



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

APRIL 2, 1999

WARNING LETTER

NWE-17-99W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Paul R. Freddura, Owner and President
Calamari Fisheries, Inc.
36 Boston Pier
Boston, Massachusetts 02210

Dear Mr. Freddura:

On December 10, 11, and 15, 1998, the Food and Drug Administration (FDA) conducted an inspection of your seafood processing plant, located at 36 Boston Pier, Boston, Massachusetts. The Investigator documented serious violations from the seafood processing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123), and the Good Manufacturing Practices (GMPs) requirements in 21 CFR 110. These violations cause the calamari processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

- Critical Control Points are not properly identified in your HACCP plan (21 CFR 123.6(c)(2)), for example, you should target the control of pathogen growth at your storage critical control point.
- Appropriate critical limits for pathogen control during the cooking step are not established in your HACCP plan. Your critical limit for cooking is, "cook at or above 180 degrees for three minutes." It is not clear whether the 180 degrees represents

water temperature or internal temperature of the squid and the plan does not distinguish between squid rings or tentacles.

In addition, we would expect the critical limits for the control of undeclared sulfites to be set at critical control points such as product labeling and receipt of raw materials (see chapter 19, page 216 of the Fish and Fishery Hazards and Controls Guide, Second Edition, 1998).

- Monitoring record data are missing, (21 CFR 123.6(c)(7)), for example you fail to record activities for critical control points at the cooking, mixing, or storage steps as listed in your firm's HACCP plan.
- Failure to maintain sanitation control records (21 CFR 123.11(c)) that document the monitoring and corrections of sanitation conditions specified in the regulations.

The above violations are not intended to be an all-inclusive list of deficiencies at your seafood processing plant. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

Additionally, the predetermined corrective actions listed in your HACCP plan do not adequately describe the steps that are to be taken, nor do they include assignment of responsibility for taking those steps, to ensure that the cause of the deviation is corrected and that no product enters commerce that is either injurious to health or otherwise adulterated as a result of the deviation.

You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

We request that you 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 and to prevent their reoccurrence. Your response should include copies of any documentation demonstrating that corrections have been made. If corrections cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Bruce R. Ota, Compliance Officer, at the address noted above.

Calamari Fisheries, Inc.
36 Boston Pier
Boston, Massachusetts 02210
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If you have any questions concerning this matter, please contact Mr. Ota at (781) 279-1675, x119.

Sincerely,

John R. Marzilli
District Director
New England District

NWE: 

cc: 