



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(617)279-1675 FAX: (617)279-1742

January 15, 1997

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NWE-2-97W

Mr. Alfred Eaton, President
Nasoya Foods, Inc.
23 Jytek Drive
Leominster, MA 01453

Dear Mr. Eaton:

A surveillance sample (96-749-429) of Extra Firm Tofu, lot Nov 20 B, was collected from your establishment on September 30, 1996 for analysis.

The product is misbranded within the meaning of section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act, in that the number of grams of "Protein" per serving declared on the label ("11 g") is false and misleading, based on laboratory analyses which show that the product contains 7.93 g and 7.37 g protein per serving (original and check analyses), and 72.1% and 67% of the declared protein per serving (original and check analyses).

The above cited violations are not intended to be an all inclusive statement of the deficiencies which may exist with your product labeling. 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 the FDA.

You should take prompt action to correct this deviation. Failure to promptly correct this deviation may result in regulatory action being initiated by FDA without further notice. These include seizure and/or injunction.

You should notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violation along with a copy of the revised label. If corrective action cannot be completed with fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to E. Frank Gesing, Compliance Officer, Food and Drug Administration, One Montvale Avenue, Fourth Floor, Stoneham, Massachusetts 02180. If you have any questions concerning this matter, please contact Mr. Gesing at (617)279-1675x127.

Sincerely,


James A. Rahto
District Director
New England District Office