



April 5, 2001

**VIA FEDERAL EXPRESS**

Helmut F.J. Holzer, Co-Owner  
Culinary Masters Corporation  
6825 Shiloh Road East  
Alpharetta, GA 30005

**Warning Letter**  
01-ATL-41

Dear Mr. Holzer:

On August 21-22, 2000, the Food and Drug Administration (FDA) conducted an inspection of your importing operation located at Alpharetta, Georgia. Our investigator documented deviations from FDA's seafood HACCP importing regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause the seafood (perch) terrines imported by your firm to be adulterated within the meaning 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](http://www.fda.gov).

The deviations of concern are as follows:

1. You must establish product safety specifications for each seafood product imported into the U.S., in order to comply with 21 CFR 123.12(a)(2)(i). However, you have not establish written food safety specifications for the perch terrines you import to ensure they are not injurious to health or processed under insanitary conditions.
2. You must take one or more affirmative steps to ensure imported seafood products have been processed in accordance with FDA's seafood HACCP regulations, in order to comply with 21 CFR 123.12(a)(2)(ii). However, the affirmative step you have chosen, i.e. maintaining a "Producer's Certificate" for the Fish & Seafood Terrines is unacceptable as follows:
  - a. The certificate does not state that the product has been manufactured under sanitation and HACCP procedures that comply with the requirements of Title 21 United States Code of Federal Regulations, Part 123 (21 CFR Part 123).
  - b. If it is a lot-by-lot certificate, then it should include the lot # and amount of product in addition to the product's name and/or description. If it is a continuing

certificate, then it should include an expiration date. We believe a continuing certificate should not remain in effect for more than one year after it is issued.

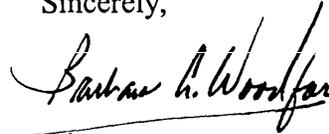
The above deviations were previously brought to your attention in my letter dated September 30, 1998. It is your responsibility to ensure that all seafood products imported and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination until your firm is fully in compliance with the Seafood HACCP regulation.

Please respond in writing, within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations, including an explanation of each step taken to prevent the recurrence of similar deviations. 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 deviations.

Your written reply should be directed to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have any questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277

Sincerely,

A handwritten signature in cursive script, appearing to read "Ballard H. Graham".

Ballard H. Graham, Director  
Atlanta District