



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

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60 8th Street, N.E.
Atlanta, Georgia 30309

December 6, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Al Rowland, President
Winn Dixie Stores, Inc.
Box B
Jacksonville, FL 32703-02997

Warning Letter
02-ATL-11

Dear Mr. Rowland:

On July 30 - 31, 2001, an investigator from the Food and Drug Administration (FDA), Richard L. Garcia, conducted an inspection of your distribution center located at 2425 Nevada Boulevard, Charlotte, North Carolina. During that inspection, our investigator documented deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your fresh histamine-producing fish 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.

The HACCP deviations of concern are as follows:

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your HACCP plan
 - a. Does not list a critical limit at the "product receiving" critical control point to control the hazards of Pathogens from Harvest Area associated with molluscan shellfish. Chapter 4 (copy attached) of the Fish & Fisheries Products Hazards & Controls Guidance: Third Edition can provide guidance in determining the most appropriate method of control for the live molluscan shellfish you receive.
 - b. Lists a critical limit, "Refrigerated storage maintained $< 41 \pm 1.5^{\circ}\text{F}$," that is inadequate to control the hazard of histamine formation in scombroid fish at the "Refrigerated Storage" critical control point (CCP2). Critical limits must be absolute values, not approximations. Your plan's current critical limit potentially allows unfrozen scombroid fish to be stored at temperatures as high as 42.4°F . Any

exposure time above 40°F can contribute to conditions favorable for histamine formation. FDA recommends 40°F or less as an acceptable storage critical limit.

- c. Lists a critical limit, "Product temperature $< 41 \pm 1.5^\circ\text{F}$ at time of delivery," that is inadequate to control the hazard of histamine formation in scombroid fish and Pathogen Growth in Ready to Eat Seafood (Live Molluscan Shellfish) at the "Product Receiving" critical control point (CCP1). FDA does not consider individual internal temperatures an appropriate method of monitoring the conditions that a lot has been exposed to during shipment. FDA recommends requiring and reviewing transportation records showing that the fish were held at adequate temperatures (40°F or less in case of scombroid fish species) throughout shipment or making visual observations of the adequacy of ice or cooling media in a representative number of containers.

Note: Your firm has chosen to use a HACCP plan for all incoming seafood products, the critical limits listed in your plan must apply to all products. For example, your listed target hazards are histamine formation and pathogen growth. Since histamine formation occurs at lower temperatures than most pathogen growth, your critical limits at Receiving and Storage must be set to control histamine (40°F). If, during future investigations, we determine that you are receiving refrigerated vacuum packaged products, you would be required to set your critical limit for Receiving and Storage at a temperature that will control *Clostridium botulinum*, 38°F. It is in your best interest to develop HACCP plans that target specific hazards. Fish that do not have those hazards would not be subject to the critical limits.

2. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plans at CCP1 (Receiving) and CCP2 (Storage) to control histamine are not appropriate. You have listed that you will "Hold and evaluate seafood products." "Evaluate" is too vague a term, and does not specify measures that are adequate to determine the presence of histamine at objectionable concentrations. Histamine testing is the only recommended and reliable method of determining the presence of histamine concentrations of 50 ppm or higher. Products that have been exposed to abusive temperatures for periods of time exceeding FDA safety guidelines must either be rejected or tested for histamine.

Note: During our review of your records, we noted that the corrective action for CCP1 lists that warehouses will not accept products from suppliers that have not been verified for the HACCP program. You do not appear to have procedures or records in place at the warehouse facilities for personnel to make that determination. FDA does not currently consider it necessary for secondary processors to determine if U.S. processors or importers have HACCP plans since all U.S. seafood processors and importers are required to be operating in accordance with the U.S. Seafood HACCP regulation.

3. You must retain records at the warehouse facility for at least 1 year after the date they were prepared in the case of refrigerated products, to comply with 21 CFR 123.9(b)(1). However, your firm's monitoring records, which document the internal temperature of incoming refrigerated seafood (including scombroid fish) for the period between 7/30/00 and 7/30/01, were not available for FDA review. Similarly, your firm's sanitation control records for that period of time were not available for FDA review. All of your HACCP monitoring records must be available for review by FDA at reasonable times. This includes the Corporate Supplier Records you have chosen to list in your plan. Your current system of forwarding the monitoring records to a corporate office for review by a HACCP trained individual and maintaining listed monitoring records at that corporate office precludes your warehouse from meeting this requirement. In addition, when our investigator requested the necessary records from your corporate office (when they were unavailable at your warehouse), he was still unable to obtain them.

Note: You have chosen to use a standardized HACCP plan and standardized monitoring records for eleven different warehouses and all seafood products. Records from these different warehouses are forwarded from each warehouse to a single individual at your corporate office for review. The documents do not contain identifying addresses on the individual monitoring records to designate their point of origin. The North Carolina Department of Agriculture commented on the absence of identifying addresses or locations on the HACCP plan and records in their letter dated March 26, 1999. A response from your representative stated that you felt placing the warehouse addresses on a single separate page of the HACCP plan was sufficient and that no changes to your HACCP plan were necessary. After further evaluation of your record keeping and verification procedures, FDA recommends that you review this decision. 21 CFR 123.9(a)(1) requires processors to include their name and location on all records.

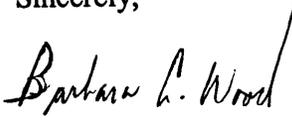
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

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 HACCP plans, and 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 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 Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,


for Ballard H. Graham, Director
Atlanta District

Attachment