



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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-17

December 17, 2001

Mr. Carl L. Frazier, Co-Owner
Mr. Donald R. Frazier Co-Owner
Carl & Don Frazier, Inc.
Corner of Arbor St. & Main St.
Naubinway, MI 49762

Dear Messrs Frazier:

On August 29th – 30th, 2001 the Food and Drug Administration (FDA) conducted an inspection of your facility located at Corner of Arbor St. & Main St., Naubinway, 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 hot-smoked whitefish, trout, and whitefish sausage 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 to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for hot-smoked whitefish, trout and whitefish sausage to control the food safety hazard of pathogen growth.

2. You must adequately monitor sanitation conditions and practices, to comply with 21 CFR 123.11(b). However, during the investigation the following sanitation deficiencies were noted:
 - Failure to protect food, food packaging material, and food contact surfaces from adulteration with chemical, physical, and biological contaminants as evidenced by an open container of trout fillets being stored under a ceiling with flaking paint.
 - Failure to maintain sanitary conditions and cleanliness of food contact surfaces as evidenced by deep cuts and grooves with embedded dark brown residues on the firm's plastic cutting boards and knife storage rack.
3. You are required to have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). However, your sanitation control records do not document the monitoring of water safety; condition and cleanliness of food contact surfaces; prevention of cross-contamination; protection of food, food packaging material and food contact surfaces from adulterants/contaminants; proper labeling, storage and use of toxic compounds; and exclusion of pests from the processing facility.

The failure to monitor and document sanitation conditions is of particular concern since you produce ready-to-eat products.

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.

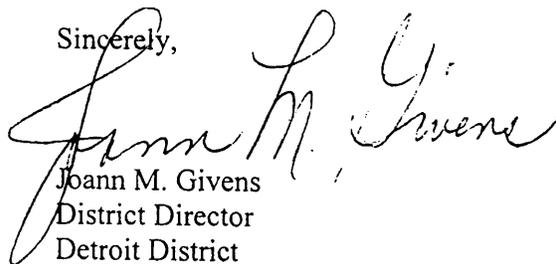
Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. If corrections cannot be completed within 15 working days, state 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.

Messrs. Frazier
Carl & Don Frazier, Inc.

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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