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January 29, 1999

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell, WA 98041-3012

Telephone: 425-486-8788
FAX: 425-483-4996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-06

Vinh Trinh, President and Owner
Hoa Ying Trading Corporation
1571 6th Avenue South
Seattle, Washington 98134

WARNING LETTER

Dear Mr. Trinh:

On November 5, 6, and 17, 1998, the United States Food and Drug Administration conducted an inspection of your firm located at 1571 6th Avenue South, Seattle, Washington. The inspection was conducted to evaluate your firm's compliance with FDA's seafood processing regulations (21 CFR 123) and the good manufacturing practice (GMP) requirements for foods (21 CFR 110). At the conclusion of the inspection our investigators issued you a Form FDA 483 (copy attached) which delineated a number of gross insanitary conditions present in your firm at the time of our inspection. These conditions cause the products stored at your firm to be adulterated within the meaning of Sections 402(a)(4) and 402(a)(3) of the Federal Food, Drug, and Cosmetic Act.

The following is a list of insanitary conditions observed by our investigators during the inspection.

1. Examination of a [redacted]/50 lb. bag lot of [redacted] brand broken Jasmine Rice found the following:
 - a. rodent excreta pellets on bag surfaces and at bag seams;
 - b. rodent urine stains on bag surfaces;
 - c. rodent gnawed holes that penetrate into the rice product;
 - d. dead insects on the bag surfaces; and
 - e. one live insect inside a bag.

Our investigators collected samples from the above-described lot and our laboratory analyses of those samples confirmed their observations.

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2. Examination of a [redacted]/50-lb. bag lot of [redacted] brand Thai fragrant rice found the following:

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- a. rodent excreta pellets on bag surfaces and at bag seams;
- b. rodent urine stains on bag surfaces; and
- c. rodent gnawed holes that penetrate into the rice product.

Our investigators collected samples from the above-described lot and our laboratory analyses of those samples confirmed their observations.

3. On the first day of the inspection, four dead mice were found in glue traps and ketch-alls, including one mouse that was decomposed. On the second day of the inspection, after the pest control service had visited, one dead mouse still remained.
4. On the first day of the inspection, rodent excreta pellets were found along the wall/floor juncture in several areas of the firm.
5. One live bird was observed inside the warehouse, perched on boxed product near an open dock door. The loading dock door was open throughout the entire first day of the inspection.
6. A hole was found leading directly to the outside at the floor/wall juncture of the north wall. This could provide a potential rodent access point.
7. Garbage, debris, and weeds were noted along the outside of the south and west walls of the facility, providing a potential harborage for pests.

You admitted to our investigators that you have had problems with rodent activity since last year. And, although you responded to the problem by hiring a pest control company, it is clear that this action alone has not resolved the problem. Our inspection, coupled with your firm's inspectional history, demonstrates to the FDA that you have an ongoing problem with rodent and insect activity. I agree with our investigators in that your firm needs more aggressive pest control. The FDA acknowledges that you voluntarily destroyed the lots in question. However, we remain concerned that if our inspection had not revealed the rodent and insect problems, the products would have been distributed and eventually consumed.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice.

You should notify this office in writing within 15 working days of the receipt of this letter of the specific steps you have taken to correct the noted violations. If correction cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

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HACCP

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). A HACCP program involves the identification of food safety hazards that, in the absence of controls, are reasonably likely to occur in your products. Once hazards are identified, you must establish critical control points where controls can be applied to eliminate or minimize the likelihood that the identified hazards will occur. A HACCP program also involves the establishment of sanitation procedures that include sound sanitation practices, sanitation monitoring, and sanitation control records. HACCP provides a systematic approach that demonstrates to us, to your customers, and to consumers, that you routinely practice food safety by design. Seafood processors that have been operating under a HACCP system advise us that they benefit by having a more safety-conscious workforce, less product waste and fewer problems in general.

During the inspection, the FDA investigators observed shortcomings in your HACCP system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the regulation. The FDA investigators provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501) and the Inspectional Observations (form FDA 483) which present their evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are listed below.

1. By your own admission, you were not familiar with the HACCP Regulation, nor had your firm conducted, or had conducted for it, a hazard analysis. 21 CFR Part 123.6(a) requires seafood processors to conduct, or have conducted for them, a hazard analysis for each product processed, to determine whether food safety hazards that are reasonably likely to occur exist. 21 CFR Part 123.3(k)(1) defines handling or storing seafood products as processing.
2. As described earlier in this letter, your firm has an ongoing problem with rodent and insect activity. 21 CFR Part 123.11(b) requires you to monitor eight areas of sanitation as they apply to your firm. 21 CFR Part 123.11(c) requires you to maintain records of that monitoring and any corrections made as a result of that monitoring. As a seafood warehouse, you may not need to monitor all eight areas of sanitation. Besides meeting the sanitation requirements in the HACCP Regulation, the FDA reminds you that your firm should continue to follow the Good Manufacturing Practices outlined in 21 CFR Part 110.

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We encourage you to make the necessary improvements as soon as possible. If you disagree with FDA's preliminary assessment of deviations from HACCP Regulations, you should explain how your system identifies hazards and implements controls in a manner that the agency should regard as complying with the regulations. We understand HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and there may be more than one right way to control a hazard.

It is essential that you respond to this office on these HACCP deviations within 30 working days of the receipt of this letter. Upon receipt of a timely response, we will work with you to resolve any outstanding issues associated with your HACCP system. If we do not hear from you, or if your response is inadequate, we will assume that our preliminary conclusions are correct. We will plan a follow-up inspection for the immediate future.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Janelle K. Main, Compliance Officer, P.O. Box 3012, Bothell, WA 98041-3012. If you have questions regarding the implementation of the HACCP Regulation or the application of HACCP to your specific process, you may contact me at (425) 483-4928. If needed, we can direct you towards guidance and sources of training that may help you in designing a HACCP program for your firm.

We look forward to working with you to achieve a successful HACCP program in your plant.

Sincerely,



Roger L. Lowell
District Director

Enclosures:

Form FDA 483
Section 402 of the Act
21 CFR Part 123
21 CFR Part 110

cc: With Disclosure Statement
