



March 5, 1999

FOOD & DRUG ADMINISTRATION  
466 FERNANDEZ JUNCOS AVENUE  
SAN JUAN, P.R. 00901-3223WARNING LETTER  
SJN-99-04CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Thomas Ward  
Owner/Importer of Record  
Mantecados Ltd./Payco Foods Inc.  
Calle 3, Lots 10 & 11  
Hato Tejas Industrial Park  
Bayamon, PR 00957

Re: USCS Entry # 261-0091584-7, 11/19/98

Dear Mr. Ward:

On January 22, 1999, in accordance with our Notice of Sampling dated November 20, 1998, we sampled a shipment of ice popsicles offered for import into the United States by your firm on November 19, 1998, under entry number 261-0091584-7 and found that a portion of the shipment, 636 of 6,385/24 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.

You were listed as the consignee for a previous shipment of the same product from the same foreign manufacturer; Entry # 261-0091425-3 dated November 11, 1998. Notice of sampling was also issued for this shipment and we found that 2,399 of 6,457 cases from this entry were also unavailable when we attempted to sample the product. 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. 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.

Mr. Thomas Ward

3/5/99

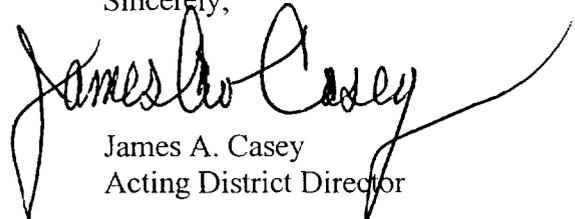
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Failure to follow the procedures for importation of products regulated by the Food & Drug Administration may result in regulatory action, such as seizure, injunction or prosecution, without further notice. It is your responsibility, as the importer, 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,

A handwritten signature in black ink that reads "James A. Casey". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

James A. Casey  
Acting District Director

Cc: R. E. Delgado, Owner  
R. E. Delgado, Inc.  
P.O. Box 9024136  
San Juan, PR 00902-4136

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