



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g1414d

June 11, 2001

WARNING LETTER  
CHI-35-01

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Tamotsu Nakamura, President  
True World Foods, Inc.  
32-34 Pepetti Plaza  
Elizabeth, NJ 07206

Dear Mr. Nakamura:

On March 27 and 28, 2001, an investigator with the Food and Drug Administration (FDA) conducted an inspection of your plant located at 950 Chase Avenue, Elk Grove Village, Illinois. The inspection was conducted to determine compliance with FDA's seafood processing regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), and Good Manufacturing Practice (GMP) regulations for foods (21 CFR 110).

The inspection found that you have serious deviations from the Seafood HACCP regulations. These deviations, some of which were previously brought to your attention, cause your scombrotoxin forming 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](http://www.fda.gov).

These serious deviations are as follows:

- You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for fresh tuna:
  - Does not list all critical limits necessary at receipt critical control point to control histamines, or
  - Lists a critical limit, 42°F, at receiving and storage critical control points that are not adequate to control histamines.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and or enjoin your firm from operating.

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. You may wish to include in your response documentation such as updated HACCP plans, critical control points, critical limits, time/temperature/ice/icepack monitoring records for seafood products, with corrective action reports 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 deviations.

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 (21 CFR Part 123) and the Good Manufacturing Practice (21 CFR Part 110) regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Paul Boehmer, Compliance Officer at the Chicago District Office, 300 S. Riverside Plaza, Suite 550 South, Chicago, IL 60606. If you have questions regarding the implementation of the HACCP regulations or the application of HACCP to your specific process, you may contact Investigator Darrell Luedtke at the Gurnee Office for answers and/or direction toward guidance and sources of training in achieving compliance. His telephone number is (847) 249-8632, extension 28.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director

cc: Mr. Jack Sato, Vice President  
True World Foods, Inc.  
950 Chase Ave.  
Elk Grove Village, IL 60007