



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

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

WARNING LETTER  
2000-DT-40

August 23, 2000

Mr. Ming Gee  
Lake Sun Company  
18704 Dix-Toledo Highway  
Brownstown, Michigan 48192

Dear Mr. Gee:

During the period of August 8 and 9, 2000, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 18704 Dix-Toledo Highway, Brownstown, Michigan. The inspection was conducted to determine compliance with The Federal Food, Drug and Cosmetic Act (hereafter referred to as "The Act") and in particular to determine if your mung bean sprout processing operations were conducted under sanitary conditions.

During the inspection, the FDA investigator observed significant shortcomings in your operations that are not in compliance with The Act. The FDA investigator presented your firm with a list of inspectional observations (form FD-483) which presents the investigator's evaluation of your firm's performance with respect to compliance with The Act.

During the inspection, it was determined that your firm is not analyzing the spent irrigation water for your mung bean sprout operation.

As such, your sprout products are adulterated within the meaning of 402(a)(4) of The Act because they are being produced under insanitary conditions that may render sprouts injurious to health. The conditions under which these sprout products are being produced are considered unsanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your sprouting facility.

Your firm's sprouts are further adulterated within the meaning of 402(a)(4) of The Act because they have been prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health. Examples of these conditions include:

- 1.) █ gallon plastic drums of sprouts were observed to sit directly on wet floors. It was further observed that these wet drums were then poured into the dehuller/washer, allowing floor water to drip directly into the sprouts that had just been dumped.
- 2.) It was observed that during the dumping of drums of sprouts into the dehuller/washer, hands were placed on the bottom of drums of sprouts that had been sitting on floor water. It was further observed that after handling the bottom of the drums, the hands then made direct contact with the sprouts.
- 3.) It was observed that washed sprouts are scooped from the dehuller/washer and placed in █ gallon perforated drums with approximately one-inch holes. These perforated drums of finished sprouts were then moved across the wet floor en route to the spin dryer and packaging operation.

It was also noted that due to ceiling/roof damage at the far west end of the building in an area that connects to storage and production, there is an approximately 2 foot by 5 foot opening to the outside. This condition has reportedly existed for several years, and exposes the facility to water and/or pest entry.

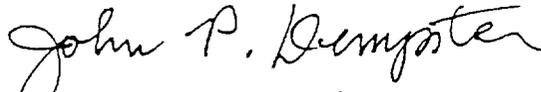
The above is not intended to be an all inclusive list of deviations at your facility. It is your responsibility to assure that your establishment is in full compliance with all requirements of the federal regulations.

You should take prompt measures to correct all deviations and take action to prevent their recurrence in the future. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and or injunction.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct this violation, including an explanation of each step taken to prevent its recurrence. If corrections cannot be completed within 15 working days, please state the reason for the delay, and the time in which the corrections will be completed.

Your written reply should be directed to Mr. Dennis P. Degan, Compliance Officer, U.S. Food and Drug Administration, 1560 E. Jefferson Avenue, Detroit, MI 48207, telephone 313-226-6260, extension 135.

Sincerely yours,

  
for Raymond V. Mlecko  
District Director