



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g1790d

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 2953566

September 24, 2001

Barry H. Katcher, President  
Caviar Royale, Inc.  
2965 Industrial Road  
Las Vegas, NV 89109

**WARNING LETTER**

Dear Mr. Katcher:

On August 28, 2001, we inspected your seafood processing facility and found that you have a serious deviation from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). This deviation causes your caviar products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the products have been prepared, packed, and held under insanitary conditions whereby they may be rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov). See attached handout which gives a brief overview of the Seafood HACCP regulations.

The HACCP deviation is, as follows:

Your firm has no written HACCP plan to control pathogen growth, at the receiving and finished product storage steps, for your refrigerated caviar products.

We observed a similar deviation with your smoked fish products during the previous inspection of your facility on June 11, 1998. On June 20, 1998, we notified you that you needed a HACCP plan for smoked fish to address, at a minimum, *Clostridium botulinum* growth at the cooler storage step and that you needed to maintain cooler temperature records. In addition, we informed you that you needed to assess if critical control points are necessary at receiving and distribution.

At the conclusion of the inspection, the deviation was listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the

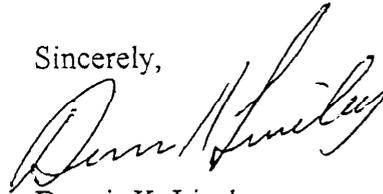
Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct the deviation. You may wish to include in your response documentation such as copies of the HACCP plans, temperature 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.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Dennis K. Linsley  
District Director  
San Francisco District

Enclosure:

Form FDA 483  
Reducing Hazards with HACCP