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June 23, 2003

Chicago District  
550 West Jackson Blvd., 15th Floor  
Chicago, Illinois 60661  
Telephone: 312-353-5863**WARNING LETTER**  
**CHI-17-03****CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Hei Yeng Kwok, Owner  
K&W Trading, Inc.  
1419 W. 15<sup>th</sup> Street  
Chicago, IL 60608

Dear Mr. Kwok:

On March 4, 10, 11, and 14, 2003, the Food and Drug Administration (FDA) conducted an inspection of your plant, which manufactures and/or distributes both USDA and FDA-regulated products. This letter refers to our findings concerning FDA-regulated products only. The inspection was conducted to determine your compliance with FDA's seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, Code of Federal Regulations (CFR), Part 123, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products," and the Good Manufacturing Practice (GMP) regulations for foods, 21 CFR Part 110. The seafood HACCP regulations were issued pursuant to Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §§ 301-97. Seafood that is processed in violation of the HACCP regulations is adulterated, according to the Act, because it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious to health. You can find this Act, the seafood HACCP regulations, and the GMP regulations through links in FDA's home page at <http://www.fda.gov>.

The inspection revealed numerous deviations from the Good Manufacturing Practice (GMP) regulations set forth in 21 CFR Part 110. 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 plant at the time of the inspection. These conditions cause the chopped cabbage that you manufacture, store, and distribute to be adulterated within the meaning of Section 402(a)(4) of the Act in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth.

Specifically, the inspection disclosed the following insanitary conditions:

- Inadequate equipment and utensils – You must use plant equipment and utensils that are designed of such material and workmanship as to be adequately cleanable, and these must be properly cleaned and maintained, to comply with 21 CFR §§ 110.35, 110.40, and 110.80. However, your firm is using inadequate and

improperly maintained equipment and utensils during your cabbage processing operation. Specific observations include:

- › Our investigator detected an off-odor while examining your cabbage spinner machine, indicating that the equipment had not been adequately cleaned. This observation, and your statement to our investigator that the machine could not be disassembled for cleaning, demonstrates that your cabbage spinner machine is not of sufficient design as to enable adequate cleaning and maintenance when used for food processing. The tag on this piece of equipment indicates that it was manufactured by the [REDACTED]
  - › Food contact surfaces within the interior of your cabbage spinner machine are uneven, pitted, and corroded. Also, peeling paint was observed on the center spindle of this machine.
  - › Bagged, chopped cabbage was stored on a rusty shelving unit located outside of the cooler, on the first floor. The plastic bags holding the cabbage were in direct contact with the rusty shelving. These bags have ventilation holes dispersed throughout, and were open at the top.
  - › Food strainers were being stored on the floor. Strainers and scoops contained cabbage particles, even though the cabbage processing operations had been completed for the day. Knives were stored on a window ledge. A scoop was resting directly on a rusty shelf.
- Failure to exclude pests from the food plant [21 CFR § 110.35(c)]:
    - › Live birds were on the first floor of your warehouse. These birds were observed flying inside the warehouse, between the dock area on the southeast side of the building and the windows on the north side of the building. The birds were flying in areas above netted bags containing whole cabbage, and had access to the cabbage processing room, which is also located on the first floor.
    - › Apparent bird excreta was observed on overhead pipes which run along the north wall of your warehouse, and was also present on product packages of rice, corn starch, and soy sauce that were stored beneath these pipes.
    - › More than 50 rodent-like pellets were observed on the first floor of your warehouse, along the east wall.
    - › Dead flies were in the light fixtures of the cabbage processing room.
    - › The bottom of the southernmost dock door had a one inch gap. Gaps along the underside of loading doors provide access for insects and rodents.

- **Inadequate hand washing and toilet facilities (21 CFR § 110.37).**
  - For example, on 3/4/2003, no functioning hand washing sinks, hand soap, or hand towels were available in the cabbage processing room, nor were these available in the toilet facilities located in the northwest and east areas on the first floor of the warehouse. Other deficiencies with hand washing and toilet facilities are listed on the FDA-483, which was presented to you at the conclusion of the inspection.
  
- **The plant is not constructed in such a manner as to allow floors, walls, and ceilings to be adequately cleaned and kept clean and in good repair [21 CFR § 110.20(b)(4)].**
  - Ice and puddles of water were present in various locations on the first floor of the warehouse. The concrete flooring is uneven and cracked in many places. The north wall in the cabbage processing room was covered with a layer of ice. A broken pipe in the northwest corner of the building had produced an accumulation of ice which had spread under pallets of food products.
  
- **Failure to properly store equipment and remove litter and waste that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings or structures [21 CFR § 110.20(a)(1)].**
  - Specifically, trash was piled up along the east exterior wall of the building. Birds were congregating and feeding in that area, and along the dock doors.

In addition, our investigator observed various seafood products being stored in your freezer at the time of the inspection. A representative of your firm stated to the investigator that your firm processes seafood products in addition to those present during the inspection, however, a complete listing of the seafood products that your firm handles was not provided to the investigator. We wish to remind you that, as a seafood processor, your firm must comply with FDA's seafood-processing regulations, 21 CFR Part 123.

The above is not intended to be an all-inclusive list of deficiencies at your facility. Several of the deficiencies noted in this letter are similar to deficiencies that were documented in our January/February 2001 inspection, and described in the subsequent Warning Letter that was issued to you on March 13, 2001. You are reminded that it is your responsibility to assure adherence to each requirement of the Act, and its implementing regulations. We request that you take prompt action to correct all violations. Failure to promptly correct these violations may result in regulatory action without further notice, including seizure and/or injunction.

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Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you will take to correct these violations, including an explanation of steps that will be taken to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made. Your written reply should be sent to Patrick J. Brown, Compliance Officer, at the address listed in the letterhead.

Sincerely,

\s\

Arlyn H. Baumgarten  
District Director