



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

December 5, 2001

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 02-15

Kathy Thuy Tran, President
Chu Minh Tofu, Inc.
6754 Martin Luther King Jr. Way South
Seattle, Washington 98118

WARNING LETTER

Dear Ms. Tran:

The Food and Drug Administration (FDA) has reviewed your labels for your "Chuminh" tofu products which were collected by Rebecca T. Davis, Investigator, during an inspection of your plant located at 6754 Martin Luther King Jr. Way South, Seattle, Washington, on October 25, 2001. Our review reveals these labels cause the above products to be in violation of section 403 of the Federal, Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101 - Food Labeling, as follows:

The labels for your "Chuminh" tofu products are misbranded within the meaning of section 403(q)(1) of the Act in that the labels fail to bear nutrition labeling as required by 21 CFR 101.9 and the products are not exempt from this requirement under section 403(q)(5) of the Act.

The above violation concerns certain labeling requirements and is not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA. Section 403 of the Act is enclosed for your review, in addition to a copy of the Food Labeling Guide.

The FDA maintains a list of small businesses requesting exemptions from the nutrition labeling requirements of conventional foods. This exemption is based on number of employees and number of product units sold. This exemption deals only with the necessity of having the "Nutrition Facts" panel, and has no effect on the mandatory labeling information (i.e., common name of product, net contents, ingredient statement, name and address of responsible firm).

Kathy Thuy Tran, President
Chu Minh Tofu, Inc., Seattle, WA
Re: Warning Letter SEA 02-15
Page 2

As of November 26, 2001, we observed that your firm is not on that list. I have enclosed a copy of the regulations (21 CFR 101.9) and the Small Business Food Labeling Exemption form. If you qualify, the exemptions are for a twelve-month time period only and must be reapplied for annually.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations along with a copy of the revised labels. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Lisa M. Althar at (425) 483-4940.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", written over a horizontal line.

Charles M. Breen
District Director

Enclosures:

21 CFR Part 101.9
Section 403 of the Federal Food, Drug, and Cosmetic Act
Small Business Food Labeling Exemption Information
Food Labeling Guide

cc: WSDA with disclosure statement