



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

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PHILADELPHIA DISTRICT

900 U.S. Courthouse  
2nd and Chestnut Streets  
Philadelphia, PA 19106

Telephone: 215-597-4390

December 12, 1996

Warning Letter

97-PHI-07  
CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

RELEASE

Ms. Michele J. D'Ambrosio, President  
Michele's Original  
6441-43 Haverford Ave.  
Philadelphia, PA 19151

Reviewed by: Pa. Agency (12)  
C.O. DATE

F# \_\_\_\_\_ GEN.  SPEC.

Dear Ms. D'Ambrosio:

The Food and Drug Administration has reviewed the labels of your Tofu Tahini Spread, Humus Tahini Spread, and New Fat-Free Sunburger collected during an inspection conducted May 16 & 22, 1996. Based on this review, we have determined that these products are misbranded under the Food Drug and Cosmetic Act (Act) and Title 21 Code of Federal Regulations (CFR) Part 101 as follows:

New Fat-Free Sunburger

The product is misbranded under Section 403(r)(1)(A) because the label bears the claim "Fat Free", and the sandwich does not qualify for this claim because the nutrition labeling on the roll used in assembling the sandwich declares 2.5g fat per roll. Thus the level of fat in the sandwich exceeds 0.5 g per and therefore the product does not qualify for the fat free claim [21 CFR § 101.62(b)(1)].

The product label fails to bear an appropriate statement of identity as required by Section 403(i)(1) and 21 CFR § 101.3 in that the term "sunburger" is not an adequate statement of identity. The identity of the product should be expressed in terms of common or usual name of the food, or in the absence thereof an appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such a food.

Section 403(i)(2), in that the ingredient statement fails to declare all the ingredients by their common or usual names. The ingredient listing identifies fat-free sauce, fat-free soy cheese, and corn boules as ingredients, however the ingredients in these multicomponent foods are not included in the ingredient statement for the "sunburger" [21 CFR § 101.4].

Humus Tabini Spread and Tofu Tabini Spread

These products are misbranded under Section 403(r)(1)(B) of the Act, and 21 CFR § 101.14 in that a heart symbol with the words "Heart Smart Eat Right" is an implied health claim. However, these products do not qualify for either authorized health claim that pertains to Coronary Heart Disease (21 CFR §101.75 - Dietary saturated fat and cholesterol and risk of coronary heart disease or 21 CFR §101.77 - Fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease) based, in part, on the declared level of fat which exceeds 3g per 50g of product. Both 21 CFR §101.75 and 21 CFR §101.77 require, in part, that the food meet the nutrient requirements for a low fat food [21 CFR §101.62(b)(2)].

The products are misbranded under Section 403(q)(1) and 21 CFR § 101.9 in that the nutritional labeling is not presented in the format required; e.g. omissions of: serving size in household measure and metric; % daily values; calories from fat; amount/serving, servings per container, etc.

Section 403(i)(2), in that the products is fabricated from a food that contains multicomponents (tofu), and the label fails to declare all the ingredients by their common or usual names in descending order of predominance as required by 21 CFR §101.4.

The products are misbranded within the meaning of section 403 (e)(1) of the Act since the labels fail to bear the place of business of the manufacturer, packer or distributor [21 CFR § 101.5 (a)].

We also wish to advise you that the net weight statement is required to appear on the principal display panel, which appears to be the container lid [21 CFR § 101.105(a)]. The net quantity of contents should be declared in metric units as well as ounces. Although FDA has not published final regulations on how the declaration is to be made, the Agency recommends that if a firm wishes to avoid having to change labels again when the metric regulations become effective, it should add the net quantity of contents statement in metric now, using the guidance provided in the proposed regulations in the Federal Register of December 21, 1993.

This is not meant to be an all-inclusive listing of all the deficiencies found in your food labels. Deficiencies similar to those noted in this letter were observed in the labels for other products produced by your company. It is your responsibility to ensure that all your products are labeled in compliance with the FD&C Act.

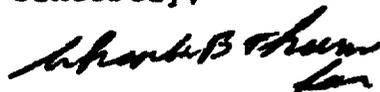
Several publications are available to assist you in making the required labeling corrections and in determining if additional corrections are required. The publications include the Code of Federal Regulations (CFR) and a booklet entitled "A Food Labeling Guide." The regulations covering the labeling of foods are found in 21 CFR volume 100 to 169. This book can be obtained from the government book store located in the Robert Morris Building, 101 N. 17th St., Philadelphia, PA. It can also be ordered by phoning the bookstore at (215) 636-1900. For your convenience we have enclosed an order form for the Food Labeling Guide. You may also elect to use a consultant to assist you in revising your labels.

You should take prompt action to bring your labeling into compliance with current regulations. Please notify this office in writing within fifteen (15) working days of your receipt of this letter of the specific steps you have taken. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction. If available, copies of revised labels should be submitted with your response.

We also note that the label for your "Sunburger" fails to bear the state of the manufacturer, packer or distributor of this product [21 CFR § 101.5 (d)].

If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the correction will be completed. Your reply should be directed to Beatrice Greenberg, Compliance Officer, at the address shown above.

Sincerely,



Diana J. Kolaitis  
District Director  
Philadelphia District

enclosure

cc: Pennsylvania State Department of Agriculture  
Bureau of Foods and Chemistry  
2301 North Cameron Street  
Harrisburg, PA 17120-9408  
Attn: Leroy C. Corbin, Jr., Director  
Division of Food Control