

August 26, 1997

WARNING LETTER  
CHI-43-97

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

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Michael G. Natali, President  
IL Primo Foods, Ltd.  
1335 North 31st Street  
Melrose Park, Illinois 60160

Dear Mr. Natali:

An inspection of your food processing plant by the U.S. Food and Drug Administration (FDA) July 16, 17, 22, and 30, 1997, documented numerous insanitary conditions in the plant which caused the food products to become adulterated.

These food products are in violation of Sections 402(a)(3) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that they consist in whole or in part of filthy substances, such as live and dead insects. They are also being held under insanitary conditions whereby they may become adulterated.

During the inspection, the investigator observed hundreds of live and dead fruit flies in, on, and near foods in your food processing facility.

More than one hundred live and dead fruit flies were observed in the plastic shrink wrap of a lot of pickled peppers. The five gallon pails of peppers showed evidence of leaking.

Fruit flies were observed on the lid of several pails of stored and repackaged peppers and giardiniera products. A sample (DI 97-740-877) consisting of liquid and a fruit fly like pupa was collected from a five gallon pail containing jalapeno peppers. Our investigator observed the fruit fly like pupa fall into the pail that was sampled. Our laboratory confirmed the presence of the filthy substance, a fruit fly pupa.

The investigators also observed two man made holes through the first floor ceiling into the 2nd floor. The holes (approximately 3 inches by 3 inches) were directly over first floor production lines, into a 2nd floor storage area. There were nails, wood splinters and other debris around the rough cut holes. Pallets of packaging material were observed being dragged over the holes on two occasions while production was in progress on the first floor.

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

Products were destroyed which showed visual evidence of fruit fly contamination.

A pest exterminator was contracted to correct the fruit fly problem.

Areas were cleaned and the floor holes were patched.

Further corrections were promised including fumigation of the facility to control the fruit fly population, employee use of clean gloves in handling raw product, and purchase of closed receptacles for refuse.

The above listed violations are not intended to be all-inclusive. It is your responsibility to assure adherence with each requirement of the federal regulations. We request that you take prompt action to correct all violations.

Please provide this office in writing 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 that corrections have been made. Failure to take prompt action to correct all violations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Your reply should be directed to Paul A. Boehmer, Compliance Officer.

Sincerely,

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Raymond V. Mlecko  
District Director

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