



Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
FAX: 504-253-4520

July 10, 2001

WARNING LETTER NO. 2001-NOL-36

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. John A. Tesvich
President and Chief Executive Officer
AmeriPure Processing Company, Inc.
803 Willow Street
Franklin, Louisiana 70538

Dear Mr. Tesvich:

On May 23, 25, 31 & June 11, 2001, investigators with the U.S. Food and Drug Administration (FDA) conducted an inspection of your oyster processing facility, located at 803 Willow Street, Franklin, Louisiana, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations cause your processed oysters 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 deviations were as follows:

- You must take an appropriate corrective action when a deviation from a critical limit occurs to comply with 21 CFR 123.7(a). However, your firm did not take a corrective action to control the *Vibrio vulnificus* hazard when your processing records indicated that the process for oysters deviated from your critical limits at the heat process critical control point. Processing records for [REDACTED] total pasteurization cycles from October 16, 2000 to May 18, 2001, were reviewed and found to contain numerous deviations from the critical limits, such as: [REDACTED] cycles documented both process time and temperatures outside of the critical limits listed in your HACCP plan; [REDACTED] documented cycles were processed below the temperature critical limit; and, [REDACTED] documented cycles were processed in less time than the critical limit. There is no documentation that your firm took corrective action to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of these deviations and to ensure that the cause of the deviations were corrected.

Additionally, the cooler temperature monitoring records were reviewed for the time period, May 1 through 13, 2001, and compared with processing records for the same period. On one occasion, the shellstock storage cooler records indicated that the temperature exceeded the critical limit specified

in the HACCP plan during four consecutive readings. Again, there is no documentation that your firm took corrective action in this regard.

- You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.8(a). However, your firm did not adequately verify the adequacy of the critical limit of “submerged in water of a temperature of not less than [REDACTED] for not less than [REDACTED] for oysters at the heat process critical control point to control the hazard of *Vibrio vulnificus*. You provided the investigators with a study that concluded that an internal oyster temperature of [REDACTED] is sufficient to reduce *Vibrio vulnificus* to non-detectable levels. However, you have not verified that the critical limits for your heat process will consistently result in that internal temperature for that period of time when oysters are stacked in multiple layers in the heat process crate or tray.
- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor sanitation conditions and practices in a manner and with sufficient frequency to ensure compliance with the Current Good Manufacturing Practice regulations (21 CFR 110). Your firm’s HACCP sanitation monitoring records for May 23, 2001, were completed at 8:00 a.m. and did not accurately reflect processing room conditions during processing from 10:00 a.m. through 1:00 p.m., which are, in part, described below.

In addition, the investigators documented numerous insanitary conditions that cause your oyster product to be adulterated within the meaning of Section 402(a)(4) of the Act. They are adulterated because they have been prepared, packed, or held under conditions whereby they may become contaminated with filth.

- Water from the floor splashed on post-processed oysters and on food contact surfaces as processed oysters were transferred from the pasteurizer to the finished product cooler;
- A shovel was used to pack ice on processed oysters after the shovel had been used to collect ice from the floor of the ice cooler. An employee’s boots contacted the ice. The shovel was not observed to be washed or sanitized during the inspection;
- A dead fly was observed in a container of ice, and the ice was placed directly on the half gallon containers of shucked oysters;
- Plastic cooler curtains, extending to and touching the floor, routinely contacted processed oysters in trays and crates. The curtains were not observed to be washed or sanitized during the inspection;
- Employees working in the unprocessed oyster area routinely worked in the oyster processing area without sanitizing or washing their hands. They did not cover their street clothing, nor did they remove ornamental jewelry while working in the processing area. Their unprotected street clothing and jewelry contacted food contact surfaces and processed oysters; and,
- During the inspection, two dock doors remained open to the outside during processing. A live bird was observed in the processing area during post-process clean up.

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.

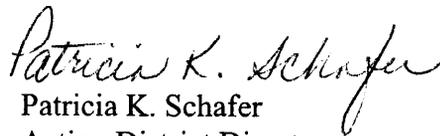
We are in receipt of your letter dated June 22, 2001, in response to the May - June 2001 inspection. We considered your response in preparing this letter. FDA will provide further response to your letter at a later date.

Please respond in writing within three (3) weeks from 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 copy of your HACCP plan 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 Current Good Manufacturing Practice regulations (21 CFR 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 Patricia K. Schafer, Compliance Branch Director, at the above address.

Sincerely,



Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483