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VIA FEDERAL EXPRESSFood and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751WARNING LETTER

FLA-00-21

January 6, 2000

Edouard Kaelbel, Owner
Kaelbel Wholesale, Inc.
2501 SW 31st Street
Ft. Lauderdale, Florida 33312

Dear Mr. Kaelbel:

The Florida Department of Agriculture and Consumer Services (FDACS) conducted an inspection of your firm on April 21, 1999 under contract with the Florida District Office of the Food and Drug Administration (FDA). This letter is based on information provided to us by FDACS from that inspection which found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your vacuum-packed mahi-mahi fillets 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 are as follows:

You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b) and (c)(1). However, your firm's HACCP plan for vacuum-packed mahi-mahi fillets does not list the food safety hazard of Clostridium botulinum toxin formation.

You must have a HACCP plan that lists the critical control points, in order to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for vacuum-packed mahi-mahi fillets does not list the critical control points of raw material storage, butchering/packaging and finished product storage for controlling the food safety hazard of scombrototoxin (histamine) formation.

These deviations were brought to the attention of your general manager, Jason Conner, by the FDACS inspector at the conclusion of the inspection. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

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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 copies of your revised 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 firm operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,



Edward R. Atkins
Acting Director
Florida District