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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

WARNING LETTER
2000-DT-39

August 18, 2000

Mr. Trung V. Huynh, President
Ho Ho Beansprouts, Inc.
372 South Saginaw
Pontiac, Michigan 48341

Dear Mr. Huynh:

During the period of July 18-19, 2000, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 372 South Saginaw, Pontiac, 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.) Part of the process of mung bean sprouting operations includes sprouts in perforated drums. These drums have holes on all sides and on the bottom of the drum. Thus, these drums of sprouts are subject to possible cross contamination with extraneous materials if not handled properly. During the inspection, it was observed that the drums of sprouts were in fact not being handled properly, exposing the finished sprouts to potential contamination at various points during processing. Examples of such instances include:

- Mung bean sprouts in perforated drums were observed to be routinely exposed to contact with wet floors. Some of the water on the floors appeared to be derived from the sprouting operations themselves, such as spent irrigation water, water from hoses, and/or other unknown sources. These areas where perforated drums are exposed to wet floors, include floor areas where employees routinely walk about.
 - It was observed that the perforated drums of finished sprouts, after dragging them across wet floors, are placed on the floor next to the shaker. Employees were then observed to pick up these drums, emptying the finished sprouts onto the shaker, and in so doing, inverting the perforated drums with the drum rims sitting directly on finished sprouts.
 - Employees wearing gloves who handled perforated drums of finished sprouts that had been dragged across the wet floors, were then observed to directly handle finished sprouts at the shaker, touching those sprouts with the same gloved hands that handled the containers.
- 2.) Tubing for the irrigation system, in both the west and east growing rooms, were observed to have accumulations of a brownish substance, which appeared to be mold. In addition, a soft black material, appearing to be mold was observed on the watering nozzles for the irrigation systems. The black mold appearing material covered the nozzles and the

surrounding metal frame. It was further observed that irrigation system pipes had condensation droplets on them. In each instance, open containers of finished sprouts were observed directly under the equipment described above.

- 3.) Employees harvesting sprouts were observed to reach into sprout growing bins and drum containers with their uncovered arms (in some cases up to their elbows) coming into contact with the finished sprouts in these containers. Some employees were also observed to wipe sweat and water from their faces with their forearms, and then reach back into drums to touch the finished sprouts.

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 David M. Kasubski
Raymond V. Mlecko
District Director