



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region g1358d

Telephone (973) 526-6005

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

May 31, 2001

WARNING LETTER

CERTIFIED MAIL-  
RETURN RECEIPT REQUESTED

Mr. Ron Smith  
Owner  
Ron Smith Seafood Inc.  
1889 Route 9 Unit 41  
Toms River, NJ 08755

File # 01-NWJ-25

Dear Mr. Smith,

We inspected your firm, located at 1889 Route 9 Unit 41 in Toms River, New Jersey, on May 8, 2001, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh Tuna and Mahi-Mahi to be in violation of section 402(a)(4) of the Federal Food Drug and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The following are repeat violations and were previously brought to your attention in an Untitled Letter sent to you on August 10, 1999.

1. The monitoring procedure for recording the temperature in your cooler/processing room is not followed. This procedure is listed as a critical control point in your HACCP plan for processing all histamine producing fish such as your Tuna and Mahi-Mahi. For example, the temperature in the cooler/processing room was not recorded for the time periods 12/1/00 through 12/8/00, 4/2/01 through 4/10/01 or from 5/1/01 through 5/8/01. You must follow your monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(c)(7).

2. The temperature of all incoming histamine producing fish was not monitored and recorded upon receipt by your firm. This procedure is listed as a critical control point in your HACCP plan for histamine producing fish. For example, there was no record of the amount of visual ice or the internal temperature of the Tuna received by your firm on April 26, 2001.
3. There was no documentation to show that calibration of process monitoring equipment such as thermometers was performed even though your HACCP plan for histamine producing fish states thermometers will be calibrated on a weekly basis. Additionally, the temperature monitoring logs for the cooler/processor room as well as for the receipt of Scombroid species fish are not reviewed by management.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of monitoring records or other useful information that would assist us in evaluating your corrections. If you can not complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

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 (21 CFR Part 110). 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, Attn: Joseph F. McGinnis R.Ph, Compliance Officer, at the address and telephone number listed above.

Sincerely,



Douglas I. Ellsworth  
District Director  
New Jersey District