



March 20, 1998

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell, WA 98041-3012Telephone: 206-486-8788
FAX: 206-483-4996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 98-09

Mr. Kevin Hoangminh Dang, Owner
Thanh Son Tofu
9688 Westminster Avenue
Garden Grove City, CA 92644WARNING LETTER

Dear Mr. Dang:

The Food and Drug Administration (FDA) recently conducted an inspection of your firm's manufacturing facility located at 118 12th Avenue, Seattle, Washington, on January 14, 1998. During the inspection, our investigators collected labels for various products manufactured by your firm. Our review of the label for "THANH SON TOFU***FRIED TOFU" revealed that this label causes the product 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 product is misbranded within the meaning of section 403(q)(1) of the Act, in that the label fails to bear nutrition labeling as required by 21 CFR 101.9, and is not exempt from this requirement

The above violation concerns certain new labeling requirements and is not meant to be an all-inclusive list of deficiencies on your label. Other label violations can subject the food to legal action. It is your responsibility to assure that all your products are labeled in compliance with all applicable statutes enforced by FDA.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure.

Our investigators confirmed that, during processing, the above described tofu is fried in soybean oil; however, soybean oil is not listed as an ingredient on the label. Per 21 CFR 101.4(a)(1) you are required to list all ingredients contained in the product. Per 21 CFR 101.4(b)(14) you are required to list the fat and/or oil in the ingredient statement by its specific common or usual name (e.g. soybean oil).

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Kevin Hoangminh Dang, Owner
Thanh Son Tofu

In addition to labeling deficiencies, several adverse practices and conditions were observed during this inspection. These observations were listed on an FDA-483 - Inspectional Observation form (copy enclosed). The FDA-483 was issued to and discussed with, Mr. Hung Do, Manager, at the conclusion of the inspection. The cited observations are not intended to be an all-inclusive list of the problems that may exist at your facility. Your firm has an ongoing responsibility to assure that your manufacturing plant maintains conformance with current Good Manufacturing Practices (GMPs).

You should notify this office within 15 working days of the receipt of this letter of the specific steps you have taken to correct the above noted violations along with a copy of the revised label. If corrective action can not be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Your reply should be addressed to Janelle K. Main, Acting Compliance Officer, P.O. Box 3012, Bothell, WA 98041-3012.

Sincerely,



Roger L. Lowell
District Director

cc: Washington State Department
of Agriculture
Thanh Son Tofu
ATTN: Mr. Hung Do, Manager
118 12th Avenue
Seattle, WA 9898142

Enclosures
FDA-483
Food Labeling Guide