



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1171d

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 19, 2001

W/L 38-01

Mr. Jay F. Kato
President
Marutama Company, Inc.
714-720 Towne Avenue
Los Angeles, CA 90021

Dear Mr. Kato,

On December 14-15, 2000 Investigators from the Food & Drug Administration ("FDA") conducted an inspection of your seafood processing facility located at 714-720 Towne Avenue, Los Angeles, California. At the conclusion of these inspections, you were presented with Form FDA 483 listing significant deviations from Title 21 of the Code of Federal Regulations ("21 CFR") Part 123 - Fish and Fishery Products Regulation, and 21 CFR Part 110 - Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food. Based on these deficiencies, the products processed at your facility are adulterated within the meaning of Section 402 (a)(4) of the Food, Drug and Cosmetic Act ("the Act").

Specifically, our investigator found the following deficiencies, related to ready-to-eat, vacuum-packaged, broiled, steamed and fried fishcake products that are stored and sold as refrigerated products:

1. You must have a written HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for vacuum-packaged, cooked, ready-to-eat fish cakes called "Tenpura", "Chikuwa" and "Kamaboko" lists a critical limit of an internal temperature minimum of [REDACTED] F at the cooking critical control point that is not adequate to control *Clostridium botulinum* toxin formation. In addition, your firm's HACCP plan for cooked, ready-to-eat, vacuum packed fishcakes, made from surimi, lists a critical limit of [REDACTED] at the cooling area critical control point that is not adequate to control pathogen growth. To control pathogen growth during cooling after a cooking process, FDA recommends that the internal temperature of the product should generally be cooled from 140°F to 70°F or below within two hours and to 40°F or below within another four hours.

To control *Clostridium botulinum* toxin formation, we do not know of any scientific basis that the critical limit of [REDACTED] F internal temperature for the "cooking process" critical control point ("CCP") found in your HACCP plan will destroy the spores *Clostridium botulinum* type E and nonproteolytic type B and F. Moreover, a temperature parameter alone (e.g. [REDACTED] F internal temperature) is not sufficient to ensure proper thermal processing of the products; the time that the products are subjected to this temperature would also be necessary.

We feel that your cook step of [REDACTED] F internal temperature (provided you specify an appropriate length of time the products are subjected to this temperature) would be sufficient to control non-sporeforming pathogenic bacteria, but would be insufficient to control sporeforming bacteria such as *Clostridium botulinum*. Documentation such as a scientific study must be provided if you choose to continue using this step, to control *Clostridium botulinum*.

Other inhibitory mechanisms are available to control the development of *Clostridium botulinum* toxin formation in your products, such as controlling the water activity (a_w) of 0.97 or below, the salt level of your product at 5% or above, or a pH of the product at or below 5.0. Any control measure that you choose should have adequate verification to document that it will accomplish its intended function to eliminate this food safety hazard. Please note that two samples collected at your firm on December 15, 2000, Fried Fish Balls and Steamed Fish Cakes were analyzed and found to contain water activities [REDACTED]

If you are unable or unwilling to conduct these scientific studies, or cannot design your operations to consistently adhere to one of the inhibitory levels described in the paragraph above, it would appear that refrigeration is your sole barrier for *Clostridium botulinum* toxin formation. As such, refrigerated storage would need to be strictly controlled at 38 °F or below. Based on the current practices and abuses at the retail and consumer level of distribution, controlling the temperature at 38 °F or below is not possible. Therefore, if refrigeration is the sole barrier for *Clostridium botulinum* toxin formation, this product should be frozen and labeled to be held frozen and to be thawed under refrigeration immediately before use, or to break the vacuum seal (e.g., important, keep frozen until used, thaw under refrigeration; or vacuum seal must be broken when thawed).

2. You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11 (b). However, your firm did not monitor your processing facility adequately, as evidenced by the serious sanitation deficiencies noted during the December, 2000 inspection. These conditions included:
 - Employees were observed not washing or sanitizing their hands after breaks or after touching non-sanitized surfaces. These employees were then observed working in direct contact with unpackaged, ready-to-eat fishcake products.
 - Equipment is not being cleaned or sanitized properly. Observed cleanup of your mixing machine and extruder assembly on 12/14/00 found that no soaping agent or sanitizer is used.
 - Thermally processed fishcake products before packaging were observed being placed on a non-sanitary surface.

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- Unlabeled sanitizer was observed in the processing area during fishcake manufacturing operations.
 - Sanitizers that are being used are not being prepared or monitored to ensure that these are safe and appropriate for their intended uses, and do not contribute to contamination of in-process fishery products.
3. You must properly implement your HACCP plan in order to comply with 21 CFR 123.6(b). However, your firm did not record all monitoring observations as listed in your HACCP plan for fried vacuum packed fish balls to control the hazards of pathogen growth and metal fragments. Monitoring records were missing: 1) at the cook critical control on 12/14/2000 between 5:00 am and 8:00 am, 2) at the cooling critical control point on 12/14/2000 at 10:30 and the day of 9/25 & 28/2000, and 3) at the cooler and metal detection critical control points since 11/15/2000.

The above-cited violations are not intended to be an all-inclusive statement of the deficiencies that may exist with your HACCP plan(s). It is your responsibility to assure that all of your fishery products are processed in compliance with the requirements of the Act, seafood HACCP regulations, and the Good Manufacturing Practice for Foods 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.

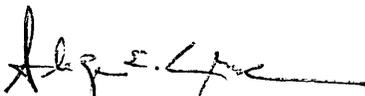
Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within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

Your written reply should be directed to:

Director, Compliance Branch
U.S. Food & Drug Administration
1990 MacArthur Blvd, Suite 300
Irvine, CA 92612-2445.

We request that your firm contact this office to arrange a meeting with us at our District Office in Irvine, CA to discuss the serious nature of the violations found at your firm over the past several inspections, and to review and discuss your HACCP plan in detail. We request this meeting as soon as possible. You may schedule this meeting by calling the District Director's office at (949) 798-7774.

Sincerely,



Alonza E. Cruse
District Director
Los Angeles District