



DEPARTMENT OF HEALTH & HUMAN SERVICES

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2002-DT-20

January 22, 2002

Mr. Michael J. Hermes, President/Vice-President
Mr. James P. Hermes, Secretary/Treasurer
Big Bay De Noc Fisheries, Inc.
Vans Harbor Road
Garden, MI 49835

Dear Messrs. Hermes:

On August 27th – 28th, 2001 the Food and Drug Administration (FDA) conducted an inspection of your facility located at Vans Harbor Road, Garden, MI. The inspection was conducted to determine compliance with the FDA's Seafood Hazard Analysis Critical Control Point (HACCP) Regulation (21 CFR 123) and the current Good Manufacturing Practice requirements for foods (GMP) (21 CFR 110).

During the inspection, the FDA investigator observed shortcomings in your system that are serious deviations from the principles of HACCP and the significant requirements of the program. These deviations, some of which were previously brought to your attention, cause your whitefish roe and chub roe products to be in violation of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's homepage www.fda.gov.

These deviations were as follows:

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for whitefish roe and chub roe lists a critical limit, maximum water phase salt, at the brining critical control point that is not adequate to control the food safety hazard of Clostridium botulinum toxin formation. In order to control Clostridium botulinum toxin formation at the brining step you must ensure a minimum water phase salt of 5%.

Messrs. Hermes
Big Bay De Noc Fisheries, Inc.

January 22, 2002
Page 2

You should be aware that if your roe products are immediately frozen after processing, maintained frozen throughout distribution, and labeled "Important, keep frozen until used, thaw under refrigeration immediately before use," formation of Clostridium botulinum toxin may not be a significant hazard. Please refer to Chapter 13 in the FDA Fish & Fisheries Products Hazards & Controls Guidance, Third Edition, June 2001.

2. You are required to have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). However, you failed to maintain sanitation control records for all 8 required sanitation steps with a sufficient frequency. For example, the last available "Daily Sanitation Audit Form" was dated 9/27/99 and only half of the listed "sanitation conditions" had been monitored.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Also, please include copies of any available documentation demonstrating that corrections have been made.

Your written reply should be directed to David M. Kaszubski, Director Compliance Branch, U.S. Food and Drug Administration, 1560 E. Jefferson, Detroit, MI 48207, telephone (313) 226-6260 ext. 185.

Sincerely,


Joann M. Givens
District Director

Detroit District