



VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Our Reference: FEI 3000719304

October 5, 2004

Sebastiano Galletti, President  
Southwind Foods, LLC  
2900 Ayers Avenue  
Los Angeles, California 90023

**WARNING LETTER**

Dear Mr. Galletti:

On May 17, 18, and 19, 2004, we inspected your seafood processing facility, Southwind Foods, LLC, located at 3840-A North Civic Center Drive, North Las Vegas, Nevada. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulation, 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 whenever a HACCP plan is necessary, or to 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 refrigerated histamine forming fish, e.g., tuna, mackerel, Mahi Mahi, your refrigerated, ready-to-eat fish and fishery products, e.g., pasteurized crab meat in hermetically sealed containers, herring products, and vacuum packaged smoked salmon are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation, and the Food and Drug Administration's (FDA) Fish & Fisheries Products Hazards & Controls Guidance, 3<sup>rd</sup> edition, June 2001, through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

We listed the deviations on a Form FDA 483 and discussed them with Timothy L. Waldron, General Manager, at the conclusion of the inspection. We are enclosing a copy of the Form FDA 483 for your reference. Your serious deviations were as follows:

1. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as “the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard. However, your firm’s HACCP plan for Cooked, ready-to-eat products, fresh, smoked vacuum packed, RTE, lists a critical limit, “Product to be received at not higher than 40°F,” at the Receiving critical control point, which is not adequate to control pathogen growth and toxin formation in refrigerated products that have been transported over four hours. FDA recommends that:
  - All lots that you receive be accompanied by records that show continuous monitoring in the truck to ensure temperatures were at, or below 40°F, throughout transport; or
  - For products held under ice or cooling media, monitoring for an adequate quantity of ice or other cooling media, on a representative number of containers at the time of delivery.
2. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However,
  - (a) Your firm’s HACCP plan for “Tuna, Mackerel, Mahi-mahi, Yellowtail...All histamine producing finfish” lists a monitoring frequency, “Minimum 1 day” at the Refrigerated Storage critical control point that is not adequate to control histamine formation. For refrigerated storage of scombroid species, FDA recommends continuous monitoring of product temperatures by either maintenance of storage coolers at 40°F or less, or by visually monitoring the adequacy of ice or cooling media on your fish at least twice a day.
  - (b) Your firm’s HACCP plan for “Cooked, ready-to-eat products, fresh, smoked vacuum packed RTE” lists a monitoring procedure, “thermometer verify delivery truck temp.” at the Receiving critical control point that is not adequate to control pathogen growth and toxin formation in product transported over four hours. FDA recommends monitoring internal product temperatures of a representative sample upon receipt as an appropriate control for refrigerated products transported less than four hours.

- (c) Your firm's HACCP plan for "Cooked, ready-to-eat products, fresh, smoked vacuum packed RTE" lists a monitoring frequency of "██████" at the Storage critical control point that is not adequate to control pathogen growth and toxin formation. FDA recommends that temperatures be monitored continuously.

In addition, our investigator observed that your firm uses a █████-hour alarm system that is set at 45°F for the cooler. You should correct your plan to indicate your use and implementation of this system. However, the temperature that the alarm is set to should be adjusted to reflect your critical limit, █████°F, which is appropriate to control the hazard. Once you have made changes to your HACCP plan, as indicated in items 1 and 2(b) above, you must implement the monitoring and recordkeeping system as listed.

3. You must maintain sanitation control records that, at a minimum, document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm does not have records to ensure control of key sanitation areas related to:
- (a) Maintenance of hand washing, hand sanitizing, and toilet facilities;
  - (b) Proper labeling, storage, and use of toxic compounds;
  - (c) Control of employee health conditions; and,
  - (d) Exclusion of pests from the food plant.

You must immediately take appropriate steps to correct the violations. We may take further action if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

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 deviations. You may wish to include in your response documentation such as copies of your revised HACCP plans, HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot 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 regulation, and the Current Good Manufacturing Practices (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.

Your response should be directed to: Ms. Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

A handwritten signature in black ink, appearing to read "Barbara J. Cassens". The signature is fluid and cursive, with a large initial "B" and "C".

Barbara J. Cassens  
District Director  
San Francisco District

Enclosure

cc: Ernest Y. Doizaki, Chief Executive Officer