

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

FLA-00-37

February 27, 2001

Jack Roberts, President
Collier County Produce, Inc.
A.k.a. Captain Jerry's Seafood
D.b.a. IncredibleFresh
4206 Mercantile Avenue
Naples, Florida 34101

Dear Mr. Roberts:

We inspected your seafood importing and repacking facility located at 1421 NW 89th Court, Miami, Florida, on April 11-13, 2000, and found that you continue to have serious deviations from the import requirements of the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your Tuna and other scombrototoxin forming fish products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find the Act and these regulations through links in FDA's home page at www.fda.gov.

The deviations are as follows:

You must implement an affirmative step, which ensures that the fish and fishery products that you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for tuna processed by [REDACTED] and imported by your firm. It appears that your firm has chosen to maintain on file a copy of the foreign processor's HACCP plan in English and a letter of guarantee as your affirmative step. At the time of the inspection, you did not have a copy of [REDACTED] HACCP plan on file. In addition, the HACCP plan for [REDACTED] does not include species related hazards including histamine formation or ciguatera fish poisoning.

You must maintain records in English that document the performance and results of the affirmative steps to comply with 21 CFR 123.12(c). However, the HACCP plan provided to your firm for tuna manufactured by [REDACTED] is not in English.

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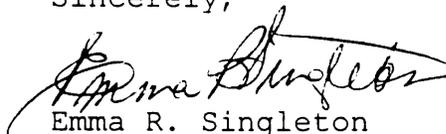
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your scombrotoxin forming fish products and/or enjoin your firm from operating.

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 this deviation. You may wish to include in your response documentation such as a copy of your written HACCP plan for scombrotoxin forming fish species or other useful information that would assist us in evaluating your corrective action. If you cannot complete correction before you respond, we expect that you will explain the reason for your delay and state when you will correct this deviation.

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 Current Good Manufacturing Practice (CGMP) regulations for foods (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,



Emma R. Singleton
Director, Florida District