



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

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

June 24, 2004

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-38

Vadim Shoyhin, President
International Groceries, LLC
1075 Andover Park East
Tukwila, Washington 98188

WARNING LETTER

Dear Mr. Shoyhin:

On May 10, 2004, we inspected your seafood processing facility, located at 1075 Andover Park East, Tukwila, Washington. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or to otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C 342(a)(4). Accordingly, the hot smoked vacuum-packaged mackerel you store in your facility is adulterated in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You can find the Act, the Seafood HACCP regulations and the Fish and Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001 (the Hazard Guide), through links in FDA's homepage at www.fda.gov.

The deviations are as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (b). Your firm does not have a HACCP plan for the hot smoked vacuum-packaged mackerel you receive and store at your facility to control for the food safety hazards of *Clostridium botulinum* and histamines.
2. You must monitor and maintain records that, at a minimum, document sanitation conditions and corrections to comply with 21 CFR 123.11 (b) and (c). Your firm did not monitor or maintain sanitation monitoring records for the areas of sanitation that pertain to your particular operation.

Vadim Shoyhin, President
International Groceries, LLC, Tukwila, WA
Re: Warning Letter SEA 04-38
Page 2

For example, areas of sanitation you could be monitoring for your facility are:

- protection of food from adulterants,
- proper labeling, storage, and use of toxic compounds
- exclusion of pests.

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 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.

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 Current 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.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact CO Elrand at (425) 483-4913*al*.

Sincerely,



Charles M. Breen
District Director

Enclosures:

Form FDA 483
21 CFR 123.6 and 123.11

cc: WSDA with disclosure statement