



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

December 3, 2001

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-12

Mr. Byung Park, Owner  
Pal Do World  
8730 South Tacoma Way  
Tacoma, Washington 98499

**WARNING LETTER**

Dear Mr. Park:

On October 30, 2001, Investigator Mark E. Moen conducted an inspection of your firm. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations [21 Code of Federal Regulations (CFR) 123]. The seafood processing regulations, which became effective on December 18, 1997, require that you have and implement written verification procedures to verify that your foreign suppliers have implemented a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP) in accordance with U.S. requirements.

The products covered during this inspection were frozen fish cakes from [REDACTED] and frozen round, yellow croaker from [REDACTED]

At the conclusion of that inspection a list of violations (Form FDA 483) was presented to Mr. Seung Y. Lee, Systems Manager. These HACCP violations cause your imported products to be adulterated within the meaning of 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. Specifically,

**You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health in order to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for frozen fish cakes and frozen round, yellow croaker from Korea.**

The above HACCP violations are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the HACCP violations. Failure to promptly correct these violations may result in regulatory action without further notice such as seizure and/or injunction. Furthermore, your firm and the foreign

Mr. Byung Park, Owner  
Pal Do World, Tacoma, Washington  
Re: Warning Letter SEA 02-12

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processor may be placed on import alert and future shipments of the product may be subject to detention without physical exam.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply to these concerns should be addressed to Thomas S. Piekarski, Compliance Officer, at the address given above.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', written over a horizontal line.

Charles M. Breen  
District Director

Enclosures:  
FDA 483  
21 CFR 123.12