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San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 3002277610

November 26, 2003

David C. Ly  
Owner  
Henh Wong Fresh Product  
2630 5<sup>th</sup> Street  
Sacramento, CA 95818

**WARNING LETTER**

Dear Mr. Ly:

On July 18, 21, 23 and 24, 2003, we inspected your food manufacturing facility located at 2630 5<sup>th</sup> Street, Sacramento, CA 95818.

Our investigators observed numerous insanitary conditions during the inspection. These conditions and practices cause products manufactured in your facility to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth. Your soy and sprout products could be considered high-risk in that this type of food can easily serve as a growth media for pathogenic microorganisms that can cause foodborne illness. The criteria and definitions in the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations in Title 21 of the Code of Federal Regulations Part 110 (21 CFR 110), apply in determining whether a food is considered adulterated. You can find links to the Act and the regulations on FDA's web site, [www.fda.gov](http://www.fda.gov).

Examples of insanitary conditions observed during the inspection include:

1. Failure to exclude pests as evidenced by live insects in the production area (21 CFR 110.35(c)). At least forty-five cockroaches were seen in the tofu processing room--behind the stove and beneath a press, tables, and rim of the cooling tank.

At least two adult flies were seen on and around this same equipment. One live adult fly was inside a plastic container ready to receive tofu and water. Two ants were seen crawling on plastic bins holding soaked soybeans.

2. Failure to adequately clean food-contact surfaces as evidenced by variously colored residues on pieces of production equipment (21 CFR 110.35(d)).
3. Failure to handle and maintain equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food in a manner that protects against contamination, as evidenced, for example, by allowing disassembled sprout growing bins, identified as clean, and tofu press molds and cutting guide, to contact soiled walls and/or floor (21 CFR 110.80(b)(7)).

At the conclusion of the inspection, these and other observations were listed on Form FDA 483, Inspectional Observations, which was issued to and discussed with Kin S. Ly, Manager. A copy of this form is enclosed for your ready reference. It is your responsibility to adopt an effective, ongoing sanitation program to eliminate these serious conditions.

The introduction or delivery for introduction of an adulterated food into interstate commerce is a violation of section 301(a) of the Act. The adulteration of a food after receipt in interstate commerce while such article is held for sale is a violation of section 301(k) of the Act.

The violations listed above are not meant to be an all-inclusive list of deficiencies. It is your responsibility to ensure that all of your products are manufactured and labeled in accordance with all applicable laws and regulations enforced by FDA.

We may take further action if you do not correct these violations, including seizure of your products and/or injunction of your operation.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct the violations. It has been four months since the completion of our inspection, which should have afforded you ample time to make corrections. If you cannot complete all corrections before responding, we expect you will explain the reason for any delay and the time period within which the corrections will be completed. We acknowledge certain corrections accomplished during the inspection, including your voluntary destruction of raw materials and finished products on hand at the time.

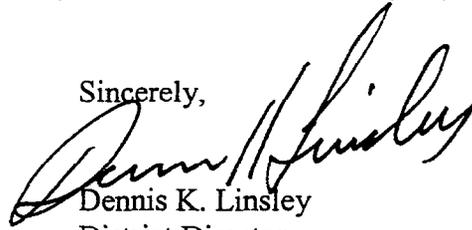
Your response should be directed to Paul A. Peterson, Compliance Officer, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502. If you have any

David C. Ly, Owner  
Henh Wong Fresh Product

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questions regarding any issue in this letter, you may contact Mr. Peterson at (510) 337-6856.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley". The signature is fluid and cursive, with a large initial "D" and "L".

Dennis K. Linsley  
District Director  
San Francisco District

Enclosure:  
Form FDA 483