



DEPARTMENT OF HEALTH AND HUMAN SERVICES

ms023n  
Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
FAX: 425-483-4996

January 4, 2001

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 01-16

Kie Pong Kim, President  
Chang Tuh Foods  
1965 Claxter Road NE  
Salem, Oregon 97303

WARNING LETTER

Dear Mr. Kim:

On May 12, 2000, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 1965 Claxter Road NE, Salem, Oregon. During the inspection, our investigator collected samples of Udon Sauce, manufacturing code "March 03 2002" (#85142), and Soba Sauce, manufacturing code "EXP DATE 2001.60 11" (#85143). Our analysis of these products found the products to have serious deviations from Title 21 of the Code of Federal Regulations 21 CFR Part 101- Food Labeling and to be in violation of Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Food Labeling regulations through links in FDA's homepage at [www.fda.gov](http://www.fda.gov).

The deviation is as follows:

These products are in violation of 21 CFR 101.9, Food Labeling, in that the percent of sodium declared on the label is false and misleading. Our analysis of the Udon sauce found the percent of sodium contained 219% of the declared amount on the label. Our analysis of the Soba sauce found the percent of sodium in the product was 194% of the declared amount on the label.

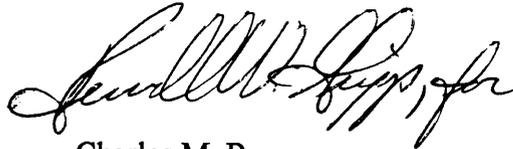
The above violations concerns labeling requirements but is not meant to be an all-inclusive list of deficiencies on your label or in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

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. 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.

Kie Pong Kim, President  
Chang Tuh Foods, Salem Oregon  
Re: Warning Letter SEA 01-16  
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Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421. If you have any question regarding any issue in this letter, please contact Lisa M. Elrand at (425) 483-4813.

Sincerely,

A handwritten signature in cursive script, appearing to read "Charles M. Breen".

Charles M. Breen  
District Director

Enclosures:

21 CFR Part 101  
Section 403 of the Federal Food, Drug, and Cosmetic Act

cc: OSDA with disclosure statement