



93503d

**VIA FEDERAL EXPRESS**

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

Ref: Customs Entry No. 406-0318899-2 /001  
Product: Frozen Langostinos (shrimp)

**WARNING LETTER**

**FLA-02-59**

September 10, 2002

Mr. Mario Gatica, President  
Nico's Seafood & Products Corp.  
13860 S.W. 100 Lane  
Miami, Florida 33186

Dear Mr. Gatica:

On May 14, 2002, the Food and Drug Administration ("FDA") issued a Notice of FDA Action to you, advising you that it would be examining the shipment of langostinos that was being offered by you for import into the United States under Customs Entry No. 406-0318899-2/001. On May 28, 2002, FDA attempted to examine this entry.

Upon examination, FDA Investigators found that the product presented by you for examination was not the product received under entry number 406-0318899-2. When the FDA Investigators informed you of this fact, you told them that you had distributed the entry. This is a serious violation of Title 21, Code of Federal Regulations, Section 1.90, which requires you to hold an entry intact and to not distribute it when FDA has notified you that it will be examining the shipment, as it did in this instance. Since the entry was not held, FDA has requested U.S. Customs to issue a Demand for Redelivery of this entry.

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 also remind you that knowingly filing a false import entry and knowingly making fraudulent misrepresentations or false statements to federal officials are criminal offenses under Title 18, United States Code, sections 542 and 1001, respectively, and under Title 18, Section 545. Further, when evidence demonstrates that an article presented to FDA for examination is not from the original entry, but was substituted for the entry, the article may be seized by U. S. Customs Service under Title 19, section 1595a (c) and civil monetary penalties may be assessed under Title 19 section 1595a(b). Liquidated damages may also be assessed for articles not redelivered.

Your failure to promptly correct this situation and prevent future premature distribution of imported product may result in regulatory action without further notice, such as seizure, injunction, or detention of future entries without examination. In addition, such failure may result in FDA recommending to the U. S. Customs Service that it is requiring that future entries by you be held in secured storage. Secured storage would be under the supervision and direction of the U. S. Customs Service, such as in a bonded warehouse and you would be responsible for all costs incurred for such storage.

Please notify this office in writing within 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, if the U. S. Customs Service orders you to redeliver the entry, please inform this office in writing when redelivery is accomplished. Your written reply should be addressed to the Food and Drug Administration, Attention: Carlos W. Hernandez, Compliance Officer, P.O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

  
for Emma R. Singleton  
Director, Florida District

cc: Thomas Winkowski  
Port Director  
U. S. Customs Service  
P. O. Box 02-580  
Miami, Florida 33102-5280

