



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
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September 12, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Haru Yamamoto, Owner/President
Denver Tofu Company
3825 Blake St.
Denver, CO 80205

Ref. # : DEN-00-38

Dear Mr. Yamamoto:

On July 12 and 13, 2000, Investigator Eric S. Myskowski of this office conducted an inspection of your food and seafood processing facility at the above address. The inspection revealed that Shrimp Egg Roll Products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act. They are adulterated because they were processed and held under conditions contrary to the seafood processing regulations [Title 21, Code of Federal Regulations, Part 123 (21 CFR 123)], which constitute insanitary conditions whereby the food may have been rendered injurious to health.

The seafood processing regulations, which became effective December 18, 1997, require implementation of a preventative system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.

Our inspection revealed serious deviations from the seafood processing regulations that include, but are not limited to, the following:

Failure to develop and implement a written hazard analysis and critical control point (HACCP) plan to control hazards in Shrimp Egg Roll manufacturing at your firm as required under 21 CFR 123.6(b).

Page 2 - Warning Letter
September 12, 2000

Failure to maintain sanitation control records that document the monitoring and corrections of relevant sanitary conditions and practices during processing as required by 21 CFR 123.11(c).

For your information, practices were also noted in your tofu processing operation that are contrary to the Good Manufacturing Practices (GMP) requirements for foods as defined in 21 CFR 110:

Failure to insure the accuracy of instruments and controls used for measuring and recording temperatures as required by 21 CFR 110.40(f). Specifically, the digital temperature recording device used to monitor pasteurization and cooling temperatures of tofu products has not been calibrated since it was put in use several years ago.

Similar deviations were observed during your previous FDA inspection on February 16, 17 and 22, 2000. Following the February 2000 inspection, the FDA investigator presented a written list of inspectional observations and discussed the findings with you. Our office also reported these deviations to you by correspondence on March 30, 2000. We are concerned that you have not corrected the deviations cited in our previous letter although you told the investigator that you would correct them.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility as the Owner/President to ensure adherence to each requirement of the Act and regulations.

You must immediately take appropriate steps to correct the violations at your facility. Failure to correct the violations may result in legal sanctions such as seizure and/or injunction without further notice.

Please advise this office in writing, within fifteen (15) working days of receipt of this letter, of the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Please direct your response to Mr. H. Tom Warwick, Compliance Officer (telephone: 303-236-3054), at the above address.

Sincerely,



Thomas A. Allison
District Director