



August 2, 2001

WARNING LETTER NO. 2001-NOL-42

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Archie A. Griffin, Co-Owner
3-G Enterprises, Inc. d.b.a. Griffin's Seafood
24225 Highway 1
Leeville, Louisiana 70357

Dear Mr. Griffin:

We inspected your firm, located at 24225 Highway 1, Leeville, Louisiana on June 28, 29, & July 10, 2001, 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, some of which were previously brought to your attention, cause your fresh fish products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). They are adulterated because they have been prepared, packed or held under conditions whereby they may become contaminated with filth. You can find this Act and the seafood HACCP regulations through links in FDA's home page at <http://www.fda.gov>.

The deviations were as follows:

- 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(b). However, your firm does not have HACCP plans for the following:
 1. King mackerel, amber jack, small bar jacks, large bar jacks, and black fin tuna to control the food safety hazard of scombrototoxin formation. This deviation was previously brought to your attention in our letter of September 14, 1999.
 2. King mackerel, yellow fin tuna, cobia, gag (black grouper), speckled trout, yellow eyed grouper, small bar jacks, large bar jacks, queens (long tail sea bass), black fin tuna, white trout (sheep head), marble grouper, carborita, speck hind, flounder, red grouper, and strawberry grouper to control the food safety hazard of parasites;
 3. Pompano, red snapper, lane snapper, gag (black grouper), trigger fish, amber jack, yellow eyed grouper, small bar jacks, large bar jacks, yellow eyed snapper, black fin snapper,

silky snapper (ball bats), carborita, speck hind, red grouper, and strawberry grouper to control the food safety hazard of ciguatera fish poisoning; and,

4. Puppy drum, croaker, and flounder to control the food safety hazard of environmental chemical contamination.
- 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 firm's HACCP plan for yellow fin tuna does not list the internal temperature of the fish upon receipt as a critical limit at the critical control point to control histamine formation.
 - You must have a HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4).
 1. Your firm's HACCP plan for yellow fin tuna does not list the monitoring of the internal temperature of a representative number of the largest fish in the lot at the time of delivery along with the date and time of off-loading. This deviation was previously brought to your attention in our letter of September 14, 1999.
 2. Your firm's HACCP plan for amberjack, snapper, grouper, pompano, and triggerfish indicates labeling shipping invoices with a statement "This Product Not Intended for Raw Consumption" at the receiving critical control point to control chemical contaminants. Instructing the buyer to cook the product is not adequate to control environmental chemical contaminants.
 3. Your firm's HACCP plan for mahi-mahi, wahoo, red fish, cobia, striped bass, flounder, and mullet lists labeling shipping invoices with a statement "This Product Not Intended for Raw Consumption" at the receiving critical control point to control natural toxins. Instructing the buyer to cook the product is not adequate to control natural toxins.

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 aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. 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 your HACCP plans, harvest vessel records, temperature 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 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 send your reply to the Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,



Richard D. Debo
Acting District Director
New Orleans District

Enclosure: FDA Form 483

cc: Mr. Ben John Griffin, President
3-G Enterprises, Inc. d.b.a. Griffin's Seafood
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