



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

November 3, 2003

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 04-07

Sonia L. Andrus, Owner
Steven Andrus, Owner
Napoleon Deli, Incorporated
439 Portland Avenue
Gladstone, Oregon 97027

WARNING LETTER

Dear Mrs. and Mr. Andrus:

On October 8 and 9, 2003, we inspected your firm, located at 439 Portland Avenue, Gladstone, Oregon. 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 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 sandwiches are adulterated in that the products 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 can find the Act, the Seafood HACCP regulations and the Fish and Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001 (the Hazard Guide), through links in FDA's homepage at www.fda.gov.

The deviations are 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 to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a), and (b). However your firm does not have a HACCP plan for tuna sandwiches to control the food safety hazards of pathogen growth and allergens. This deviation was previously brought to your attention in our letter of March 29, 2000.**

Sonia L. and Steven Andrus, Owners
Napoleon Deli, Incorporated, 439 Portland Avenue, Gladstone, Oregon 97027
Re: Warning Letter SEA 04-07
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We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks 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 completed HACCP plan 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.

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 Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Michael J. Donovan, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Donovan at (425) 483-4906.

Sincerely,



Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: OSDA with disclosure statement