



DEPARTMENT OF HEALTH AND HUMAN SERVICES

1701d
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

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

September 3, 2001

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-83

John H. Cao, President/Treasurer
King's Oriental Foods Company
1238 South Weller Street
Seattle, Washington 98144

WARNING LETTER

Dear Mr. Cao:

The Food and Drug Administration (FDA) conducted an inspection of your noodle manufacturing plant and warehouse located at 1238 South Weller Street, Seattle, Washington, on July 16-18, 2001. The inspection revealed numerous deviations from the Good Manufacturing Practice (GMP) regulations, Title 21, Code of Federal Regulations (21 CFR) Part 110 and (21 CFR) Part 123-Seafood HACCP regulations. At the conclusion of the inspection, you were issued a Form FDA-483 (copy enclosed) which delineated a number of gross insanitary conditions present in your warehouse at the time of the inspection. These conditions cause the food products stored in your warehouse to be adulterated within the meaning of Section 402(a)(4), (copy enclosed) 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. You can find this Act through links in FDA's homepage at www.fda.gov.

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

1. Rodent activity in the warehouse:
 - a. A lot of 20 lb. paper bags of [REDACTED] Bread Crumbs stored on a shelf in the center of the warehouse had an apparent rodent stain on the bag surface with three rodent gnawed holes that penetrate into the product. Numerous rodent excreta pellets were found on the pallet board storing the bread crumbs, on the shelf, and underneath the pallet on the shelf. Two rodent excreta pellets were found on the pallet touching the bottom of a bag of product.

- b. A lot of 40 lb. paper bags of Tempura Batter Mix found three gnawed holes that penetrated to the product. This lot was stored on a shelf in the center of the warehouse on the same pallet as "a" above. Two rodent excreta pellets were found underneath a bag on the pallet.
 - c. A lot of 50 lb. bags of Brand Jasmine Rice found rodent excreta pellets on the woven plastic bag surfaces. This lot was stored approximately five feet from the processing area. One rodent gnawed hole was observed on one bag. Sixteen rodent excreta pellets were found on one layer of bags, and at least twelve rodent excreta pellets on the seam of one bag.
 - d. One dead rodent and one live rodent were found on a glue board on the first day of the inspection demonstrating you have an active rodent problem in your facility.
2. Insect activity found in the warehouse:
- a. A lot of 25 lb. plastic bags of Brand Jasmine Rice found dead insects inside the bags of rice. This lot was stored on a pallet on a shelf on top of another lot of rice (see d) approximately five feet from the processing area.
 - b. Live insects were observed on the floor and on top of processing equipment in the processing area.
3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b) because you are storing frozen seafood products in your warehouse. Your firm did not monitor the eight areas of sanitation which are as follows:
- a. safety of process water
 - b. conditions and cleanliness of contact surfaces
 - c. prevention of cross contamination
 - d. maintenance of hand washing, hand sanitizing, and toilet facilities
 - e. protection from adulterants
 - f. employee health
 - g. proper labeling, storage, and use of toxic chemicals
 - h. exclusion of pests

Our inspection has revealed that you have a serious pest infestation problem in your warehouse. It is your responsibility to have an effective, ongoing sanitation program that eliminates the insanitary conditions we have observed. It is also your responsibility to adhere to the seafood HACCP sanitation requirements.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. Other violations can subject the food to legal action. It is your responsibility to assure that all of

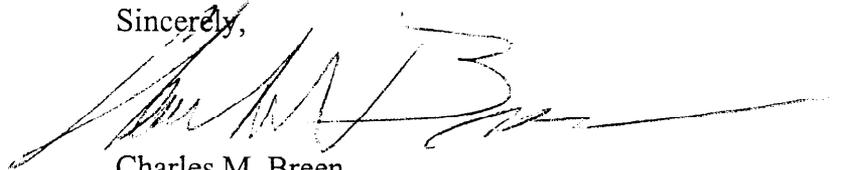
John H. Cao, Owner
Kings Oriental Foods Company, Seattle, Washington
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your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa Elrand, Compliance Officer at (425) 483-4913 or via e-mail at leland@ora.fda.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', written over a horizontal line.

Charles M. Breen
District Director

Enclosures:

Form FDA 483 -7/18/01
21 CFR PART 110 and 123.11(b)
Section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement