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VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

Ref: Customs Entry No. D97-0205381-7/001/001
Product: Fresh Swordfish (294 pounds)

WARNING LETTER

FLA-01-81

August 30, 2001

Ricardo P. Wojciechowski, President
Brave Coast, Inc.
9381 N.W. 13th Street
Miami, Florida 33172

Dear Mr. Wojciechowski:

The Food and Drug Administration (FDA), on July 17, 2001, attempted to examine a [REDACTED] case ([REDACTED] pounds) shipment of fresh swordfish in accordance with our Notice of FDA Action, dated July 14, 2001. The shipment was offered for import (imported) into the United States by your firm on July 13, 2001, under the above referenced entry. During our visual examination, we noted that [REDACTED] cases ([REDACTED] pounds) out of the original [REDACTED] cases were already distributed without a FDA release. Reportedly, these [REDACTED] cases were brought back to the facility on or about July 18, 2001, and a private laboratory sampled this swordfish entry on July 19, 2001.

On July 30, 2001, we returned to your facility to verify the return of the [REDACTED] cases previously distributed and to verify that the entry was still held intact. Our examination noted that some of the original product was not available. There were [REDACTED] pounds of product missing, and you stated in an affidavit that some of the product had been sold to several customers in the Miami area after your private laboratory indicated to you that the sample was found to be acceptable for mercury.

Not holding an entry intact pending a FDA release is in violation of Title 21, Code of Federal Regulations (21 CFR), Section 1.90. This section requires the importer to hold an imported article intact pending a release notice from FDA. Furthermore, an article cannot be distributed solely based on the results submitted to you from a private laboratory for those articles which are under Detention Without Physical Examination. The private laboratory package is required to be reviewed by FDA, and the entry held intact until a release is given by FDA.

Failure to promptly correct this situation and prevent future premature distribution of imported product may result in requiring that future shipments be held in secured storage. Secured storage will be under the supervision and direction of U. S. Customs Service, such as in bonded warehouses. You will be responsible for all costs incurred in secured storage.

We will be requesting that U. S. Customs Service order redelivery of the 294 pounds which were distributed without a FDA release. Failure to redeliver the missing portion to Customs' custody may result in a penalty action at a later date.

We request a response in writing within fifteen (15) working days of receipt of this letter outlining the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent recurrence. In the event that the product is still available, you should inform Customs and FDA if and when redelivery is accomplished.

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

Sincerely,


Emma R. Singleton
Director, Florida District

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cc: Port Director
U. S. Customs Service
P. O. Box 52-2207
Miami, Florida 33152-2207

Alpha Brokers Corporation
7001 N.W. 25 Street
Miami, Florida 33122