



94185J

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

VIA FEDERAL EXPRESS

Our Reference: 2939642

July 31, 2003

Gary Berndt, Chief Operating Officer
LSG Sky Chefs
Sky Chefs, Inc.
6191 North State Highway 161
Irving, Texas 75038

WARNING LETTER

Dear Mr. Berndt:

On March 7 and 25, 2003, we inspected your processing facility, located at 385 Commercial Street, San Jose, CA. 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).

We acknowledge receipt on June 11, 2003 of a revised HACCP Plan for Tuna Salad Sandwiches from Eleanor Garlit, LSG Cky Chefs, San Jose, CA, updated on April 7, 2003. This letter is based on the March 2003 inspection and review of this revised April 7, 2003 HACCP Plan.

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 otherwise operate in accordance with the requirements of this part, 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 sandwich product is adulterated, in that the product has been prepared, packed, or held under insanitary conditions whereby it 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.

The deviations 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 have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR 123.3(b) as a "point, step, or procedure

in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.” However, your firm’s HACCP plan for Tuna Salad Sandwiches does not list the critical control points of preparation and finished product storage for controlling the food safety hazards of histamine and pathogen formation.

2. You must maintain sanitation control records that, at a minimum, document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for

- 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

required for the processing of tuna salad sandwiches on the following dates:
February 12 to 18, 2003 and February 21 to March 15, 2003.

3. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However your firm’s monitoring records do not list all eight areas of sanitation as specified in 21 CFR 123.11(b).
4. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR 123.3(f) as “any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.” However, your firm’s revised HACCP Plan for Tuna Salad Sandwiches does not specifically list the food safety hazards of histamine formation and pathogen growth. Histamine formation is a chemical hazard and pathogen growth is a biological hazard.

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 15 working days from your 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 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.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulations and the Current Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed 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,

Charles D. Moss, Acting DD

for

Dennis K. Linsley
District Director
San Francisco District

cc: VIA FEDERAL EXPRESS
Robert M. Templin, General Manager
LSG Sky Chefs
385 Commercial Street
San Jose, CA 95112
(408) 971-3034