



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94805d

Food and Drug Administration

San Juan District
Compliance Branch
466 Fernández Juncos Avenue
San Juan Puerto Rico 00901-3223

Telephone: 787-474-9500
FAX: 787-729-6658

June 18, 2004

WARNING LETTER

SJN-04-09

Certified Mail
Return Receipt Requested

Jacinto Vergel, President
Vizcaya Foods, Inc.
P.O. Box 50988
Toa Baja, Puerto Rico 00950-0988

Dear Mr. Vergel:

On March 11, 13 & 17, 2004, the Food and Drug Administration (FDA) conducted an inspection of your importing operation located at Road 869, Parque Industrial Barrio Palmas, Bldg. M, Cataño, Puerto Rico. During our inspection, the FDA investigator documented serious deviations from FDA's seafood processing regulations under Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause the dried/salted Pollock fillets, and imitation crab flakes imported by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood processing regulations through links in FDA's home page at www.fda.gov.

The deviations of concern to us are as follows:

1. 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 dried Pollock fillets, and imitation crab flakes, made with Pollock/Whiting fish and other seafood ingredients (some of these are vacuum packed) imported from and/or
2. You must implement an affirmative step which ensures that the fish and fishery product(s) 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 imitation crab flakes and Pollock fillets imported from

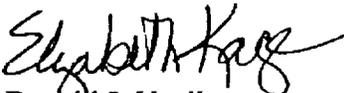
The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. Other violations can subject the food to legal action. It is your responsibility to ensure that all seafood products imported, processed, and/or distributed by your firm are in compliance with 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.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, and to prevent their recurrence. 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 within which the corrections will be completed.

Your written reply should be addressed to the Food and Drug Administration, attention: Carlos I. Medina, Compliance Officer, at 466 Fernández Juncos Avenue, San Juan, Puerto Rico 00901-3223. If you have any questions concerning the violations noted please contact Mr. Medina at (787) 474-9539.

Sincerely,


for Donald J. Voeller
District Director
San Juan District

Enclosure