



DEPARTMENT OF HEALTH & HUMAN SERVICES

VIA FEDERAL EXPRESS

Our Reference: 2952538

January 6, 2003

David A. Noland, President
Mercer Processing, Inc.
1836 Lapham Drive
Modesto, California 95354-3900

WARNING LETTER

Dear Mr. Noland:

On August 26 and 27, 2002, we inspected your seafood processing facility located at 1836 Lapham Drive, Modesto, California and found that you have serious deviations from the seafood HACCP regulations in 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 or 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). Accordingly, your freeze-dried seafood products are adulterated within the meaning of Section 402(a)(4) of the Act in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

Your serious HACCP deviations are as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for the shrimp freeze-dried by your firm to control the hazard of undeclared sulfite inclusion. The document you supplied to our investigator failed to list this hazard and did not include the necessary elements of a HACCP plan.

Your HACCP plan must include critical control points, which are the steps in your process where hazard(s) can be reduced to an acceptable level; the necessary critical limits; the specific monitoring procedures used to ensure that your critical limits are not exceeded; the records used to record your observations; and the verification

procedures you will use to ensure that your HACCP process will result in a safe product. The Fish and Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001, can provide you with guidance in determining what hazards are associated with your products and examples of controls that FDA considers sufficient. In addition, the guidance outlines the specific information we would expect you to include in your HACCP plan and the necessary records we would expect you to maintain. The attached handout provides information on how to obtain the guidance, which is also available electronically through links in FDA's home page at www.fda.gov.

In addition to the freeze-dried shrimp you process, you must conduct hazard analyses for all of the seafood products processed by your firm, determine if hazards are associated with those products, and maintain HACCP plans addressing those hazards.

2. 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 did not maintain sanitation monitoring records for the necessary areas of sanitation required for the processing of freeze-dried seafood. The required areas for which you are missing necessary records are as follows:

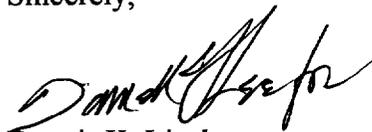
- Condition and cleanliness of food-contact surfaces
- Prevention of cross-contamination
- Maintenance of hand-washing, hand-sanitizing, and toilet facilities
- Protection of food and food packaging from adulterants
- Labeling, storage, and use of toxic compounds
- Employee health conditions

At the conclusion of the inspection, the deviations were listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110). We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. More than four months have elapsed since FDA inspection. Please provide this office with information on what progress you have made in achieving FDA compliance with the seafood HACCP regulations. You may wish to include in your response documentation 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.

Your response should be directed to: Ms. Harumi Kishida, 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. Kishida at (510) 337-6824.

Sincerely,



Dennis K. Linsley
District Director
San Francisco District

Enclosures:

Handout on Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition
Form FDA 483

cc: Scott R. Denney, Quality Assurance Manager