DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

San Juan District
Compliance Branch
466 Fernandez Juncos Avenue
San Juan, Puerto Rico 00901-3223
Telephone: 787-474-9500
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March 30, 2006

WARNING LETTER
SJN-06-06

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Felicito Montero-Suárez
President
Karina Manufacturing Inc.
dba Flanes Kopelia dba Karina Bakery
P.O. Box 1805
Sabana Seca, PR 00952-1805

Dear Mr. Montero-Suárez:

This letter is in reference to the inspection of your facility located at 1169 Canada Street, Puerto Nuevo, Rio Piedras, Puerto Rico on November 7, 8, 17, and 22, 2005, by an investigator from the U.S. Food and Drug Administration (FDA). During the inspection, labels of your gelatin and custard products were collected. Our review of your labeling and other evidence collected by the investigator indicates serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR). You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov.

1- Your "Flan Queso" and "Flan Calabaza" products are adulterated under section 402(c) of the Act [21 U.S.C. 342(c)] in that they contain FD&C Yellow No. 5, and the presence of that ingredient is not declared on the product labels. You must specifically declare the presence of FD&C Yellow No. 5 in the ingredient statement on your product labels to comply with 21 CFR 74.705(d)(2). The declaration of FD&C Yellow No. 5 as an ingredient is a condition for safe use of this color additive in food products.

2- Your "Flan Vainilla" (3 oz., 3-3 oz. units, 6-3 oz. units), "Flan Calabaza" (3 oz.), and "Flan Queso" (3 oz.) are misbranded within the meaning of section 403(i)(2) and section 403(k) of the Act [21 U.S.C. 343(i)(2) and 343(k)] because they contain artificial flavoring, artificial coloring, or chemical preservatives that are

not declared on the product labels. Under 21 CFR 101.22(j), preservative ingredients must be declared on the product label by common or usual name along with a description of the ingredient's function (e.g., ——— or "to ———. Under 21 CFR 101.22(k)(1), certified color additives must be individually declared in the ingredient statement by the name specified in the listing regulation for the color additive (e.g., 21 CFR 74.705 for FD&C Yellow No. 5). The name may be abbreviated to omit the "FD&C" prefix and the abbreviation "No." (e.g., "Yellow 5" instead of "FD&C Yellow No. 5"). Specific violations for each product are as follows:

- "Flan Vainilla" (3 oz., 3-3 oz. units, 6-3 oz. units) contains the undeclared preservatives ——— and ——— Also, the artificial flavoring in this product is not declared as such. Although information provided to our investigator indicates that the product is flavored with artificial vanilla, the product label does not list this ingredient by its common or usual name as required by 21 CFR 101.4(a)(1), but instead declares it incorrectly as "vanilla.".
- "Flan Calabaza" (3 oz.) contains undeclared Yellow 5, Yellow 6, and Red 40, which are certified color additives.
- "Flan Queso" (3 oz.) contains the undeclared preservatives potassium sorbate and sodium propionate. This product also contains undeclared Yellow 5, Yellow 6, and Red 40, which are certified color additives.

Furthermore, your "Flan Vainilla" (3 oz., 3-3 oz. units, 6-3 oz. units), "Flan Calabaza" (3 oz.), "Flan Queso" (3 oz.), "Gelatinas Deliciosas" (6-3 oz. units) and "Gelatina de Fresa Con Frutas" (7 oz. and 12 oz.) are misbranded within the meaning of section 403(i)(2) of the Act [21 USC 434(i)(2)] because they are formulated with two or more ingredients, but their labels fail to bear the common or usual name of each ingredient as required by 21 CFR 101.4; for example, in addition to the preservatives and certified color additives previously mentioned:

- Your "Flan Vainilla" product contains undeclared ——— and does not declare the ———, and ——— individually by their common or usual names.
- Your "Flan Queso" product contains undeclared ——— and does not declare the ——— and ——— ingredients individually by their common or usual names. ———
- Your "Gelatinas Deliciosas" is a variety pack of gelatins, which consists of strawberry gelatin containing Red 40 and Blue 1; grape gelatin containing Red 40 and Blue 1; and orange gelatin containing Yellow 6. The product label declares "Artificial Color" in the ingredient statement but fails to declare each certified color additive by the name specified in the applicable color additive listing regulation, as required by 21 CFR 101.22(k)(1).

