



M4292 n

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

PURGED RJK

October 13, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 04

William P. Harvey
President
Neptune Sandwiches
4706 W. State Street
Milwaukee, Wisconsin 53208

Dear Mr. Harvey:

We inspected your firm located at 4706 W. State Street, Milwaukee, WI, on August 28-30, 2000, and found serious deviations of the seafood HACCP regulations (Title 21, Code of Federal Regulations, Part 123 [21 CFR 123]). These deviations, some of which were previously brought to your attention, cause your tuna salad sandwiches to be in violation of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links on FDA's homepage at www.fda.gov.

The deviations associated with your tuna salad sandwich operation are as follows:

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(b). However, your firm does not have a HACCP plan for seafood sandwiches to control the food safety hazards of introduction/growth of pathogens during manufacture and storage of ready-to-eat tuna sandwiches.

You must maintain sanitation control records to comply with 21 CFR 123.11(c). However, your firm does not maintain sanitation control records for the manufacture and storage of ready-to-eat tuna sandwiches.

The product is also misbranded within the meaning of Section 403(q)(1) of the Act in that the label fails to bear nutrition labeling as required by 21 CFR 101.9 and is not exempt from this requirement.

Page Two

William P. Harvey
October 13, 2000

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 actions you are taking to correct these deviations. You may wish to include documentation such as your tuna salad sandwich HACCP plan, standard sanitation operating procedure monitoring record format, and any other useful information that will assist us in evaluating your corrective actions. If you cannot complete all corrective actions 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 Good Manufacturing Practice regulations of 21 CFR 110. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your response to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead. If you have any questions regarding this matter you may direct them to Mr. Nelson at (612) 334-4100 ext. 177.

Sincerely,


James A. Ranto
Director
Minneapolis District

TPN/ccl