Dockets Management Branch (HFA-305)
Attn: Docket No. 2004D-0510
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852
December 9, 2004

Garbo Lobster
We put our name on it

RE: REQUEST FOR EXTENSION OF COMMENT PERIOD
[DOCKET NO. 2004D-0510]

Dear Sir or Madam:

In accordance with 21 C.F.R. 10.40, I am requesting a 90-day extension of the comment period for the Notice announcing the "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", published in the Federal Register on November 21, 2004 (p.68948).

The purpose of this Notice was to inform exporters of live and perishable fish products that the Food and Drug Administration (FDA) intends to transfer its EU certification activities to the National Oceanic and Atmospheric (NOAA) Office of Seafood Inspection (SIP). The stated purpose of this proposal is to "expedite the exportation of live and perishable fish and fishery products" from the U.S. to the EU. Once the referral program goes into effect, the FDA would cease issuing EU Health Certificates for live and perishable fish products for a period of two years.

Garbo Lobster Company Inc., a Connecticut-based U.S. owned company, exports more than $50 million worth of live lobsters to the EU annually. We purchase millions of pounds of lobsters from fishermen all along the New England coast from Maine to Connecticut, which are shipped to the EU on an almost daily basis. Garbo Lobster employs more than 50 workers in our Groton, Connecticut and Hancock, Maine facilities, not including the large number of independent contractors we use to transport our products. All of our U.S. facilities are registered with and regularly inspected by the FDA. Our company has been on the Approved Shippers List to the EU (or EU Export Certificate List) for more than a decade and on average we receive approximately 100 a month from the FDA New England District. We have worked extremely hard to build one of New England's largest lobster export companies.

The live lobster export business is extremely time-sensitive due to the perishable nature of our product and the amount of lead time we are given by our customers. Lobsters can only survive in shipping cartons for a very limited period and this requires us to pack, transport and ship our product as quickly as possible. And typically, we do not receive final orders from our customers until 4 am of the day we are expected to ship. We go to great lengths to arrange our shipments to ensure that our customers receive the highest quality of product on time. Because of the value of our shipments (usually in the tens of thousands of dollars) we can not afford any disruptions or delays in the supply chain. A flat tire on a truck, a cancelled air line flight or the lack of an EU Health Certificate can mean the loss of a shipment or even worse, the loss of a customer. In this regard we have developed a very good working relationship with the FDA over the years to ensure that we have the proper EU Health Certificates available to us when we need them.

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Garbo Lobster Limited Deer Island New Brunswick Canada

We are extremely concerned about the proposed referral program and the devastating impact this could have on our business. Any significant change in the way export certificates are issued to our company (and to other exporters as well) could ruin our business and eliminate a lucrative export market for New England lobstermen. While the Draft Guidance to Industry states the referral program is intended to "expedite the exportation of live and perishable fish and fishery products" it could have the opposite effect. Specifically, the Draft Guidance proposes that NOAA's SIP issue EU Export Certificates but provides no details on how this will be done. The Draft Guidance provides a very general discussion of NOAA's SIP role [NOAA's SIP will issue requested EU Export Certificates on a fee-for-service basis to establishments] but provides no assurances that the same process employed by the FDA will be used by NOAA.

On June 2, 2000 FDA's New England District issued instruction for obtaining EU health certificates to the seafood industry in New England. Those very specific instructions (which remain in place today) provided a detailed process that enables Garbo Lobster to obtain the certificates we need to conduct our business and more importantly assurances that the FDA will issue certificates within a very short period of time of being requested. The Draft Guidance provides no such assurances. From our past experiences with NOAA's SIP we know for a fact that they follow a much different process and have different policies. Moreover, our initial contact with NOAA's SIP office in Gloucester, MA indicates that they are not prepared to handle the volume of requests for export certificates that this proposal would entail and DO NOT intend to follow the same process as currently employed by the FDA. This is extremely disconcerting!

It is critical that all affected parties have adequate time to examine the proposal and formulate meaningful responses. Unfortunately, the deadline for comments falls within the winter holiday season which, coincidentally, is the busiest time of the year for our industry. All of us involved in the EU export business will be working round the clock for the next several weeks. Because this change could literally cost my firm tens of millions of dollars I respectfully request a 90-day extension of the comment period, to March 27, 2005. I believe this extension is in the public interest as it would provide Garbo Lobster and other affected parties the ability to submit comprehensive comments on the proposed referral program.

Sincerely,

David Garbo
President