



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

24526d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 2915995

February 4, 2004

Soren P. Sorensen, President
Rel's Foods Inc.
4681 Telegraph Avenue
Oakland, California 94609

WARNING LETTER

Dear Mr. Sorensen:

On November 4, 10, and 12, 2003, we inspected your processing facility located at 975 W. Grand Avenue, Oakland, California. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or to otherwise operate in accordance with the requirements of 21 CFR Part 123, renders the fishery products **adulterated** within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly your tuna salad sandwiches are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov. See the attached handout explaining how you can obtain a copy of the Fish & Fisheries Products Hazards and Controls Guidance, 3rd edition, June 2001.

The deviations observed were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and you must have a written HACCP plan for tuna salad sandwiches to control the food safety hazard of pathogen growth, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for tuna salad sandwiches to control the food safety hazard of pathogen growth and toxin formation as a result of time/temperature abuse. We acknowledge receipt of your letter of November 10, 2003 stating that your firm will immediately begin preparation of an appropriate HACCP program.

2. You must maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by 21 CFR 123.11(b), to comply with 21 CFR 123.11(c). However, your firm does not maintain the following sanitation monitoring records, which are required for the processing of tuna sandwiches to control the food safety hazard of pathogen growth and toxin formation as a result of time/temperature abuse:
 - Safety of the water
 - Condition and cleanliness of food-contact surfaces
 - Prevention of cross-contamination
 - Maintenance of hand washing, hand sanitizing, and toilet facilities
 - Protection of food, food packaging material, and food contact surfaces from adulteration with contaminants
 - Proper labeling, storage, and use of toxic compounds
 - Control of employee health conditions that could result in microbiological contamination, and
 - Exclusion of pests from the facility.
 - You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b).

3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm failed to monitor prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, as evidenced by FDA observation of a wet, balled-up paper towel on your firm's [REDACTED], which was fabricated to act as a tension pulley support for your conveyor belt.

At the conclusion of the inspection, the observed deviations were listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the Seafood HACCP Regulations, and the Current Good Manufacturing Practice Regulations (21 CFR 110).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation 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.

Please send your reply to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', with a long horizontal flourish extending to the right.

Charles M. Breen
Acting District Director
San Francisco District

Enclosures:

- Handout on Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001
- Form FDA 483