



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

October 31, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Andrew P. Goldman
Vice President
Mountain Valley Fish and Oyster, Inc.
25 N. Willerup Avenue
Montrose, Colorado 81401

Ref. # : DEN-01-4

Dear Mr. Goldman:

We inspected your firm, located at the above address on August 22 - 24, 2000 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your fresh and vacuum packed fish products 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):

Your HACCP Plan states that as a corrective action, histamine-producing species of fish will be tested for histamines if the internal temperature of the fish is over 40° F at the time of receipt. Your histamine testing method of sampling from only one site from one fish in a shipment that exceeds the critical limit of 40° F is inadequate to assure acceptable histamine levels throughout the entire shipment.

Your HACCP Plan states that as a corrective action, vacuum packed and smoked fish will be frozen if the receiving temperature exceeds 37.8° F. On occasions between 1/16/00 and 8/16/00, vacuum packed and smoked fish shipments were received above your critical limit of 37.8° and only of the shipments were subsequently frozen as required by your HACCP Plan.

PURGED

Page 2 - Mountain Valley Fish and Oyster, Inc.
October 31, 2000

Your HACCP plan must list monitoring procedures for each critical control point, to comply with 21 CFR 123.6(a)(4). Your firm's HACCP plan for histamine producing species of fish lists 40° F internal temperature of the fish as the critical limit during refrigerated storage. Monitoring of this critical limit is by checking "cooler temperature and adequate ice." The cooler temperature may not be indicative of the internal temperature of the fish. Further, you informed the Investigator during the inspection that your cooler had difficulty holding below 40° F in the hot summer months.

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 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 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 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 direct your response to the Food and Drug Administration, Attention: Mr. H. Tom Warwick, Compliance Officer, at the above letterhead address. If you have questions regarding any issue in this letter, please contact Mr. Warwick at (303) 236-3054.

Sincerely,


Thomas A. Allison
District Director

PURGED