



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M 30127

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

VIA FEDERAL EXPRESS

September 27, 1999

Our Reference: 2951533

Charles A. Higa, President
Zippy's Inc.
1765 South King Street
Honolulu, Hawaii 96826

WARNING LETTER

Dear Mr. Higa:

On May 8 and 10, 1999, we inspected your seafood processing facility, Zippy's, Inc., doing business as Fresh Fish Hawaii, located at 1808 Republican Street, Honolulu, Hawaii. We conducted this inspection to determine compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deficiencies. The deficiencies cause your histamine-forming fishery products 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 has been prepared, packed, or held under insanitary conditions whereby they may be rendered injurious to health. We listed the HACCP deficiencies on a Form FDA 483 and discussed them with Mr. Garrett A. Kato, General Manager, at the conclusion of the inspection. Attached is a copy of the Form FDA 483 for your reference. Your serious HACCP violations are as follows:

1. You must take corrective action when a deviation from a critical limit occurs [21 CFR 123.7(a)]. However, between October 1, 1998 and May 1, 1999, on at least thirty-five (35) different occasions, you received fish with internal temperatures ranging from 41°F to 52°F. The critical limit specified in your firm's HACCP plan for the receiving critical control point (CCP) is not to exceed 40°F for the internal temperature of fish.

2. You must have a HACCP plan that lists the necessary critical control points [21 CFR 123.6(b) and (c)(2)]. However, your firm's HACCP plan for histamine-forming fish species does not list the critical control point of processing for controlling the food safety hazard of histamine formation. During the inspection, we observed that fresh fish including tuna, marlin, mahimahi, and opah were held in the processing room for at least three hours without ice. We observed internal fish temperatures in tuna and mahimahi of 42-44°F and 43-44°F, respectively.

3. You must implement the monitoring procedures and frequencies listed in your HACCP plan [21 CFR 123.6(c)(7)]. Your HACCP plan for histamine-forming fish species lists monitoring procedures for recording internal fish temperatures at receiving, for controlling the food safety hazard of histamine formation. However, you are not following the monitoring procedures. We found that you were missing monitoring records for the following dates: October 18-26, 1998; December 11-12, 1998; January 9-17, 1999; January 20-26, 1999; January 28-February 16, 1999; February 18-23, 1999; March 11-14, 1999; April 7-17, 1999; and April 17-19, 1999.

4. You must describe appropriate corrective actions in any corrective action plan that you choose to list in your HACCP plan in order to comply with 21 CFR 123.7(b). However, your corrective action listed for the cold storage critical control point relies solely on sensory analysis to determine the acceptability of the fish. Sensory examination is not a reliable method for the detection of histamine.

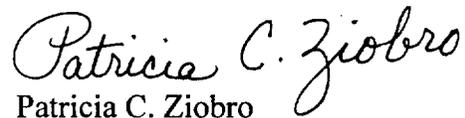
During our current inspection, we performed organoleptic examinations on all of the fish species held in the processing room. We found odors indicative of decomposition on the lots of swordfish, tombo tuna, and mahimahi. We collected and tested samples of these lots. Our analysis confirmed the presence of decomposition in each of the fish species sampled. You voluntarily destroyed the decomposed fish during the inspection. Fish is adulterated within the meaning of Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act, if it is entirely or partially decomposed. Your products must not be adulterated and they must be manufactured under Current Good Manufacturing Practices.

At the end of the previous inspection, we discussed our inspectional observations which we listed on Form FDA 483, with Ms Michelle M. Chang, Plant Manager, who verbally promised to correct the problems. We also sent a letter, dated September 22, 1998, to Ms Eileen T. Abe, Vice President of Operations, outlining your firm's violations. However, we did not receive any response from your firm. Our recent inspection shows that your firm did not correct the HACCP deficiencies that we cited in our previous letter.

You must immediately take appropriate steps to correct the violations at your facility. We may initiate regulatory action without further notice if you do not correct these problems. Regulatory action may include seizure and/or injunction.

Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Additionally, your reply should include the steps that you have taken to preclude distribution of decomposed fish. Direct your response to Ms Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795; FAX: 510-337-6707).

Sincerely,



Patricia C. Ziobro

Director

San Francisco District

Attachment

cc VIA FEDERAL EXPRESS

Garrett A. Kato, General Manager
Zippy's, Inc. dba Fresh Fish Hawaii
1808 Republican Street
Honolulu, Hawaii 96819
Phone No. (808) 842-6188