



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35 437 7/31/97  
Public Health Service

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

July 17, 1997

WARNING LETTER  
SJN-97-21

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Roberto Lamberty  
Owner  
Robin's Products  
P.O. Box 441  
Hormigueros, Puerto Rico 00613

Dear Mr. Lamberty:

Our review of the labels of "Vainilla" (Vanilla), and "MIEL PURA\*\*\*Del Pais" (Pure Honey), and laboratory analysis of the product labeled as "MIEL PURA\*\*\*Del Pais" show that these products, imported and re-packed by your firm, are in violation of Sections 402 and 403 of the Federal Food Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations Parts 101 and 169.

The product labeled as "MIEL PURA\*\*\*Del Pais" is in violation of Section 402(b)(4) of the Act in that a sample collected at your firm of product re-packaged in your facility has been confirmed by laboratory analysis to contain 52% sugars from cane or corn origin. The honey is adulterated in that the sugar profile found on the sample does not correspond to the sugar profile of authentic honey, as defined under USDA, ARS Technical Bulletin 1261 (April 1962).

The product labeled as "MIEL PURA\*\*\*Del Pais" is also in violation of Section 403(a)(1) of the Act in that its labeling is both false and misleading.

The labeling on this product is false in that sugars from cane and corn sources have been added to the product "pure honey". The label bears no declaration of ingredients listing cane or corn sugars.

The labeling is also misleading in that it suggests the product is sourced in Puerto Rico, whereas the same is a product of the Dominican Republic. Documentation collected during the inspection of 5/8/97 shows that the product re-packaged at your facility and labeled "MIEL PURA\*\*\*Del Pais" is honey which was imported from the Dominican Republic on or about 3/24/97. The labeling lacks any reference that this is a product from the Dominican Republic.

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Our examination of the labeling for the "Vainilla" (vanilla) flavoring repacked by your firm reveals that the product is misbranded within the meaning of Section 403(c) of the Federal Food, Drug and Cosmetic Act and Title 21, Code of Federal Regulations, Parts 101 and 169.

The product labeled as "Vainilla" is in violation of the Act in that the label fails to bear the appropriate statement of identity. The term "Vainilla" (vanilla), by itself, does not adequately describe the product labeled as containing the ingredients "caramel", "vanillin", "coumarin substitute", "sodium benzoate", and "water" [(21 CFR 101.3(b)(3)]. If the product contains these ingredients, it may be appropriately labeled "Imitation Vanilla Flavoring".

You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice, such as seizure or injunction.

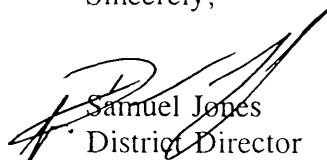
In addition, the declaration of the net quantity of contents in the product labeled as "VAINILLA" is not in terms of fluid ounces and it does not appear in the bottom 30 percent of the principal display panel as required by 21 CFR 101.105(b)(2) and 21 CFR 101.105(f). Please consider this when implementing corrective action on your label for this product.

This letter is not intended to address all of your firm's violative practices, products, or all of the deficiencies which may exist with your products' labeling. It is your responsibility to assure that all requirements of the Act and regulations promulgated thereunder are being met.

Please notify San Juan District Office in writing 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: Maridalia Torres, Acting Compliance Officer.

Sincerely,

  
Samuel Jones  
District Director