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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
2000-DT-07

January 14, 2000

Donald P. McFarling, President
McFarling Foods, Inc.
333 West 14th St.
Indianapolis, IN 46241

Dear Mr. McFarling:

On July 23, 26, and 30, 1999, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 333 West 14th St. in Indianapolis, IN. 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's) (21 CFR 110).

During the inspection, the FDA investigators observed shortcomings in your system that are deviations from the principles of HACCP and the significant requirements of the program. The FDA investigators presented your firm with a form FDA-483 which provides the investigators' evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. We have reviewed your letter of September 27, 1999 and the enclosed HACCP plan. In spite of some of the corrections you have made, we still find, however, that your firm is in violation of 21 CFR 123 and 110 causing your products to be deemed adulterated under the provisions of 21 USC 342(a)(4) because of the following:

1. You must have a HACCP plan that lists the critical limits that must be met in order to comply with 21CFR 123.6(c)(3). However, your firm's HACCP plan for fresh tuna and mahi mahi lists a critical limit at the receiving critical control point that is not adequate to control histamine formation. The critical limit requiring that [REDACTED] does not provide adequate assurance that the product was maintained at adequate temperatures during transport to your facility. Secondary processors of these products should check for adequacy of cooling media at the time of delivery or obtain documentation of continuous monitoring during transport of each shipment.

2. You must have a HACCP plan that lists the critical limits that must be met in order to comply with 21CFR 123.6(c)(3). However, your firm's HACCP plan for fresh tuna and mahi mahi lists a critical limit at the cooler storage critical control point that is not adequate to control histamine formation. The critical limit allows cooler temperatures to reach up to [REDACTED] for up to [REDACTED] hours a day. Fish that has not previously been frozen should not be exposed to temperatures above 40 F for more than four hours **cumulatively**, but not on a daily basis as permitted in your plan.
3. You must have a HACCP plan that lists the critical limits that must be met in order to comply with 21CFR 123.6(c)(3). However, your firm's HACCP plan for live oysters and clams lists a critical limit at the receiving critical control point that is not adequate to control the growth of pathogens. Since oysters and clams may be consumed raw without further processing, pathogen growth must be minimized. The critical limit, i.e., "must have [REDACTED] temperature", does not specify if the requirement is a minimum or maximum allowable temperature, nor is it specific to product or ambient temperatures in the transport container, nor does it provide adequate assurance that the product was maintained at adequate temperatures **during** transport to your facility. Your receiving critical limits should address temperature maintenance during the duration of transport, not just at the time of receipt. Secondary processors of these products should check for adequacy of ice or cooling media at the time of delivery or obtain documentation of continuous monitoring during transport of each shipment.
4. You must have a HACCP plan that lists monitoring procedures for each critical control point in order to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for live oysters and clams lists monitoring procedures at the receiving critical control point that are not adequate to control pathogen growth. The monitoring for harvester tags will not give assurance of proper temperature maintenance during transport. Monitoring each shipment for transportation records showing that the shellfish were held at appropriate temperatures throughout transport is recommended.
5. In the case of refrigerated products, you must retain records at the processing facility for at least one year after the date they were prepared in order to comply with 21 CFR 123.9(b)(1). However, your firm did not retain cooler storage monitoring records for refrigerated seafood products held at your facility for the period from 3/3/99 to 7/13/99 (excepting the period from 4/8-15/99) for the required length of time.

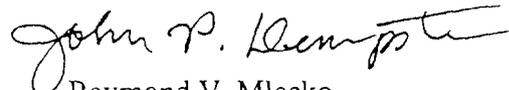
The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

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 Mr. Dennis P. Degan, Compliance Officer, U.S. Food and Drug Administration, 1560 E. Jefferson, Detroit, MI 48207, telephone 313-226-6260 x 135. If you need further assistance, all technical questions should be directed to either Nicholas L. Majerus, Shellfish Specialist at extension 107 or Sally S. Eberhard, Seafood Monitor at extension 109.

Sincerely,



Raymond V. Mlecko,
District Director
Detroit District

cc: Michael U. McFarling
Executive Vice President
and Chief Operating Officer
McFarling Foods, Inc.
333 West 14th Street
Indianapolis, Indiana 46241