



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

WARNING LETTER

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 27, 2001

W/L 43-01

Anderson Vuong, President
Meiko Food Company, Inc.
2526 Chico Avenue
South El Monte, California 91733

Dear Mr. Vuong:

We inspected your firm, located at 2526 Chico Avenue, South El Monte, California, on January 10 and 11, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123) and the Current Good Manufacturing Practice regulations (21 CFR Part 110). These deviations, some of which were previously brought to your attention, cause your ready-to-eat, vacuum-packaged, boiled and fried fishcake products that are stored and sold as refrigerated products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. Some of your products are also misbranded within the meaning of Section 403 of the Act, and the Food Labeling Regulations (21 CFR 101). You can find this Act and the applicable regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

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 refrigerated, vacuum-packaged, cooked, ready-to-eat fishcake products lists a critical limit of an internal temperature minimum [REDACTED] at the cooking critical control point that is not adequate to control *Clostridium botulinum* toxin formation.

It appears that your thermal process step [REDACTED] could be sufficient to control non-sporeforming pathogenic bacteria in your vacuum-packaged fishery products, and you should continue to have and implement this CCP to control these types of pathogens. However, a thermal processing step would be insufficient to control sporeforming bacteria such as *Clostridium botulinum*. We do not know of any scientific basis that a thermal process would be sufficient to control *Clostridium botulinum* type E and nonproteolytic type B and F for unpackaged products that are air-cooled and handled prior to packaging, as your products are. Documentation such as a scientific study must be provided if you choose to continue using this step to control *Clostridium botulinum*.

Other inhibitory strategies 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.

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 January, 2001 inspection. These conditions included:
 - a) Improper storage of un-packaged, exposed finished products in walk-in cooler in close proximity to uncovered, raw in-process fish paste. The conditions observed in the cooler were such that cross contamination is likely from raw to cooked.
 - b) Improper storage of in-process fish balls after the cooking process. Shallow totes containing cooked, exposed fish balls were observed being placed on dirty cardboard surface. These totes are designed with numerous air holes, allowing contact of the cooked product with this non-sanitary surface.
 - c) No hand sanitizer present for processing employees handling un-packaged, ready-to-eat fishcake products on 1/10/01.
 - d) An employee was observed handling non-sanitary objects, then handling in-process fish paste without first cleaning and sanitizing his hands.
3. You must properly implement your HACCP plan in order to comply with 21 CFR 123.6(b). However, on several occasions during the January 2001 inspection, our Investigators found that you were not monitoring designated critical control points. These CCP's included:
 - a) Receiving Shrimp (monitoring for sulfites in shrimp)
 - b) Thawing (monitoring length of time product is exposed to unrefrigerated conditions)

- c) Cooking (monitoring the length of time and internal temperature)
 - d) Cooling (monitoring the time and internal temperature of cooling product)
 - e) Cooler (monitoring of the cooler and freezer temperatures).
4. You must have a HACCP plan(s) that lists the monitoring procedures necessary to provide adequate control for each critical control point, in order to comply with 21 CFR 123.6 (c)(4). However, your monitoring procedures are deficient as follows:
- a) Monitoring procedures listed for the critical control point "cooking" are not sufficient. Your plan states that monitoring frequency for the minimum internal temperature of your products will be [REDACTED]. This frequency seems to be a contradiction in terms, neither of which (e.g. [REDACTED]) would be sufficient. It is our opinion that you should monitor the minimum internal temperature and the time of cooking for each batch of product manufactured, to ensure adequate control over the food safety hazard of pathogen survival through cooking (i.e. for pathogens other than *Clostridium botulinum* – see item #1)
 - b) Monitoring procedures listed for the critical control point "Cooler For Packaged Products" are not sufficient as listed at "Visual Check Once Daily". These temperatures should be checked either continuously using an appropriate continuous recording device, or more frequent visual checks using an adequate temperature recording device to ensure that the cooler is at or below your critical limit throughout the processing day.

LABELING:

A review of your finished product labels reveals that some of your products are considered misbranded within the meaning of Section 403 of the Act, and the Food Labeling Regulations (21 CFR 101). Specifically:

Failure to include the common or usual name of each ingredient used in your multi-component seafood products, as required under section 403(i)(2) of the Act, and 21 CFR 101.4(b)(2). For example:

- a) Six of your firm's ten retail labels list the ingredient "FISH" as the predominant ingredient, and fail to list the common or usual name of the fish, fishes, or fishery product used, most likely either Ladyfish, pollock surimi or whiting surimi. Pursuant to 21 CFR 101.4(b)(23), you may list fish protein ingredients in the ingredient statement by stating the specific common or usual name of each fish species that may be present in parentheses following the collective name "fish protein", e.g. "fish protein (contains one or more of the following: Ladyfish, pollock surimi and/or pacific whiting surimi)".

However, if surimi is used as a raw material, and/or you label the ingredients as above, you must list all sub-ingredients of this multi component food. Pursuant to 21 CFR 101.4(b)(2)(i), you may either list these sub-ingredients parenthetically after the "surimi" ingredient declaration, or pursuant to 21 CFR 101.4(b)(2)(ii) each sub-ingredient can be listed within the ingredient statement, according to their predominance by weight, without listing the ingredient itself.

- b) Several of your products bear the term "fillet" in the ingredient statement. "Fillet" is not the common or usual name of an ingredient.

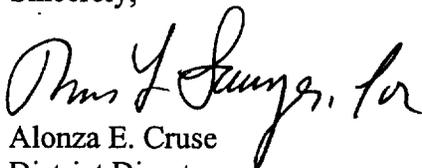
The above-cited violations are not intended to be an all-inclusive statement of the deficiencies that may exist with your HACCP plan(s). It is your responsibility to assure that all of your fishery products are processed in compliance with the requirements of the Act, seafood HACCP regulations, and the Good Manufacturing Practice for Foods and the Food Labeling regulations 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 respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan(s), revised CCP monitoring records with actual monitoring data, and revised sanitation monitoring records showing the time the data was recorded, or other useful information that would assist us in evaluating your corrections. 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.

We acknowledge your response dated 6/17/98 to the letter sent to your firm covering the initial inspection of 4/26-28/98. Your response, however, does not address all HACCP deficiencies and other deficiencies found during our most recent inspection, and as evidenced by the aforementioned items.

If you have any questions relating to this letter you should contact Robert B. McNab, Compliance Officer, at (949) 798-7709. Your written reply should be directed to Mr. Thomas L. Sawyer, Director, Compliance Branch, U.S. Food & Drug Administration, 19900 MacArthur Blvd, Suite 300, Irvine, CA 92612-2445.

Sincerely,



Alonza E. Cruse
District Director
Los Angeles District