



D1094B

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: FDA Sample No. 3108377
Customs Entry No. 630-0042679-9
Product: Frozen Shrimp

WARNING LETTER

FLA-97-15

January 13, 1997

Mr. Michael Arenal
Importer
801 N.E. 50th Court
Ft. Lauderdale, Florida 33334

Dear Mr. Arenal:

The Food and Drug Administration (FDA) attempted to examine a shipment of frozen shrimp offered for entry into the United States by your firm on December 9, 1996, under the above referenced entry number, and found that the shipment was not held intact for FDA examination. Our inspector observed only 113/50 cases that were available for sampling from the original, declared entry of 160 cases. There were 47/50 lb. cases of frozen shrimp which were not available for FDA examination. Regulation Title 21, Code of Federal Regulations (CFR), Part. 1.90, requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We have requested the U. S. Customs Service (Customs) to order redelivery of the 47/50 lb. cases, which are missing (copy enclosed).

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. FDA may also request Customs to revoke immediate delivery privileges. 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. In addition, you should inform Customs and FDA if and when redelivery is accomplished.

Mr. Michael Arenal
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Your written reply should be addressed to the Food and Drug Administration, Attention: Paul R. Bagdikian, Compliance Officer, Food and Drug Administration, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,



Douglas D. Tolen
Director, Florida District

Enclosure