



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

01131d

WARNING LETTER

NWE-17-01W

VIA FEDERAL EXPRESS

April 10, 2001

Mr. Robert Snyder
President
Sinco Inc.
750 Pleasant Street
Belmont, MA 02478-9109

Dear Mr. Snyder:

Your firm is the importer of record for FDA entry number FD6-3006815-9, consisting of a shipment of approximately [REDACTED] cases of canned tuna. We have since learned through a conversation between FDA and your personnel that product from this entry was at least partially distributed without a proper release from us. This is a violation of Title 21, Code of Federal Regulations, Section 1.90, which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from FDA. We have issued a Notice of Refusal of Admission (copy enclosed) for the above referenced entry.

While your company did attempt to recover product that had been distributed, [REDACTED] of the [REDACTED] cases of canned tuna were not recovered.

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

Within 15 working days of receipt of this letter, 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 the recurrence of the violation.

Sinco Inc.
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You may direct your reply to Richard B. Midwood, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Mr. Midwood at (781) 279-1730.

Sincerely,



Gail T. Costello
District Director
New England District Office

cc: United States Customs Service
Attn: Ms. Michelle Bickford
10 Causeway Street
Boston, MA 02222-1059

Dynasty International, Inc.
Attn: Ms. Linda LaBrecque
365 Chelsea Street
East Boston, MA 02138

Enclosure: copy of Sinco letter dated 4/4/01
copy of Refusal