



September 15, 1997

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863WARNING LETTER  
CHI-48-97CERTIFIED MAIL  
RETURN RECEIPT REQUESTEDMr. James Woo, President  
Nomura Tofu Co., Inc.  
2904 W. Fullerton  
Chicago, IL 60647-2921

Dear Mr. Woo:

An inspection of your facility on April 17, 1997, conducted by an inspector from the Illinois Department of Public Health revealed discrepancies in your labels for Tofu. The product is misbranded in that it fails to bear nutrition labeling as required under Section 403(q)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Section 101.9 and is not exempt under Section 403(q)(5) from this requirement.

Additionally, the product is misbranded under Section 403(r)(1)(A) in that the labels bear nutrient content claims "LOW FAT - HIGH PROTEIN", but fail to bear nutrition labeling in the format required under 21 CFR Section 101.9. See 21 CFR Section 101.13 and Subpart D of Part 101 for authorized nutrient content claims.

These violations concern new labeling requirements and are not meant to be an all-inclusive list of deficiencies of your labels. Other label violations can subject the food to legal actions. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by the Food and Drug Administration (FDA).

Materials are available which explain general food labeling requirements (including nutrition labeling). These include:

1. Code of Federal Regulations (CFR) - 21 CFR Parts 100 to 169. Available from the local Government Printing Office (GPO) Bookstore (telephone 312 353-5133).
2. A booklet entitled "A Food Labeling Guide" which provides additional guidance in understanding the food labeling regulations. A copy of this Guide is enclosed.

You should 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 label. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

page 2

Your reply should be sent to the attention of Mr. Paul Boehmer, Compliance Officer, Food and Drug Administration, 300 South Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,

*RSI*

Raymond V. Mlecko  
District Director