



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

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

July 31, 2001

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-74

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

WARNING LETTER

Dear Mr. Alves:

On March 9, 2001, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 497 Highway 99N, Eugene, Oregon. During the inspection, our investigators collected Sample 122379-Toby's Original Tofu Pate, Sample 122380-Toby's Lite Tofu Pate, and Sample 122381-Toby's Lite & Spicy Tofu Pate. Manufacturing codes for all three samples were "MAR 30" pull date. 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.

The deviations are as follows:

1. Toby's Original Tofu Pate is in violation of 21 CFR 101.9(c)(2), Food Labeling, in that the percent of total fat and saturated fat declared on the label of this product are false and misleading. Sample 122379 was found to be 182% of label declaration for total fat and contained 0.771 grams of saturated fat, with a 0% label claim. "Total fat" in this product was found to be 9.12 grams per serving. In accordance with 21 CFR 101.9(c)(2), the amount shall be expressed to the nearest gram, provided the total fat is above 5 grams. Since this product was found to contain 9.12 grams, it would be expressed as 9 grams on your label. Since the "Saturated fat" in this product was found to be 0.774 grams per serving, in accordance with 21 CFR 101.9(c)(2)(i), this would be expressed as 1 gram on your label, since the amount is below 5 grams.
2. In addition, Sample 122379-Toby's Original Tofu Pate, Sample 122380-Toby's Lite Tofu Pate, and Sample 122381-Toby's Lite & Spicy Tofu Pate, shall be labeled in accordance with

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21 CFR 101.9(8)(iii). The percentage for vitamin C declaration on these labels is inaccurate. This regulation requires that vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the nearest 10-percent level. Thus the level of vitamin C would be expressed as 4% for each of these products.

The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. 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 15 working days 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,

A handwritten signature in black ink, appearing to read "Charles M. Breen", written in a cursive style.

Charles M. Breen
District Director

Enclosures:

Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act
21 CFR Part 101.9(c)(2) and 101.9(8)(iii)

cc: OSDA with disclosure statement