



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-02

October 6, 1999

George A. Michael, Manager
Jowdy Industries Inc.
5300 Georgia Ave.
West Palm Beach, FL 33405

Dear Mr. Michael:

On May 19, 1999, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 5300 Georgia Avenue, West Palm Beach, FL. Based on our investigation, we have concluded that histamine-forming fish processed by your firm are adulterated within the meaning of 402(a)(4) of the Federal Food, Drug, and Cosmetic Act because you do not have and have not implemented a HACCP plan that complies with the requirements of 21 CFR 123 as follows:

Your HACCP plan does not meet the requirements of 21 CFR 123.6(c)(2) because there are no critical control points (CCPs) for raw material or finished product storage. Your plan must include assurance that histamine-forming fish are brought under temperature control before and after processing, either by icing or refrigeration, even if they are destined for immediate delivery. These critical control points must include appropriate critical limits, monitoring procedures, corrective actions and records.

The above identified deviation is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA will not issue any certificates for export of any of the seafood products processed at your facility until your firm is fully in compliance with the Seafood HACCP regulation.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,



Douglas D. Tolen

for Director, Florida District