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Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

November 15, 2001

WARNING LETTER

CHI-9-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Frank Ryser, President
PDI Distribution Plus, Inc./Skandia Foods
615 East Brook Drive
Arlington Heights, IL 60005-4691

Dear Mr. Ryser:

On August 9 and 13, 2001, the Food and Drug Administration (FDA) conducted an inspection of your facility. The inspection was conducted to determine your firm's compliance with the FDA's seafood processing regulations (Title 21, Code of Federal Regulations (CFR), Part 123).

During our inspection, the FDA investigator observed continued deviations from the Import seafood HACCP requirements.

The FDA investigator also provided you with a copy of the Import Seafood HACCP Report (Form FDA 3502), which presents his evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observations of concern to us are as follows:

- You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for herring from [REDACTED].
- You must implement an affirmative step that ensures the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for ready to eat herring manufactured and imported from [REDACTED].

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility. We are aware that you have taken some steps to correct the deviations per your letter of August 27, 2001 and attachments.

Please notify this office in writing within 15 working days of receipt of this letter of further specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply relating to these concerns should be directed to the attention of Paul Boehmer, Compliance Officer.

If you have questions regarding the implementation of the HACCP regulations, you may contact Darrell Luedtke at our Gurnee, Illinois Office, telephone (847) 249-8632, for answers and/or direction towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP program.

Sincerely,

\s\

Raymond V. Mlecko
District Director