



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202

February 16, 1989

REGULATORY LETTER BUF 89-2

David R. Scovronick, President
Ithaca Soyfoods Co., Inc.
403 North Plain Street
Ithaca, New York 14850

Dear Mr. Scovronick:

An inspection of your Ithaca, New York factory and review of the labeling for the 8 ounce Tofu-Kan soybean curd and 16 ounce product labeled "Tofu Tortellini" collected by Food and Drug Administration (FDA) Investigator Steven J. Libal on October 13 through 20, 1988 revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21 Code of Federal Regulations (CFR), as follows:

SECTION

BRIEF DESCRIPTION

403(a)(1)
201(n)

A food is misbranded if its labeling is false or misleading in any particular. Nutritional claims, such as HIGH PROTEIN, LOW CALORIE, are made on the label of Tofu-Kan. However, the product lacks nutrition labeling in accordance with 21 CFR 101.9.

"Tofu Tortellini" is falsely represented as a "low calorie" food in that it fails to comply with the requirements of 21 CFR 105.66, which defines a low calorie food as one which provides no more than 40 calories per serving and no more than 0.4 calories per gram. Your manufacturing process does not indicate your soybean curd would have such significant difference from other soybean curd in the ratio of calories to other food constituents.

403(j)

A food is misbranded if it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other

dietary properties as the Secretary determines to be, and by regulation prescribes as necessary, in order to fully inform purchasers as to its value for such uses. Your Tortellini mentioned above bears certain nutritional claims, but the label does not comply with 21 CFR 105.66.

You should take prompt action to correct these violations and set up procedures whereby such violations will not recur. If such action is not taken, the Food and Drug Administration is prepared to invoke regulatory sanctions such as seizure and injunction. It is your responsibility to assure your products and labeling comply with all appropriate regulations.

In addition, I offer the following comments on labeling for the two food products mentioned above.

TOFU TORTELLINI

1. We question whether the term "tofu" has general recognition in the United States as a common or usual name. We believe the term "soybean curd" is more descriptive than the name "tofu" but do not object to "tofu" being used in conjunction with the term "soybean curd".
2. Since this product is not manufactured by Ithaca Seafoods Co. Inc., the manufacturer's statement must be qualified by a phrase that reveals the connection Ithaca Seafoods Co. Inc. has with this product, for example, Manufactured for Ithaca Seafoods Co. Inc., or Distributed by Ithaca Seafoods Co. Inc. (21 CFR 101.5)
3. The nutrition labeling is not in the format specified by 21 CFR 101.9.
 - a. Calories are not expressed to the nearest 50 calories increment for a product with a calorie content above 50 calories/serving.
 - b. Fat content is not expressed to the nearest gram/serving. Since a serving of the product contains less than one gram of fat (0.4 gm/4 oz. serving), the statement "less than one gram" may be used as an alternative.
 - c. The label lacks a declaration of protein, vitamins and minerals in terms of the percentage of the US RDA.

4. The net contents declaration is not separated, by at least a space equal to the height of the lettering used in the declaration, from other printed label information printed above.
5. The required label information (nutrition labeling, ingredient declaration, manufacturer's name and address) are not together on the information panel without intervening matter.
6. The product bears the hypoallergenic claim "LACTOSE FREE" but does not comply with 21 CFR 105.62. In addition, since all soybean curd does not contain lactose, it is misleading to state "Lactose Free". We would not object to a statement "soybean curd a lactose-free food".
7. The terms "organically grown" and "natural" should not be a part of the ingredient declaration.
8. Reference in the label to usefulness of this product for "...families who want to watch their ... calorie content" also subjects this label to the requirements of 21 CFR 105.66 that it be low calorie, reduced calorie or bear a conspicuous statement of the basis upon which the food claims to be of special dietary usefulness.

Tofu-Kan

1. This product lacks an appropriate identity statement in accordance with 21 CFR 101.3.
2. The label claims "NO CHOLESTEROL" "HIGH PROTEIN" and "LOW CALORIE" are nutrition and special dietary claims that subject the labeling to the requirements of 21 CFR 101.9, 101.25 and 105.66.
3. Since soybeans have a Protein Efficiency Ratio (PER) value less than the PER of casein, we question whether this soybean product, containing 4 grams of protein per ounce, may appropriately bear a claim "HIGH PROTEIN". No claims may be made that a food is a significant source of a nutrient unless that nutrient is present in the food at a level equal to or in excess of 10% of the U.S. RDA in a serving.
[21 CFR 101.9(c)(7)(v)]
4. The term "NO CHOLESTEROL" may falsely imply that other soybean curd products do contain cholesterol. We suggest this claim be changed to a more truthful and non-misleading

statement such as "soybean curd, a cholesterol free food".

5. We question the appropriateness of a "LOW CALORIE" claim on this product. A food may claim to be low calorie provided it supplies no more than 40 calories per serving and 0.4 calories per gram. We question whether this product meets the caloric density requirements and, based on the nutrient analysis information shown to Investigator Libal, whether this product is within maximum calorie content/serving permitted for a low calorie claim.
6. The terms "organically-grown" and "Natural" should not be a part of the ingredient declaration.
7. "Soy sauce" is not followed parenthetically by a list of the ingredients contained in this multicomponent ingredient.

Please notify this office in writing within ten (10) days of each step you have taken or intend to take to correct these violations. Your response may be directed to Ray Moore, Compliance Officer, at the above address.

Sincerely,



E. Pitt Smith
District Director

