon Jerky). Your HACCP plan indicates you will record brine time, however, no record is being maintained.
4. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3).
 - a) Your firm's HACCP plan for tuna jerky (titled Salmon Jerky) lists a critical limit at the Smoker critical control point that is not adequate. As you explained to the investigator, the critical limit of 145°F for 30 minutes listed in the HACCP plan, and 175°F for 4.5 hours listed in the narrative/flow diagram are not the critical limits that you utilize for tuna jerky production. Your HACCP plan should incorporate the three states in the smoking/drying process that you told the investigator are critical for moisture removal.
 - b) Your firm's HACCP plan for tuna jerky (titled Salmon Jerky) lists a critical limit of "thickness of fish" at the Brine critical control point that is not adequate to control *Clostridium botulinum*. A critical limit is defined as a maximum or minimum value that must be controlled. "Thickness of fish" must be specifically defined with a numerical value so that adequate control can be assured. Your HACCP plan must then include monitoring procedures for this critical limit.
 - c) Our investigator also noted that your HACCP plan and narrative/flow diagram list conflicting brine times. If brine times are to be listed in your narrative/flow diagram, the times should be consistent with the HACCP plan.
5. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4).
 - a) Your firm's HACCP plan for tuna jerky (titled Salmon Jerky) lists a monitoring procedure of "Temp" at the Smoker critical control point that is not adequate to control pathogen growth and toxin formation. You must also list a monitoring procedure for time.
 - b) Your firm's HACCP plan for hot smoked vacuum packaged tuna lists a monitoring procedure of "Temp" at the Smoker critical control point that is not adequate to control *Clostridium botulinum* and histamine. You must list a monitoring procedure for time.
6. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). Your corrective action plan for both tuna jerky (titled Salmon Jerky) and hot smoked vacuum packaged tuna are not appropriate. Pre-determined corrective actions must address both product and process. Your corrective actions must include identifying and correcting the cause of the deviation. For

Diane L. Zollinger, Owner
Felix Custom Smoking, Monroe, Washington
Re: Warning Letter SEA 01-26
Page 3

instance, the cause of the deviation resulting in fish above 50°F, at the Fish over 50° critical control point for both plans should be addressed.

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.

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 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.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Althar at (425) 483-4940.

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: WSDA with Disclosure Statement