



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

592

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

November 24, 1997

WARNING LETTER

SJN-98-04

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Mr. Jose Gaud Negron
L'Ceiba Distributors
Camino La Cuchilla #1310
Mayaguez, PR 00680

Dear Mr. Gaud-Negron:

Our laboratory analysis and review of the labels of "Miel de Abejas DEL BATEY" (Bee Honey) show that this product, relabeled and distributed by your firm under your responsibility and control, is in violation of Section 402 and 403 of the Federal Food Drug and Cosmetic Act (the Act).

The product labeled as "Miel de Abejas DEL BATEY" is in violation of Section 402(b)(4) of the Act in that a sample collected at a local flea market after your firm relabeled the product in your facilities and sold it, has been confirmed by laboratory analysis to contain 80 - 100 % sugars from cane or corn.

The product labeled as "Miel de Abejas DEL BATEY" 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 and misleading in that sugar from cane or corn sources has been added to the product purported to be "pure honey" and the label bears no declaration of ingredients containing cane or corn sugar.

You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice, such as seizure, injunction, and prosecution. This letter is not intended to address all violative practices, products, or all deficiencies which may exist with your firm's product and operations. It is your responsibility to assure that all requirements of the Act and regulations promulgated thereunder are being met.

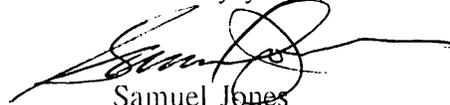
Please notify San Juan District Office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation. If corrective action cannot be completed within 15 working days, please state the reasons why and the time within which the corrections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

Mr. Francisco Palomo Decon

Page 2

Your reply should be sent to the Food and Drug Administration, Att: Jorge L. Guadalupe,
466 Fernandez Juncos Avenue, San Juan, Puerto Rico 00901-3223.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Samuel Jones', with a long horizontal flourish extending to the right.

Samuel Jones
District Director

Enclosures:

FD&C Act, Sections 402(b)(4) & 403(a)(1)
21 Code Federal Regulations, Section 1.21