



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

g1602d

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

WARNING LETTER

NWE-33-01W

VIA FEDERAL EXPRESS

August 1, 2001

Alexis Pappas
General Manager
Ipswich Shellfish Co. Inc.
8 Hayward Street
Ipswich, MA 01938

Dear Mr. Pappas:

We inspected your firm, located at 52 Tobey Road, Wareham, MA, on July 2, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, which were previously brought to your attention during previous inspections and letters, cause your seafood products 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 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 a HACCP plan for vacuum packed seafood products that you routinely warehouse and ship from your firm.

We may take further action if you do not promptly correct these above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to the European Union (EU) countries if you do not correct these deviations.

Please respond in writing within fifteen (15) days 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 modified 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 deficiencies.

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 Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675, Extension 1708.

Sincerely,



Gail T. Costello
District Director
New England District Office

Cc:

Donald P. Viera
Operations Manager
Ipswich Shellfish Co. Inc.
52 Tobey Road
Wareham, MA 02571