



DEPARTMENT OF HEALTH AND HUMAN SERVICES

01257d  
Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

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

May 11, 2001

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-54

James N. Hett, Owner  
Leo's Gourmet Smoked Fish  
58 West Cedar Place  
Elma, Washington 98541

**WARNING LETTER**

Dear Mr. Hett:

We inspected your firm located at 58 West Cedar Place, Elma, Washington, on November 30, 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 during the inspection of March 28, 2000, cause your vacuum packaged hot smoked salmon 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](http://www.fda.gov).

The deviations were as follows:

1. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6 (c)(4). Your firm's modified HACCP plan (dated 2/2/01) for vacuum packaged hot smoked salmon lists a monitoring frequency at the Smoking and Final Product Storage control points that is not adequate to control pathogen growth and toxin formation including *Clostridium botulinum*. Monitoring the temperature twice during the smoking cycle and monitoring the storage refrigerator temperature once a day is not adequate to ensure that the critical limits are met. In addition, a monitoring procedure for measuring the time that the salmon are smoked at XXXX°F is not listed at the Smoking critical control point to control pathogen growth and toxin formation including *Clostridium botulinum*.

James N. Hett, Owner  
Leo's Gourmet Smoked Fish, Elma, Washington  
Re: Warning Letter SEA 01-54  
Page 2

2. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures listed in your HACCP plan for vacuum packaged hot smoked salmon. Based on the observations of our investigator in the November 30, 2000, inspection, the firm made no production records documenting the presence or level of salt.
3. Since you chose to include corrective actions in your modified HACCP plan (dated 2/2/01), your described corrective actions must be appropriate to comply with 21 CFR 123.7(b). Your corrective action plans for vacuum packaged hot smoked salmon at the brining, smoking, and cooling from smoker critical control points list only how you will regain control of your process. An appropriate corrective action must also include steps to ensure that potentially unsafe product does not enter commerce. This would include a step in your process of holding and evaluating finished product for all three critical control points.

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 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 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: Diane J. Englund, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Diane J. Englund at (425) 483-4864.

Sincerely,



Charles M. Breen  
District Director

James N. Hett, Owner  
Leo's Gourmet Smoked Fish, Elma, Washington  
Re: Warning Letter SEA 01-54  
Page 3

Enclosures:

Form FDA 483

21 CFR PART 123

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

cc: WSDA with disclosure statement