



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
New England District

g4468d

One Montvale Avenue  
Stoneham, Massachusetts 02180  
(781) 596-7700  
FAX: (781) 596-7896

December 16, 2003

WARNING LETTER

NWE-11-04W

**FEDERAL EXPRESS**

Kameron Shabazzi, Owner  
The Food Shop Inc.  
dba Gourmet Exchange  
70 New Market Square  
Boston, Massachusetts 02118

Dear Mr. Shabazzi:

On September 18-22, 2003, we inspected your seafood processing facility located at 70 New Market Square, Boston, Massachusetts. We found that you have serious deviations from the Seafood Hazard Analysis Critical Control Point (HACCP) regulation, 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 repacked caviar, labeled as "Caviar Shop," 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 may find this Act and the Seafood HACCP regulation though links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

- 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). However, your firm did not conduct a hazard analysis, and did not have a HACCP plan for caviar to control the food safety hazard of pathogens.
- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the eight areas of sanitation required by the regulation.

In addition, based on observations we made during the inspection and a review of your labels, your repacked caviar is also misbranded based on the following violations:

- Your repacked caviar, labeled as "Caviar Shop" is misbranded within the meaning of Section 403(i)(1) of the Act (21 U.S.C. § 343(i)(1)) in that it fails to bear the common or usual name of the food. Caviar, such as yours, prepared from the roe of other fish, i.e., salmon or paddlefish, should be labeled to show the name of the fish from which it is prepared; for example, salmon caviar.
- Your repacked caviar is also misbranded within the meaning of Section 403(i)(2) of the Act (21 U.S.C. § 343(i)(2)) in that the labels fail to bear an ingredient statement. In the case where a food is fabricated from two or more ingredients, the common or usual name of each ingredient shall be declared in the ingredient statement (21 CFR 101.4). Although the containers of some of the bulk caviar used to prepare your repacked caviar list salt as an ingredient, your containers fail to list salt as an ingredient.

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 operation.

Please respond in writing within fifteen working (15) days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as a completed HACCP plan, or other useful information that would assist 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 Regulation and the Current Good Manufacturing Practice regulation (21 CFR

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Please send your reply to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issues in this letter, please contact Mr. Ota at (781) 596-7762.

Sincerely,



*for* Gail T. Costello  
District Director  
New England District