



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone 303-236-3000
FAX 303-236-3100

December 29, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Sang K. Yuh
General Manager
True World Foods, Inc.
6727 E. 50th Avenue
Commerce City, CO 80022

Ref. # : DEN-01-13

Dear Mr. Yuh:

We inspected your firm, located at the above address, on November 29 & 30, 2000 and found that you have serious deviations from the Seafood HACCP regulations [Title 21 Code of Federal Regulations, Part 123 (21 CFR Part 123)]. These deviations cause your fresh and vacuum packed fish products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find 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, at the time of the inspection, your firm did not have an adequate HACCP plan for fresh tuna to control the safety hazard of histamines. Specifically, your HACCP plan does not list filleting operations as a critical control point to prevent the hazard of histamine formation. Reportedly, filleting operations can take up to 4 hours before product is processed and returned to proper refrigeration temperatures.

You must implement a recordkeeping system that documents the monitoring of the critical control points that contain the actual values and observations obtained during monitoring, to comply with 21 CFR 123.6(c). However, your firm did not record monitoring observations at the receiving critical control point to control histamines. Specifically, receiving records for incoming shipments of tuna do not include a record of the temperature or the presence of ice and/or frozen gel packs at the time of receipt

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This letter does 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 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

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

Please respond in writing within three (3) 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 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.

Please direct your response to the Food and Drug Administration, Attention: Mr. Tom Warwick, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Mr. Warwick at (303) 236-3054.

Sincerely,

A handwritten signature in cursive script, appearing to read "Thomas A. Allison".

Thomas A. Allison
District Director

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