



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

05/20/02

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781)596-7896

WARNING LETTER

NWE-16-02W

VIA FEDERAL EXPRESS

May 13, 2002

Victor Wong
President
Cathay Foods, Inc.
960 Massachusetts Avenue
Boston, MA 02118

Dear Mr. Wong:

We inspected your firm located at 960 Massachusetts Avenue, Boston, MA on April 18, 2002 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 in our letter dated December 19, 2001, cause your vegetable egg/spring rolls with seafood 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 serious seafood HACCP deviations were as follows:

1. 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 your seafood egg rolls to control the food safety hazards of pathogens and allergens.
2. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm does not monitor or document any sanitation observations during the manufacture of your seafood products.

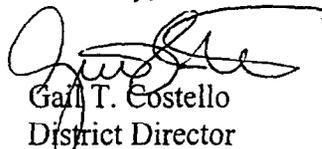
We may take further action if you do not promptly correct these above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

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, including a copy of your HACCP plan. You may also wish to include documentation such as your current monitoring records 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 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) 596-7707.

Sincerely,



Gail T. Costello
District Director
New England District Office