



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

12/1/97
SDI

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

November 24, 1997

WARNING LETTER
SJM-98-03

Certified Mail
Return Receipt Requested

Mr. Francisco Palomo Decon
President
Halcon Bakers, Inc.
P.O. Box 7348
Caguas, Puerto Rico 00626

Dear Mr. Palomo:

The recent analysis of Honey brand "De Mi Tierra" (Sample #97-747-798) repacked by your firm and collected on 8/12/97 reveals that the product is in violation of the Federal Food, Drug and Cosmetic Act, within the meaning of Section 402 and 403.

The product labeled as "De Mi Tierra" is in violation of Section 402(b)(4) of the Act in that a sample collected at your firm of product repacked in your facilities has been confirmed by laboratory analysis to contain 67% sugars from cane or corn.

The product labeled as "De Mi Tierra" is 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 have been added to the product purported to be "pure honey" and the label bears no declaration of ingredients containing cane or corn sugar.

Chapter 21 Code of Federal Regulations, Section 1.21 (a)(1) indicates that [Labeling of a food.... shall be deemed to be misleading if it fails to reveal facts that are material in light of other representations made or suggested by statement, word, design, device or any combination thereof].

You should take prompt action to correct these deviations. Failure to promptly correct this deviation may result in regulatory action such as a seizure without further notice.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations.

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,



Samuel Jones
District Director

Enclosures:

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