



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Public Health Service
Food and Drug Administration
New York District Office
850 Third Avenue
Brooklyn, NY 11232-1593

Telephone: [718] 340-7000 [EXT 5301]

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

APR 09 1998

Mr. David Lax
President
Paradise Products Corporation
58 Fifth Avenue
Hawthorne, NJ 07506

Ref: 21-NYK-98

Dear Mr. Lax:

The Food and Drug Administration (FDA) has information which shows that your firm violated the Federal Food, Drug and Cosmetic Act.

On November 19, 1997 FDA sent an electronic message to your customs broker [Barthco International, Jamaica, NY] that various olive products from entries 113-1216745-2 and 113-1212855-3 must be held intact and not distributed. These products were to be examined or sampled by FDA when available. Paradise Products Corporation or your import broker were required to provide FDA with a location and time for our examination or sample collection of the following:

Entry 113-1216745-2, Line 1-1, Spanish Green Olives Stuffed with Minced Pimento, a total of 1,078 cases.

Entry 113-1212855-3, Line 2-1, Spanish Green Olives Stuffed with Pimento, a total of 1,840 cases.

Mr. David Lax, President
Paradise Products Corporation

Product location was not provided. Subsequently, on January 9, 1998 FDA made a follow-up telephone call to Barthco International concerning the status of the olive products from the above referenced entries. We were informed by your broker on January 28, 1998 "...the goods had been distributed...and were all gone except for 1 of cases..."[copy of the letter attached], without receiving clearance from the FDA.

This action taken by your firm is in violation of 21 CFR 1.90, which requires an importer to hold an entry intact pending receipt of a "May Proceed" or "Release Notice" from the FDA. A "Release" by the U.S. Customs Service is a conditional release which merely permits you to take possession of the shipment. When other Federal agencies, such as FDA also exercise jurisdiction over a product offered for importation, their release must also be obtained before a product may be legally distributed.

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 to ensure that imported products are held intact until released by FDA. 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.

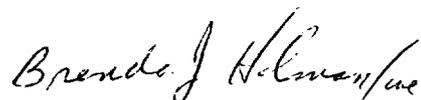
Within fifteen (15) working days of receipt of this letter, please notify our office in writing of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the reoccurrence of the violation.

A copy of this letter, except for any confidential, personal, or commercial information will be placed on public display no earlier than fifteen (15) days after the date of this letter. Your response will be on public display with any confidential, personal or commercial information purged.

Your response should be addressed to the Food and Drug Administration, Attention: Joseph V. Sollazzo - Compliance Officer, Port Elizabeth Resident Post, 1201 Corbin Street, Port Elizabeth, New Jersey 07201 (telephone 1-732-645-2386 extension 20).

Mr. David Lax, President
Paradise Products Corporation

Sincerely,

A handwritten signature in cursive script that reads "Brenda J. Holman".

Brenda J. Holman
District Director
New York District Office

Enclosure: Barthco International January 28, 1998 letter

cc: Barthco International, Inc.
150-30 132 nd Avenue
Jamaica, NY 11434