



FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENUE
SAN JUAN, P.R. 00901-3223

August 15, 1997

WARNING LETTER
SJM-97-23

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Enrique Mangual Flores
President
Productos Kikuet, Inc.
Box 1673
Canovanas, Puerto Rico 00729-1673

Dear Mr. Mangual:

During an inspection of your firm on May 21 and 27, 1997, our investigator collected a physical sample of "Sorullos de Maiz con Queso" (Corn Sticks filled with Cheese), and the labels for "Entremeses Surtidos" (Variety Cocktails), "Tacos de Jueyes" (Crab Tacos), "Tacos de Langosta" (Lobster Tacos), and "Empanadillas de Queso" (Cheese Empanadillas).

Our review of the labels collected for the products listed above show these products are misbranded within the meaning 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:

1. All five products are misbranded in that their labels fail to bear nutritional labeling as required under section 403(q)(1) of the Act, and 21 CFR 101.9. None of these products are exempt under Section 403(q)(5) and have been labeled on or after August 8, 1994.

The above violation concerns certain new labeling requirements and is not meant to be an all inclusive list of deficiencies on your labels. 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 these deviations. Failure to promptly do so may result in regulatory action without further notice.

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In addition, our laboratory analysis of the Corn Sticks with Cheese Filling found the chemical preservative sodium benzoate in the product. The label for this product fails to list sodium benzoate as an ingredient, or to otherwise identify it as a preservative. This product's label should be corrected to reflect the use of sodium benzoate as a chemical preservative under the list of ingredients, as required under Section 403 of the Act and 21 CFR 101.4- Designation of ingredients.

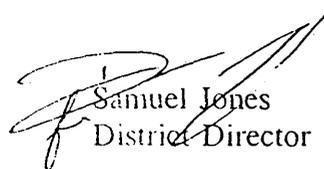
Our label review also shows that the labels for all five products include representations in two languages. All mandatory labeling information for products sold only in the Commonwealth of Puerto Rico must be in either Spanish, English, or in both languages as set forth under 21 CFR 101.15(c)(1) and (2).

For example, the common name of the product is represented in both English and Spanish, however, the declaration of ingredients and other required information is represented in English only. Your products are not exempt under paragraph (c)(2) of this part.

For your information, in the future you will also be required to declare the net quantity of contents in metric units as well as pounds and ounces. To avoid having to revise your labels again when the regulations become effective, you may wish to add the metric units to your labels using the guidance provided in the Federal Register of December 21, 1993 (enclosed). We expect that any difference between the proposed regulation printed in this federal register and the final regulation will be minor and will not by themselves require a label change.

Please notify San Juan District Office within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to the Food and Drug Administration, San Juan District Office, San Juan, Puerto Rico 00901-3223, Attention: Carmelo Rosa, Acting Compliance Officer.


Samuel Jones
District Director