



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127 JEP

February 21, 2002

VIA FEDERAL EXPRESS

Kenneth D. Linsman, Owner
North American Caviar Company
78 Barnhill Lane
Paris, TN 38242

Warning Letter No. 02-NSV-15

Dear Mr. Linsman:

We inspected your firm, located at 78 Barnhill Lane, Paris, TN, on January 8 - 10, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fish roe to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- Failure to have and implement a written HACCP plan to control the hazards associated with processed roe manufactured and received by your firm, as required by **21 CFR 123.6(b)**.
- You must adequately monitor and document sanitation conditions, practices and corrections during processing, to comply with **21 CFR 123.11(b) and (c)**. Your sanitation records do not indicate the time the sanitation checks are performed and the person conducting the check is not identified. In addition, your firm did not adequately monitor possible routes of cross-contamination and the protection of food and food contact surfaces from adulteration as evidenced by:
 1. Non-food grade fiberglass screen was used to drain roe.
 2. Employee was not washing and sanitizing hands after handling insanitary objects and then mixing roe.
 3. Employees were not wearing hair and beard restraints.
 4. Finished product containers were stored on a rusty shelf without further washing and sanitizing.

We acknowledge that you submitted a response, dated January 14, 2002, concerning our investigator's observations noted on the Form FDA 483. We have reviewed your response and have the following comments:

The HACCP plan that you submitted to control the hazards of chemicals and *Clostridium botulinum* in processed roe manufactured and received by your firm is not adequate. The problems found in your

response indicate that you may need to seek help from an outside expert who is qualified in seafood HACCP. For instance,

- Finished product storage has not been identified as a critical control point to control *C. botulinum*.
- The critical limits are inadequate to control *C. botulinum* at the processing and receiving critical control points.
- The critical limit is inadequate to control chemicals at the receiving critical control point.
- The monitoring procedures are inadequate to control *C. botulinum* at the receiving critical control point.
- The corrective actions listed in your HACCP plan are inadequate to control *C. botulinum* at the processing and receiving critical control points.
- The corrective actions listed in your HACCP plan are inadequate to control chemicals at the receiving critical control points.
- The verification procedures listed in your HACCP plan are inadequate to control *C. botulinum* at the processing and receiving critical control points.

We also noted that your bulk roe labeling does not have a refrigeration statement or include a statement of identity. Processed roe with less than 20% water phase salt, packaged in reduced oxygen packaging must be labeled with a statement such as, "IMPORTANT Must Be Kept Refrigerated To Maintain Safety".

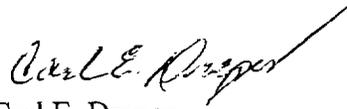
This letter may not list all the deviations at your firm. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, the Current Good Manufacturing Practice regulations (21 CFR 110), and labeling regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations. You will find the regulations and guidance documents at <http://www.cfsan.fda.gov/~dms/flg-toc.html> and <http://www.cfsan.fda.gov/~lrd/fr970224.html>.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the steps you have taken to correct the violations. For corrections that you cannot complete within the fifteen (15) working days, state the reason for the delay and your timeframe for completion. We also ask that you provide documentation of the corrections as they are made, including copies of any revised labels, and that you explain your plan for preventing these violations in the future.

Please send your reply to the Food and Drug Administration, Attention: Karen Gale Sego, Compliance Officer, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,



Carl E. Draper
Director, New Orleans District

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