DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
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September 10, 2004

WARNING LETTER NO. 2004-NOL-35

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Aubrey Ray Hopkins, President
Mississippi Seafood Exchange, Inc.
795 East McDowell Road
Jackson, Mississippi 39204

Dear Mr. Hopkins:

On July 7, 8 and 19, 2004, a United States Food and Drug Administration (FDA) investigator inspected your seafood processing facility, located at 795 East McDowell Road, Jackson, Mississippi. We found you have serious deviations from the Seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your fresh, refrigerated tuna is adulterated, as the tuna has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's Internet home page at http://www.fda.gov.

The deviations observed during the FDA inspection and of concern to us are as follows:

- You must implement the record keeping system you listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the receiving, processing, and storage critical control points to control scombrotoxin (histamine) formation listed in your HACCP plan for fresh fish products produced from histamine-producing fish species.

- You must conduct a hazard analysis to determine whether there are food safety hazards reasonably likely to occur and have a HACCP plan listing, at minimum, the critical control points to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for fresh fish products produced

from histamine-producing fish species does not list the critical control point of distribution for controlling the food safety hazard of histamine formation.

On July 8, 2004, during our inspection of your firm, the FDA investigator collected a sample of your fresh, refrigerated tuna. Analysis of the sample by the FDA Southeast Regional Laboratory (SRL) found 155 to 420 parts per million (ppm) histamine. You may have received a letter from SRL notifying you of these analytical results. SRL also analyzed a sample of tuna collected by the Mississippi State Health Department Laboratory (MSHDL) from a [redacted] restaurant. The MSHDL collected that sample during its follow-up of a consumer complaint documenting circumstances surrounding an illness believed to be caused by consumption of tuna processed by your firm. Analysis of the MSHDL sample found 502 to 901 ppm histamine. The FDA and MSHDL samples were from the same fresh tuna. The presence of histamines causes your fresh tuna product to be in violation of Section 402(a)(1) and (3) of the Act, 21 U.S.C. § 342(a)(1) and (3).

Histamine is a chemical which may cause serious illness at levels as low as 200 ppm and is commonly the result of spoilage of fish due to temperature abuse. Fish processors should take all precautions necessary to reduce the risk of development of histamine. This can be achieved by creating and following a HACCP plan and maintaining temperature monitoring records to show the temperature of the fish is being controlled. We strongly recommend you take corrective action as soon as possible.

This letter may not list all the deviations at your facility. You are responsible for ensuring your processing plant operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations, 21 CFR 110. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

The observed deviations were brought to your attention during the discussion of the FDA Form 483 issued to you on July 19, 2004. We may take further action if you do not correct these violations promptly. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

We are aware you made a verbal commitment to correct the observed deficiencies during the inspection. However, you must respond in writing, within 15 working days of the receipt of this letter, the steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as copies of receiving records, temperature monitoring records, thermometer calibration records, or other useful information to assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you to explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Cynthia R. Crocker, Compliance Officer, 100 W. Capitol Street, Suite 340, Jackson, Mississippi 39269. If

you have questions regarding any issue in this letter, please contact Ms. Crocker at (601) 965-4581, extension 106.

Sincerely,

H. Tyler Thornburg
District Director
New Orleans District

Enclosure: Form FDA 483