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

March 5, 1999

WARNING LETTER
SJN-99-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

R. E. Delgado
Owner/Importer of Record
R. E. Delgado, Inc.
P.O. Box 9024136
San Juan, PR 00902-4136

Re: USCS Entry # 261-0091425-3, 11/11/98

Dear Mr. Delgado:

On December 7, 1998, in accordance with our Notice of Sampling dated November 12, 1998, we attempted to sample a shipment of ice popsicles offered for import into the United States by your firm on November 11, 1998 under USCS entry number 261-0091425-3 and found that a portion of the shipment, 2,399 of 6,457/24 unit cases, was not available. This is a violation of Section 801 (a) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21 of the Code of Federal Regulations, part 1.90 (21 CFR 1.90), which requires the importer to hold an entry intact pending receipt of the results of examination of the sample. We are hereby requesting U.S. Customs to order redelivery of this shipment.

Our samples of this entry found the product was contaminated with *Listeria monocytogenes* and *Salmonella.spp.* The presence of these microorganisms in food products constitutes an imminent hazard to the public health. It was necessary for FDA to initiate a Class I recall (#F-211-9) to retrieve the units from the U.S. market.

Your firm was listed as broker for a second shipment of the same product from the same manufacturer to the same consignee under USCS entry # 261-0091584-7. Notice of Sampling was also issued by FDA for this shipment on November 20, 1998. When we attempted to collect samples from this shipment, we also found that a portion of the shipment, 636 of 6,385/24 unit cases, was not available. The importer of record for this shipment has received a letter similar to this one concerning this entry and a copy of the letter is enclosed with this correspondence.

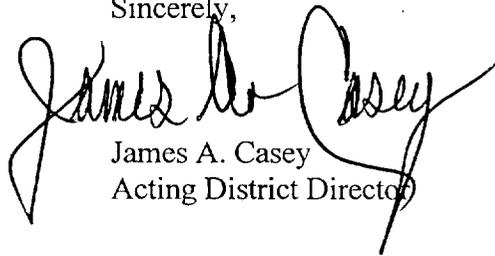
R.E. Delgado
3/5/99
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Failure to follow the procedures for importation of products regulated by the Food & Drug Administration may result in regulatory action, such as seizure, injunction or prosecution, without further notice. It is your responsibility, as the importer, to ensure that imported products meet all of the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

Within 15 working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent future violations. In addition, you should inform the U.S. Customs Service and FDA when redelivery of the goods is accomplished.

Your written response should be addressed to the Food and Drug Administration, attention: Mary L. Mason, Compliance Officer, at the address listed on the letterhead.

Sincerely,



James A. Casey
Acting District Director

Cc: Mr. Thomas Ward
Mantecados LTD/Payco Foods, Inc.
Calle 3, Lots 10 & 11
Hato Tejas Ind. Park
Bayamon, PR 00957

Hampton Carter
Supervisor, Import Specialist
U.S. Customs Service
No. 1, La Puntilla St.
San Juan, PR 00901