



DEPARTMENT OF HEALTH & HUMAN SERVICES

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA INT'L FEDERAL EXPRESS

September 14, 2001

Our Reference: 2954515

Joseph F. Fang, President
United Fisheries Corporation
1052 Cabras Highway
Guam United Warehouse
Piti, Guam 96925

WARNING LETTER

Dear Mr. Fang:

We inspected your seafood processing facility on April 9, 10, 11, 13, 17, and 18, 2001. We conducted this inspection to determine your compliance with FDA's Seafood HACCP regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deviations. These deviations cause your refrigerated vacuum packed and/or modified atmosphere packed swordfish, chilled tuna and marlin, and ready-to-eat dried tuna and marlin jerky to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed some of the deficiencies on a Form FDA 483 and discussed them with Mr. Douglas W. Stock, Managing Director, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your reference. Your serious HACCP deviations are as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for refrigerated vacuum packed **Swordfish** to control the food safety hazard of *Clostridium botulinum* toxin formation.
2. You must have a written HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for

Scombroid Fish does not list the critical control point (CCP) of Distribution for controlling the food safety hazard of *Clostridium botulinum* toxin formation as a result of time/temperature abuse during the transportation, retail storage and sale of refrigerated vacuum packed tuna and marlin. There are different ways to ensure prevention of toxin formation during distribution. One way recommended by FDA is that time/temperature integrators, with clear instructions for their interpretation, are placed on each consumer package.

3. You must have a HACCP plan that lists the critical limits that must be met, to comply with 123.6(c)(3).
 - a) However, your firm's HACCP plan for **Tuna/Marlin Jerky** lists a critical limit at the Receiving CCP that is not adequate to control histamine formation as a result of time/temperature abuse in fish received directly from the harvester. The critical limits do not include histamine testing or harvest vessel records and they do not establish an acceptable maximum limit of decomposed fish determined by sensory testing. Inclusion of the receiving critical limits added to your Scombroid Toxin HACCP plan, in your May 1, 2001 response to FDA will improve the Tuna/Marlin Jerky plan.
4. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for **Tuna/Marlin Jerky** lists:
 - a) Monitoring procedures at the Thawing and Marinating critical control points that are not adequate to control histamine formation. The Plan calls for monitoring air temperatures while the critical limits are based on product temperatures. In fact, FDA recommends the control of ambient air temperatures at 40°F or below during processing steps to prevent histamine formation (see page 90 of FDA's Fish & Fisheries Products Hazards & Controls Guidance, 3rd Edition). Modification of your critical limit from product temperature to air temperature will correct this deficiency.
 - b) Monitoring frequencies at the Thawing and Marinating CCPs that are not adequate to control histamine formation. "Daily" monitoring is not specific enough to ensure that the marinating fish are not permitted to exceed 40°F or that the air temperature exposures do not exceed 40°F.
5. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not have records to document

sensory examination of chilled tuna and marlin at the Receiving CCP to control the hazard of histamine formation listed in your Scombroid Toxin HACCP plan.

We may take further regulatory action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union countries if you do not correct these deviations.

We acknowledge Mr. Stock's response of May 1, 2001 (via facsimile) to the inspectional observations presented to him (on a form FDA 483) at the close of the inspection. We have noted your corrections and will verify them during the next inspection of your facility. There are, however, other HACCP deviations that need to be addressed, and we expect that you will quickly correct them.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response documentation such as time/temperature monitoring records, sanitation records, revised HACCP plans, etc. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice 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.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,



Darrell T. Lee
Acting District Director
San Francisco District