DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

December 12, 2012

Mr. John Williams
Executive Director
Southern Shrimp Alliance
P.O. Box 1577
Tarpon Springs, FL 34688

Dear Mr. Williams:

Thank you for your letter dated October 22, 2012, addressed to Dr. Margaret Hamburg, the Commissioner of Food and Drugs, expressing concerns with the safety of shrimp imported from Vietnam and providing information on refusals by the Food and Drug Administration (FDA or Agency) of Vietnamese seafood from 2007-2012.

Seafood safety issues, such as the use of unapproved chemicals and animal drugs in farm-raised fish products intended for human consumption, are among the Agency's greatest concerns and thus a top regulatory priority. The Agency is actively engaged in inspection, sampling, and testing of products imported to the United States which may contain unapproved drugs that would deem the fishery products to be unsuitable for use as human food.

Seafood products, shrimp products in particular, are among the most internationally traded food commodities. Shrimp imports represent 94 percent of the total shrimp consumed in the United States. The vast majority of shrimp comes from aquaculture operations in Asian countries and Vietnam is the fifth largest exporter of shrimp into the United States. Due to compliance concerns regarding farm-raised seafood encountered by FDA and reported by other countries, FDA regulatory effort has been directed toward ensuring that imports of those products do not contain harmful contaminants and are safe for American consumers. Vietnamese seafood, aquacultured shrimp products in particular, are subject to regular surveillance sampling and testing for unsafe levels of pesticides, industrial chemicals, dioxins, and unapproved animal drug residues.

All imports under FDA's jurisdiction electronically transmitted to the Agency via US Customs and Border Protection's Automated Commercial System (ACS) are screened by FDA prior to receiving an entry admissibility decisions for potential entrance into United States commerce. Different subsets of entry lines are inspected at varying rates depending on the potential risks associated with them. The information FDA gathers from country assessments, foreign inspections, and importer inspections also help to target the products the Agency chooses to examine more closely.

In Fiscal Year 2012 (FY 12), FDA oversaw more than 885,000 entry lines of seafood products from more than 140 countries, including over 104,000 entry lines of shrimp and

shrimp products. Shrimp imports from Vietnam accounted for approximately 5,560 entry lines. FDA collected approximately 973 samples of shrimp and shrimp products from 35 countries, including 83 samples from 67 lines from Vietnam. FDA samples of shrimp and shrimp products may be analyzed for filth, pesticides, heavy metals, animal drug residues, food and color additives, microbiological contamination, and/or decomposition.

Regulatory enforcement actions were taken against entries where positive samples were detected. Seafood products originating from Vietnam are subject to more than 14 separate Import Alerts (IA). Import Alerts direct FDA personnel to collect samples based on specific concerns that have been identified from various sources such as foreign and domestic inspections, past sample results, information from local, state, Federal, and foreign regulatory agencies, as well as consumer complaints. A list of all IAs for Vietnam can be found on the FDA website at: http://www.accessdata.fda.gov/cms_ia/country_VN.html

Positive results for drug residues found in shrimp imports from Vietnamese firms resulted in those entries being detained and violators were added to IAs 16-124 and 16-129. Currently, there are seven firms, manufacturers/shippers of shrimp products, listed on IA 16-124 for violative shrimp products. In FY11 there were five firms on the IA. To gain entry of subsequent shipments, these firms must adequately demonstrate that the product offered into the United States complies with FDA laws and regulations and is not contaminated with unapproved animal drug residues.

In May 2012, FDA conducted an assessment of Vietnam's aquaculture industry. During the assessment FDA looked at a variety of aquaculture products that are exported to the United States. The FDA team worked with various Vietnamese government agencies responsible for aquaculture food safety, and met with aquaculture industry representatives, including shrimp farmers and shrimp processors. Observations and recommendations were made for several components in the supply chain including shrimp farms, processors, feed mills, and the national residue monitoring program.

The information collected during this assessment trip, and from inspections, testing and information from our counterparts in Canada and the European Union, will be considered regarding any further course of action to be taken to ensure safe shrimp products from Vietnam.

Thank you again for bringing your concerns regarding this issue to our attention.

Sincerely,

William R. Jones, Ph.D.
Acting Deputy Director
Office of Food Safety
Center for Food Safety
and Applied Nutrition