

HF1-35

4/2/98
P2

d1811b

DEPARTMENT OF HEALTH & HUMAN SERVICES

Refer to: CFN 1122305

Public Health Service
Food and Drug Administration
Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

May 14, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Pic Patel, President
Jolin, Inc. (T/A Sam Sung Soy Foods)
409 Morse Street, N.E.
Washington, DC 20002

Dear Mr. Patel:

The Food and Drug Administration (FDA) conducted an inspection of your Washington, DC tofu manufacturing establishment on May 5-6, 1998. At the conclusion of the inspection, you were issued FDA Form FDA-483 (copy enclosed), which delineated a number of gross insanitary conditions present in your plant. The following list of insanitary conditions cause the tofu products manufactured at your facility to be adulterated within the meaning of Section 402(a) (4) (copy enclosed) of the Food, Drug, and Cosmetic Act (the Act):

1. Rodent activity was observed in food storage and manufacturing areas. Thirty-one rodent excreta pellets were observed in the second floor tofu ingredient storage area, and 8 pellets were observed in the tofu processing area.
2. Two dead cockroach-like insects were observed in the tofu processing area.
3. Employees without hair restraints were observed handling food products without washing or sanitizing their hands.
4. Sinks used for hand washing on both the first and second floors lacked hot running water.
5. Various equipment and utensils were used in tofu manufacturing without first being sanitized.
6. Cobwebs and a mold-like substance were observed on the walls and ceilings in the tofu manufacturing and storage areas.

Mr. Pic Patel
Page 2
May 14, 1998

7. Structural defects were observed, including gaps in the walls and cracked, pitted floors.
8. Improperly cleaned and maintained equipment was observed, including rusted tofu presses, with peeling paint and an accumulation of dirt and debris, rust in one of the ice machines, and cooling fans in the tofu processing area with an accumulation of dirt and debris.
9. Exterior loading dock doors were left open during the entire inspection, affording an opportunity for insects, rodents, and birds to enter the building.

The above is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all products are in compliance with the Act. You should take prompt action to correct these violations. Failure to do so may result in regulatory action, which may include seizure and/or injunction, without further notice.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 days, state the reason for the delay and the time within which corrections will be completed. You should notify this office when corrective actions are completed so that a verification inspection can be scheduled.

Your reply should be sent to Gerald W. Miller, Compliance Officer, U.S. Food and Drug Administration, 101 West Broad Street (Suite 400), Falls Church, Virginia 22046-4200. Mr. Miller can be reached at (703) 235-8440, extension 504.

Sincerely yours,


William M. Ment
Acting Director, Baltimore District

Enclosures