



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

November 9, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 01-03

Jonah Alves, President
Tofu Palace Products
497 Highway 99N
Eugene, Oregon 97402

WARNING LETTER

Dear Mr. Alves:

On May 9, 2000, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 497 Highway 99N, Eugene, Oregon. During the inspection, our investigator collected samples of Toby's Lite Tofu Pate, expiration date May 26 (85139) and Toby's Lite & Spicy Tofu Pate, expiration date May 26 (85140). 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(r)(1)(A) 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.

The deviations are as follows:

1. These products are in violation in the use of the term "*lite*" on the labels. In accordance with 21 CFR 101.56(b), your products fail to list a reference food representative of the same type of foods bearing the claim.
2. In addition, in using the term "*light*" or "*lite*" on your labels for these products, no statement as to "*relative claims*" is found on either label in accordance with 21 CFR 101.13(j). Your labels do not give the percentage of the amount of the nutrient in the referenced food by which the nutrient has been modified (e.g., "50% less fat than (reference food)" or "1/3 fewer calories than (reference food)").

The above violations are not meant to be an all-inclusive list of deficiencies 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.

Jonah Alves, President
Tofu Palace Products, Eugene, Oregon
Re: Warning Letter 01-03
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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.

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Diane J. Englund at (425) 483-4864.

Sincerely,



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