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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District
Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

SEP 22 1998

Mr. Terry Mangan
President
Mangan Brothers, Inc.
48-14 54th Avenue
Maspeth, NY 11378

Ref: 46-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 July 7, 1998 FDA sent an electronic message to your customs broker [Patrick Powers Custom Brokers, Inc., Lynbrook, NY] that entry 164-0129242-6, which included "pepper spice" must be held intact and not distributed. This product was to be examined or sampled by FDA when available. Mangan Brothers, Inc. or your import broker were requested to provide FDA with a location and time for our examination or sample collection of the following:

Entry 164-0129242-6, Line 1-1, Pepper, Black, Ground, Cracked,
a total of [REDACTED] cartons.

Product location was provided on July 16. Subsequently, on July 20, 1998 FDA attempted sample collection at your warehouse facility in Maspeth, NY. At that time, we determined that 13 of the [REDACTED] cartons of pepper had been sold and distributed.

Mr. Terry Mangan, President
Mangan Brothers, Inc.

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).

Sincerely,



Brenda Holman
District Director
New York District Office

Mr. Terry Mangan, President
Mangan Brothers, Inc.

cc: Patrick Powers Custom Brokers, Inc.
27 Blake Avenue
Lynbrook, NY 115634