



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

g l b 3 1 d

August 31, 2001

Dallas District Office
4040 N. Central Expressway
Suite 300
Dallas, Texas 75204

Ref: 2001-DAL-WL-34

WARNING LETTER

Certified Mail
Return Receipt Requested

Mr. Johnny D. Glass
Owner
Gainesville Seafood
424 East California
Gainesville, Texas 76240

Dear Mr. Glass:

We inspected your seafood operation at 424 East California St., Gainesville, Texas, on August 13-14, 2001, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123. These deviations cause your seafood 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 homepage at www.fda.gov.

Our inspection revealed your processing of seafood products deviates from the regulations contained in 21 CFR Part 123 as follows:

- You must have written HACCP plans to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6 (b). However, your firm does not have HACCP plans for tuna and Mahi Mahi to control the food safety hazard of histamine.
- You must maintain complete sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11 (c). However, your firm had no sanitation monitoring records or procedures in all areas of sanitation, including the maintenance of hand-washing/sanitizing.

The investigator additionally advised you that you must have an individual specifically trained in seafood HACCP to prepare your HACCP plans and review records. This letter is not intended to be an all-inclusive list of deficiencies at your facility. At the conclusion of the inspection your firm was issued a Form

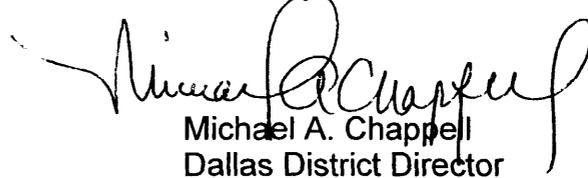
Page 2- Mr. Johnny D. Glass, Owner
Gainesville Seafood
August 31, 2001

FDA-483 which is a list of the Investigators' observations of deviations noted during the inspection. A copy of the FDA-483 is enclosed. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to seizure, and/or obtaining a court injunction against further marketing of your seafood products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your corrections. Your reply should be sent to Gwendolyn Sue Gilbreath, Compliance Officer, at the above address.

Sincerely,



Michael A. Chappell
Dallas District Director

MAC:gsg

Enclosure