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

Telephone: 425-486-8788  
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January 3, 2003

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 03-09

Lindsey C. Babich, President  
Trader Bay, Ltd.  
206 SW Michigan Street  
Seattle, Washington 98124

**WARNING LETTER**

Dear Ms. Babich:

On November 19, 20, & 22, 2002, we inspected your seafood processing facility, located in Seattle, 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 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 your frozen, ready-to-eat, salmon caviar (Ikura) 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 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 at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c)(3). A critical limit is defined in 21 CFR Part 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard. Your firm's HACCP plan for frozen, ready-to-eat, salmon caviar, packaged in rigid plastic containers with snap-on lids, lists a critical limit of [REDACTED] hours at the curing/packing critical control point that is not adequate to control the pathogens hazard identified in your HACCP plan.

To control the hazards of pathogen growth where the product is held at internal temperatures above 50°F, but not above 70°F, FDA recommends that the exposure time be limited to six hours. If the product is held at chilled temperatures of 50°F or lower, processing should be accomplished within 24 hours. Processing at 40°F or below would not require time restrictions to control pathogens. The cumulative exposure time should be accounted for from the time the eggs are exposed to the selective salted environment at the screening/brining operations through the packaging/labeling operation prior to freezing. The hazard should more accurately be reflected as pathogens in general, rather than Staphylococcus and Listeria, unless Vibrio, E. coli, Salmonella, Etc., can be specifically ruled out.

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). Your firm's HACCP plan for frozen, ready-to-eat, salmon caviar, packaged in rigid plastic containers with snap-on lids, lists a monitoring frequency of "██████" at the curing/packing critical control point that is not adequate to control the pathogens hazard. It is recommended that continuous monitoring with a time/temperature data logger or other continuous time/temperature recording mechanism be used for ready-to-eat products processed under refrigeration; and that a visual check of the monitoring instrument is made at least once per day.
3. 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 frozen, ready-to-eat salmon caviar, packaged in rigid plastic containers with snap-on-lids, at the curing/packing critical control point to control the pathogen hazard is not complete. You do not include in your plan what you will do to prevent the deviation from reoccurring.
4. You must maintain sanitation control records, that at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). Your firm did not maintain sanitation monitoring records for six of the eight areas of sanitation required for processing of your ready-to-eat product.

Labeling:

We reviewed the salmon caviar label that the FDA investigator collected during the inspection of your firm. Our review reveals that this label causes the product to be in violation of Section 403 of the Act, and Title 21, Code of Federal Regulations (21 CFR), Part 101 - Food Labeling. The product is misbranded in that it fails to bear nutritional labeling as required under Section 403(q)(1) of the Act, and 21 CFR 101.9, and is not exempt under Section 403(q)(5) from this requirement, and has been labeled on or after August 8, 1994.

Lindsey C. Babich, President  
Trader Bay, LTD, Seattle, WA  
Re: Warning Letter SEA 03-09  
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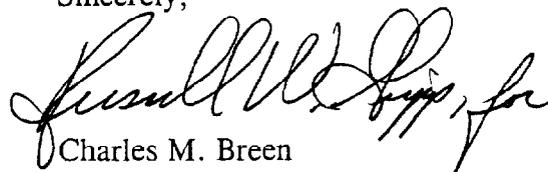
During the inspection you indicated that all salmon caviar (Ikura) is exported, however, you do not label your product "For Export Only". Exported products may be exempt from 21 CFR 123 provided the requirements for 801(e) of the Federal Food, Drug and Cosmetic Act are met. In addition, nutritional labeling requirements may not be necessary if all products are exported and appropriately labeled "For Export Only".

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 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 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 23<sup>rd</sup> Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Ms. Elrand at (425) 483-4913.

Sincerely,



Charles M. Breen  
District Director

Enclosures:  
Form FDA 483

cc: WSDA with disclosure statement