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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

May 15, 1997

WARNING LETTER
CHI-28-97

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Theodoros Mantas, Owner
Helmos Food Product
159-67 Water Market
Chicago, Illinois 60608

Dear Mr. Mantas:

An inspection of your firm by the U.S. Food and Drug Administration (FDA) during the period of March 24-28 and April 3, 1997, documented numerous insanitary conditions at your public food storage warehouse which caused the stored food products to become adulterated.

Our inspection showed that food products stored and held at your facility were found adulterated. These products are in violation of Sections 402(a)(3) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). These food products: a) consisted in whole or in part of filthy substances, such as rodent fecal pellets, live insects, moldy and decomposed products; and, b) they had been held under insanitary conditions whereby they have become contaminated with filth.

During the inspection, our investigators observed several types of live and dead food storage insects in the warehouse. These insects included adult rice weevils, adult granary weevils, adult flour beetles, adult grain beetles, and adult Indian Meal Moths. The investigators also observed rodent fecal pellets, two dead birds and a live cat in storage areas of the warehouse.

In addition, the investigators observed conditions in other lots of food products including but not limited to the following:

- Examination of burlap bags of chestnuts, (433/25 lb. bag lot), stored on the floor in the basement of this warehouse were moldy, discolored, and decomposing.
- Sixteen bags of yam flour in the basement of this warehouse were discolored and in a state of advanced decomposition.
- Two bags of an unlabeled grain product were spoiled and in a rock hard state.

- Examination of the general storage conditions/practices in the warehouse revealed the following which most likely led to the insanitary conditions and contamination associated with insects, rodents, birds, mold and decomposition at your warehouse:
 - Openings in and around doors including a door window opening approximately 2 feet by 2 feet leading to the building exterior from the basement which had no glass or screen, an open chimney clean-out door (a dead pigeon and another unidentified dead bird were found near this opening in the basement), openings around pipes and vents exiting or leading to other areas in the facility, and uncovered drain pipes, all of sufficient size to allow rodent or bird access.
 - Debris scattered throughout the warehouse especially in the basement. Shopping carts in the cooler on the first floor were full of discarded food products and debris, and located next to food storage.
 - A leaking sewage line dripping raw sewage into the north area of the basement after a toilet was flushed on an upper floor.
 - Standing water in areas of the basement.

At the close of the inspection, you reported and we observed changes you made as follows:

Food products were removed which showed visual evidence of contamination (decay).

Further unspecified corrections were promised, however, as of this date we (FDA) have not been informed of the improvements you have made.

The above listed violations are not intended to be all-inclusive. It is your responsibility to assure adherence with each requirement of the Federal Food, Drug, and Cosmetic Act and its regulations. We request that you take prompt action to correct all violations.

Please provide this office, within 15 days of receipt of this letter, a detailed response stating the actions you plan to take to correct and prevent the recurrence of these objectionable conditions. Provide the time within which the corrections will be completed, reasons why any corrective action can not be completed, and documentation to show

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that corrections have been made. Failure to take prompt action to correct all violations may result in regulatory action without further notice. Such action may include seizure and/or injunction.

Your reply should be directed to Paul A. Boehmer, Compliance Officer at the Chicago District office.

Sincerely,



Raymond V. Miecek
District Director

Enclosure: FDA-483 - Helmos
FDA-483 -