



Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260
FAX: 313-226-3076

CERTIFIED
RETURN RECEIPT REQUESTED

WARNING LETTER
98-DT-12

May 28, 1998

Mr. Mohamad Moughmia, Owner
Al-Refai Nuts Gallery
10609 W. Warren Avenue
Dearborn, MI 48126

Entry No.: TZ8-0002505-6
Product: Pate D'Amandes

Dear Mr. Moughmia:

An inspection was made of your firm on May 22, 1998 by Investigator Barbara A. Moss. The inspection found that the referenced entry, consisting of a shipment of [REDACTED] kilograms of Pate D'Amandes (soft sugar candies with almond) that had been detained by our office on or about April 23, 1998, was distributed in part into commerce without a proper release from the Food and Drug Administration (FDA). Our inspection found that approximately 42.74 kilograms were distributed following our sampling of the lot on April 17, 1998.

This is a violation of Title 21, Code of Federal Regulations, Part 1.90 (21 CFR 1.90), which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from the FDA. The U.S. Customs Service issued a Notice of Refusal of Admission and Demand for Redelivery (copy enclosed) on May 18, 1998 for the above referenced entry.

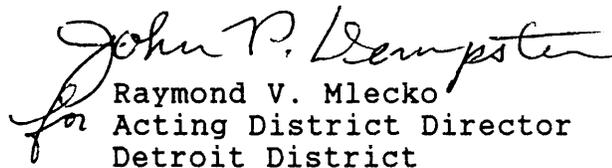
Failure to promptly correct this situation and prevent future distribution of entries prior to receipt of a May Proceed or Release Notice may result in regulatory action without further notice such as seizure, injunction, or detention without physical examination of future entries. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug and Cosmetic Act (the Act) and the regulations that are promulgated under that Act.

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Please notify us in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct this violation and to prevent it's recurrence. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which corrections will be made.

Your response should be directed to this office to the attention of Mr. John E. Klemmer, Compliance Officer.

Sincerely yours,


for Raymond V. Mlecko
Acting District Director
Detroit District