- Your "Gelatina de Fresa Con Frutas" (7 oz. and 12 oz.) products declare "coctel de frutas" as an ingredient. "Coctel de frutas", or fruit cocktail, is a multi-component ingredient, which itself contains two or more ingredients; however, the ingredient statement does not declare the component ingredients of the fruit cocktail, as required by 21 CFR 101.4(b)(2). This requirement may be met by either parenthetically listing the component ingredients after the common or usual name of the multi-component ingredient (in this case, the fruit cocktail), or by listing the component ingredients without listing the multi-component ingredient itself. Under the first alternative, the component ingredients must be listed in descending order of predominance within the multi-component ingredient; and under the second alternative, the component ingredients must be listed in descending order of predominance in the finished food.

According to information provided to our investigator during the inspection, the 7 oz. and 12 oz. sizes of "Gelatina de Fresa Con Frutas" contain the same ingredients, including the certified color additives Blue 1 and Red 40 and the preservative sodium benzoate; however, the ingredient statements on the two product labels are different. Specifically, the label of the 7 oz. product declares "Artificial Color" in the ingredient statement but fails to declare each certified color additive by the name specified in the applicable color additive listing regulation, as required by 21 CFR 101.22(k)(1); the 12 oz. product label declares Blue 1, Red 40, and "preservativo" in the ingredient statement, but does not specify the preservative ingredient used. "Preservativo" is a generic term for a category of ingredients, not the common or usual name of an individual ingredient. The name of the preservative ingredient must appear on the label, followed by its function [21 CFR 101.22(j)].

This letter is not intended to be an all inclusive review of your products and their labeling. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

An FDA-483, Inspectional Observations, was issued at the end of this inspection and our investigator discussed the observations with you. The observations listed on the FDA-483 pertained to sanitation and not to the labeling violations listed above. We have received your response to the FDA-483 and your responses appear to be adequate.

For your information when revising your product labels, please note that product labels that use both English and Spanish must include all required information in both languages. Some of your labels bear information both in English and Spanish, but not all information required to be on the label appears in both languages. For example, the nutrition information on your "Gelatinas Deliciosas" appears only in English, but the statement of identity (product name) appears only in Spanish. Products intended to be distributed in the Commonwealth of Puerto Rico may be labeled solely in Spanish [21 CFR 101.15(c)(1)]. However, if the product label contains any representations in

English, then all information required to appear on the label must appear in both Spanish and English [21 CFR 101.15(c)(2)].

Additionally, we noted that your labels do not declare *trans* fat in the Nutrition Facts panels. Regulations requiring the declaration of *trans* fat went into effect on January 1, 2006 (see 21 CFR 101.9(c)(2)(ii); 68 FR 41433). You should review all of your product labels to ensure they comply with these regulations, as appropriate. For additional information on *trans* fat labeling, go to http://www.cfsan.fda.gov/~dms/lab-cat.html#transfat.

Finally, as noted above, "Flanes Vainilla" is prepared with artificial vanilla flavoring and vanilla is declared as the characterizing flavor on the label. When the product's characterizing flavor is artificial, the name of the characterizing flavor (vanilla) must be accompanied by the words "artificial" or "artificially flavored" in the product name on the principal display panel [21 CFR 101.22(i)(2)].

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific actions you are taking to correct these deviations and an explanation of each step being taken to correct the deficiencies and prevent their recurrence. You should also include copies of any available documentation demonstrating that corrections have been made. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure or injunction.

Your response should be directed to: Food and Drug Administration, Attention: Carlos I. Medina, Compliance Officer, 466 Fernandez Juncos Avenue, San Juan, Puerto Rico 00901. If you have any questions, regarding any issue on this letter, please contact Mr. Medina at 787-474-9539 or at carlos.medina@fda.hhs.gov.

Sincerely,

Maridalia Torres
Acting District Director
San Juan District

Enclosure: FDA 483