



DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

NPS-35

m 3281n

466 Fernandez Juncos
San Juan, Puerto Rico 00901-3223
Telephone: 787-729-6894
FAX: 787-729-6834

June 21, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
SJN-00-15

Guillermo Garcia
President
Packers Provision Group
Mercado Central Street,
Building # 1229, Zona Portaria
Puerto Nuevo, Puerto Rico

Product: Frozen Kingfish
Our Reference #: N35-0063543-7
U.S. Customs Entry # N35-0063543-7

Dear Mr. Garcia:

The Food and Drug Administration (FDA) examined a shipment consisting of [REDACTED] of frozen king fish product imported into the United States by your firm on or about January 21, 1999, under entry number N35-0063543-7. The results of the sample found that the product was contaminated with Salmonella Sp., a poisonous and deleterious substance which may render the product injurious to health and adulterated within the meaning of Section 402 (a) (1) of the Federal Food, Drug, and Cosmetics Act (the Act). The product was detained on March 4, 1999 and subsequently refused on November 11, 1999, for that reason. You did not hold the product as required by Section 801 (b) 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) that requires the importer to hold an entry intact until further notice by FDA.

We are aware that your firm voluntarily destroyed [REDACTED] cases of the product, however, the remaining [REDACTED] cases were distributed into commerce contrary to the requirements of Section 801 (a) (3) of the Act and in violation of Section 301 (C) of the Act.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation.

Your written reply should be addressed to the Food and Drug Administration, Attention: Carlos I. Medina, Compliance Officer, 466 Fernandez Juncos Avenue, San Juan, Puerto Rico 00901.

Sincerely,

A handwritten signature in black ink that reads "Wayne Matthews for". The signature is written in a cursive, flowing style.

Mildred R. Barber
District Director