



7/12/99

PURGED *PH*

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

August 26, 1999

WARNING LETTER

cc: HFI-35
DWA

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 43

James A. LePine
President
Avanti Foods Corporation
605 South 94th Street
Milwaukee, Wisconsin 53214

Dear Mr. LePine:

The Food and Drug Administration (FDA) conducted an inspection of your seafood salad and seafood sandwich manufacturing operations at the above facility on June 8-9, 1999, to determine your compliance with the seafood HACCP and GMP regulations denoted in Title 21, Code of Federal Regulations, Parts 123 and 110 (21 CFR 123 and 110). At the conclusion of the inspection the FDA investigator issued a list of inspectional observations on form FDA-483 and discussed them with you.

You are required to have a written HACCP plan to control any food safety hazards that are reasonably likely to occur (21 CFR 123.6(b)). However, your firm does not have a HACCP plan for tuna salad products to control the food safety hazard of pathogen growth due to time/temperature abuse.

You are required to have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). However, your sanitation control records do not document the monitoring for the prevention of cross-contamination, maintenance of handwashing/sanitizing and toilet facilities, protection of food and food packaging material and food contact surfaces from adulterants, proper labeling and storage and use of toxic compounds, and control of employee health conditions.

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James A. LePine
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It was also noted that you have failed to establish Standard Sanitation Operation monitoring records. Please refer to form FDA-483 of June 9, 1999, for a more detailed listing of the objectionable findings.

The listing of these inspectional observations is not intended to be an all-inclusive listing of the violations at your facility. As the most responsible individual at the facility you are responsible for ensuring your operations are in compliance with both local and federal requirements.

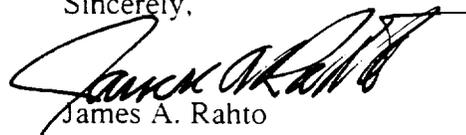
These findings cause the seafood products manufactured at your facility to be adulterated according to Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that they were manufactured and held under conditions whereby they may have been rendered injurious to health. The adulteration of previously unadulterated food after shipment in interstate commerce that is held for sale, and the shipment of adulterated food in interstate commerce, is prohibited by Section 301 of the Act.

Within 15 working days of receipt of this letter please provide a written response detailing the actions you have taken to correct these violations and prevent their recurrence. Also include a timeline as to the projected completion dates for these corrective actions so we may re-inspect to verify the effectiveness of your correction action plan.

If you fail to take timely corrective actions, FDA may initiate legal actions against you and/or your products in the form of injunction and/or product seizure.

Your response and any questions you may have regarding this matter may be directed to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead or (612) 334-4100 x. 177.

Sincerely,



James A. Rahto
Director
Minneapolis District

TPN/rfk