



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

452021

May 6, 2002

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-19-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Wenjey Chang, President/Owner
Gung Ho Corporation
2701 Grant Street
Bellwood, IL 60104

Dear Mr. Chang:

We inspected your firm, located at the above address, on March 19 and 21, 2002, and found that you have serious deviations from the seafood hazard analysis and critical control point (HACCP) regulations in Title 21, Code of Federal Regulations (CFR), Part 123. These deviations, including one which was previously brought to your attention, cause your cooked, ready-to-eat crab rangoon to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at <http://www.fda.gov>.

Our determinations and your deviations are as follows:

- You must have a written HACCP Plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Your firm does not have a HACCP Plan for cooked, ready-to-eat, surimi-based crab rangoon to control the food safety hazards of pathogen growth and metal fragments. This deviation was previously brought to your attention in our letter dated May 23, 2001.
- You must adequately monitor sanitation conditions and practices during processing, and maintain sanitation control records, in order to comply with 21 CFR 123.11(b) and 123.11(c). Your firm does not monitor six of the eight required areas of sanitation, including the following:
 - Safety of water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice.
 - Prevention of cross-contamination from insanitary objects to food, food-packaging material and other food-contact surfaces.

- › Maintenance of hand washing, hand sanitizing, and toilet facilities.
- › Protection of food, food-packaging material, and food-contact surfaces from adulteration. Our investigator noted uncovered product and uncovered raw materials in freezer and/or cooler areas.
- › Proper labeling, storage and use of toxic compounds.
- › Control of employee health conditions that could result in the microbiological contamination of food, food-packaging materials, and food-contact surfaces.

While we have noted that your firm monitors and keeps records for control of pests, your monitoring has not been effective, as evidenced by the hole (a potential rodent ingress/egress point) our investigator noted in the southeast corner of your Shipping/Receiving dock door.

- You must have an adequately trained or qualified individual review your instrument-calibration records, in order to comply with 21 CFR 123.10. Your thermometer calibration records, however, are not reviewed.

The above-cited violations are not intended to be an all-inclusive statement of the deficiencies that may exist in your operation. At the conclusion of the inspection, you were issued a Form FDA 483, which is a list of our investigator's observations of deviations noted during the inspection. (A copy of the FDA 483 is enclosed.) It is your responsibility to assure that all of your fishery products are processed in compliance with the requirements of the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110), as appropriate.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

We are aware that you made a verbal commitment to our investigator regarding certain corrections. We are also in receipt of your March 21, 2002 letter describing completed and promised changes, with respect to some of the FDA 483 items, including a statement that you would complete a HACCP Plan for crab rangoon by the end of April 2002. Your letter does not, however, address, or does not adequately address, certain remaining issues from our current inspection, relating to the lack of appropriate sanitation monitoring procedures and to the lack of sanitation monitoring records. These remaining sanitation monitoring issues include protection of food from adulteration (from e.g., condensate, lubricants and other contaminants, and through adequate equipment design,

construction and use). Remaining issues also include the proper labeling, storage and use of toxic compounds, and control of employee health conditions that could result in microbiological contamination of food, food-packaging materials, and food-contact surfaces. Additionally, your letter does not address the lack of instrument calibration record review by an adequately trained or qualified individual.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to accomplish corrections of all noted violations, and to prevent their recurrence. You may wish to include in your response documentation such as HACCP plans, monitoring forms, and recent monitoring data or other useful information that would assist us in evaluating your corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your written reply should be sent to James T. Karpus, Compliance Officer, at the above address.

Sincerely,

\s\
Arlyn H. Baumgarten
District Director

Enclosure: Form FDA 483

cc with enclosure: Mr. Victor Chang
Plant Manager and Co-Owner
Gung Ho Corporation
2701 Grant Street
Bellwood, IL 60104

cc with enclosure: Ms. Patricia Soto
Production Manager
Gung Ho Corporation
2701 Grant Street
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cc with enclosure: Mr. Adrian A. Favela, Supervisor
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