



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35  
Public Health Service

Central Region

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Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

Telephone (973) 526-6001

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED  
September 1, 2000

WARNING LETTER

Mr. Louis Puskas  
President  
Viking Village Inc.  
19<sup>th</sup> and Bayview  
Barnegat Light, NJ 08006

FILE NO: 00-NWJ-51

Dear Mr. Puskas:

On May 15-17, 2000, the Food and Drug Administration (FDA) conducted an inspection of your seafood processing facility located at the above address. The inspection was conducted to determine compliance with FDA's seafood processing regulations (Title 21 of the Code of Federal Regulations (CFR) Part 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110). The inspection documented deficiencies which cause your scombrototoxin-forming seafood processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

1. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Receiving Critical Control Point (i.e. core temperature of fish) and the Box and Ice Critical Control Point (i.e. quantity of ice) to control the histamine formation listed in your HACCP plan for scombrototoxin-forming species of fish (bluefish, herring, chub mackerel, shad, shad roe, gizzard shad, bonito, false albacore, boho, skipjack, jack, blue runner, mackerel, spanish mackerel). Specifically, you did not record the quantity of ice for the bluefish, shad roe, chub mackerel, mackerel, and/or herring you boxed from April 28, 2000 to May 9, 2000 and May 11, 2000 to May 15, 2000.
2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for scombrototoxin-forming species of fish (bluefish, herring, chub mackerel, shad, shad roe, gizzard shad, bonito, false albacore, boho, skipjack, jack, blue runner, mackerel, spanish mackerel) lists the critical limits, "If fish are delivered ~~12~~ hours or more after death, an internal temperature of ~~40~~ degrees F. or below and if fish are delivered ~~12~~ or more hours after death, an internal temperature of ~~40~~ degrees F or below", at the receiving critical control point. These critical limits are not adequate to control scombrototoxin (histamine) formation. Adequate receiving critical limits would also include parameters for harvest vessel records or histamine testing and sensory evaluation.

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 may include seizure or injunction under the Act. In addition, failure to correct the above deficiencies may affect your firm's ability to obtain European Union (EU) certificates. As you know, FDA, as a service to the U.S. seafood industry to facilitate the free flow of trade, has voluntarily undertaken to certify that seafood exports meet the EU food safety requirements. Unless the above deficiencies are corrected, FDA may remove your firm from the EU list. In addition, until these deficiencies are corrected, the agency may not issue EU certificates for shipments.

Please notify this office within 15 working days of receipt of this letter. 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 written reply should be directed to the Food and Drug Administration, Attention: Diane B. Radice, Compliance Officer, FDA, 10 Waterview Blvd., Parsippany, NJ 07054, telephone (973) 526-6006.

Sincerely,

*Edward H. Wilkins, for*  
Douglas I. Ellsworth  
District Director  
New Jersey District

slm:DBR