

SEATRADE



January 24, 2005

Dockets Management Branch (HFA-305)
Attn: Docket No. 2004D-0510
Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, MD 20852

Re: Comments on Draft Guidance Entitled "Proposed Referral Program From the Food and Drug Administration To The National Oceanic and Atmospheric Administration Seafood Inspection Program For The Certification of Live and Perishable Fish and Fishery Products For Export To The European Union And The European Free Trade Association (Docket No. 2004D-0510)"

Dear Sir/Madam,

We are a processor and exporter of both fresh and frozen scallops, monkfish, skatewings, and dogfish with two plants located in New Bedford, MA, and another facility in Portsmouth, NH. All our production plants operate under the FDA's HACCP (Hazard Analysis Critical Control Point) Program and are inspected by the FDA on a regular basis. Our company has been in existence since 1982, and we employ app. 100 people in our two New Bedford plants where most of the production of fresh fish and scallops is slated for daily export to Europe. These export shipments represent app. 25% of our total sales and are vital to our business. Our production facilities provide much needed jobs in a declining industry which continues to experience great difficulties.

However, our ability to compete in the European fresh seafood market is dependent not only on the quality of our seafood but on other factors as well. It is a business that changes from minute to minute - orders come in early in the morning but often are revised depending on the quality of the fish, available space on airplanes and customer requirements. We have participated in the FDA Export Certification Program for the European Union for most of its existence, initially at the urging of the FDA New England District Office, and have been a member in good standing during this time. When we switched from the USDC In-plant Inspection Program to the program provided by the FDA, we came to appreciate the flexibility that it gives us, which is of tremendous importance in our trade. One small example helps to illustrate my point: this past

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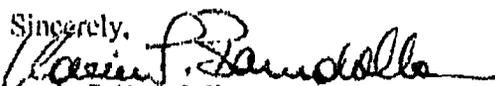
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Saturday when it became apparent that the New England area would be hit by a major snowstorm, we were able to change the departure of our weekend orders to Europe from the usual Sunday to Saturday which meant that our customers were able to receive their product because Logan Airport was closed on Sunday. We were able to do this because we had pre-signed FDA Export Certificates at our disposal that could be used for Saturday. Had we had to rely on a NOAA/NMFS Inspector to come to perform the inspections and issue certificates, we would have most likely lost the ability to ship because on a weekend it is practically impossible to change an inspection that has been arranged for a certain day.

We understand fully that the issuance of export certificates for fresh seafood puts a burden on the FDA staff. The program has proved to be very effective and is used by most exporters in our area because it allows the participating seafood companies to obtain pre-signed export certificates from the FDA, thereby allowing them to react swiftly to their export orders. This flexibility is absolutely essential for New England seafood exporters to remain competitive and responsive to their customers' needs; in fact, at this point it would prove to be almost impossible to be a successful exporter without the FDA program. However, it appears that the success of the program is stretching the FDA's resources in our area. We would suggest that this situation could be remedied by the hiring of additional staff for the New England District office; exporters could be charged an affordable fee for each certificate that is issued, e.g \$10-15/certificate to help pay for the added personnel. Our business would, however, not be able to absorb the cost of inspection should we have to revert back to the NOAA/NMFS In-plant Inspection Program which is considerably more expensive, considerably less flexible, and considerably more time-consuming than the current FDA program. Another possibility could be an on-line system whereby the FDA would approve the shipment, and we would print a laser version of the certificate with a signature; again a small fee could help defray the cost. Random inspections by a FDA inspector would ensure the quality of the program.

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The proposed referral program is of utmost concern to us because we fear that it will destroy our business, and we therefore urge you to reconsider this proposal and to leave the current procedure intact since it works well and its continued existence is of vital importance to the seafood companies who export fresh and live seafood to Europe. We appreciate your consideration and would welcome an opportunity to voice these concerns in personal discussions with the FDA staff.

Sincerely,

Karin S. Barndollar
Export Manager

Cc The Honorable Senator Judd Gregg
The Honorable Senator John Sununu
The Honorable Congressman Ed Bradley
The Honorable Congressman Charles Bass