



COPY

April 17, 1998

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell, WA 98041-3012

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

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 98-10

Michael A. Josephson, Owner
Josephson's Smokehouse & Dock
106 Marine Drive
Astoria, Oregon 97103

WARNING LETTER

Dear Mr. Josephson:

On February 4, 1998 an FDA Investigator conducted an inspection of your firm located at 106 Marine Drive, Astoria, Oregon. During that inspection, our investigator collected samples of your labeling for Hot Smoked Mussels (with Packed on Date: 2-4-98). Our review of this product found it to be misbranded within the meaning of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Part 101 - Food Labeling, as follows:

This product fails to bear a label with nutritional labeling as required under Section 403(q)(1) of the Act, and 21 CFR Part 101.9, and is not exempt from this requirement.

The above violation includes certain new labeling requirements and is not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with applicable statutes enforced by FDA.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure.

In addition to the above noted labeling violation, our review also found the following deficiencies with your label for hot smoked mussels :

1. This product fails to bear a label with a designation of ingredients as required under Section 403(i)(2) of the Act, and 21 CFR Part 101.4.
2. This product fails to bear a label that specifies the name and place of business of the manufacturer and/or distributor as required under Section 403(e)(1) of the Act, and 21 CFR Part 101.5(a).

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3. This product fails to bear a label with a statement of net quantity of contents as required under Section 403(e)(2) of the Act, and 21 CFR Part 101.105.

You should notify this office within 15 (fifteen) working days of the receipt of this letter of the specific steps you have taken to correct the noted violations, along with a copy of the revised label. 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.

A copy of *A Food Labeling Guide*, which contains applicable sections of the food labeling regulations referred to in this letter, is enclosed for your review and information. The guide should help in preparing a proper label, to include nutritional information. Some small businesses are exempt from the nutritional labeling requirements; however, it is your responsibility to determine if your firm meets exemption requirements and file an exemption notice. A small business labeling exemption notice, which includes exemption criteria and instructions on filing an exemption notice, is enclosed.

HACCP DEVIATIONS:

The inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practices requirements for foods (21 CFR 110).

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety orientated workforce, having less product waste, and having fewer problems generally.

During the inspection, the FDA investigator observed shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. The FDA investigator also provided you with a copy of the Domestic Seafood HACCP Report (Form FDA 3501) and the Form FDA 483 which presents her evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are as follows:

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1. You do not have a written HACCP Plan for the following vacuum packaged, refrigerated, seafood products listed below. All of the products have been processed since December 18, 1997:

hot smoked:	-	salmon	cold smoked:	-	salmon
	-	sturgeon		-	tuna
	-	tuna		-	black cod
	-	halibut		-	halibut
	-	black cod			
	-	black tip shark			
	-	trout			
	-	oysters			
	-	scallops			
	-	prawns			
	-	mussels			

Our inspection found at least one or more food safety hazards associated with each of the products listed on the previous page. 21 CFR Part 123.6(a) requires you to perform a hazard analysis for each seafood product that you manufacture. When you identify one or more food safety hazards associated with a product, 21 CFR Part 123.6(b) requires you to have and implement a HACCP Plan. 21 CFR Part 123.6(c) details what a HACCP Plan shall include. Firms that process smoked and smoke flavored fishery products are also required to comply with 21 CFR Part 123.16, which requires you to include in your HACCP Plans how you are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

You may want to consult the *Fish & Fisheries Products Hazards & Controls Guide: Second Edition* for information related to conducting a hazard analysis and identifying potential hazards associated with your products and processes.

2. Your firm does not maintain sanitation monitoring records. 21 CFR Part 123.11 covers sanitation under HACCP. The FDA recommends that you have and implement a written sanitation operating procedure. You are required to monitor eight aspects of sanitation as they apply to your firm. Additionally, you are required to document the monitoring of sanitation and any corrections you take as a result of your monitoring.

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's preliminary assessment of deviations from HACCP regulations, you should explain how your system identifies hazards and implements controls in a manner that the agency

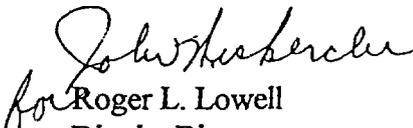
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should regard as complying with the regulations. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and that there may be more than one right way to control hazards.

In either case, it is essential that you respond to this office on these HACCP deviations within 30 working days of the receipt of this letter. Upon receipt of a timely response, we will work with you to resolve any outstanding issues associated with your HACCP system. If we do not hear from you, or if your response is inadequate, we will assume that our preliminary conclusions are correct and we will schedule a follow-up inspection for the immediate future.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Janelle K. Main, Acting Compliance Officer, P.O. Box 3012, Bothell, WA 98041-3012. If you have questions regarding the implementation of the HACCP regulation or the application of HACCP to your specific process, you may contact me at (425) 483-4928 for answers and/or direction towards guidance and sources of training in achieving compliance. We look forward to working with you to achieve a successful HACCP program in your plant.

Sincerely,


for Roger L. Lowell
District Director

Enclosures:

A Food Labeling Guide
Model Small Business Exemption Food Labeling Exemption Notice

cc: With Disclosure Statement
Oregon State Department of Agriculture