DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

FEB 29 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 expressing concerns with the safety of shrimp imported from Vietnam and providing detailed information on recent incidents of adulteration of shrimp products produced for export in Vietnam as reported by other countries.

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 U.S. 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 U.S. The vast majority of shrimp comes from aquaculture operations in Asian countries and Vietnam is the fifth largest exporter of shrimp into the U.S. Due to compliance concerns regarding farm-raised seafood encountered by FDA and reported by other countries, the FDA regulatory effort has been directed toward assuring 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.

In Fiscal Year 2011 (FY 11), the Food and Drug Administration (FDA) oversaw more than 850,000 entry lines of seafood products from more than 150 countries, including over 97,500 entry lines of shrimp and shrimp products. Shrimp imports from Vietnam accounted for approximately 5,380 entry lines exported by 93 firms.

All imports are screened prior to entering into U.S. commerce and different subsets of entries 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 help to target the products the agency chooses to examine more closely. In FY 11, more than 740,000 entry lines of seafood products underwent an initial screening and 40,250 lines had been identified for further, more comprehensive examination.

FDA collected approximately 1,400 samples of shrimp and shrimp products from 36 countries, including 169 samples from Vietnam, for surveillance testing for pesticides, animal drug residues, microbiological contamination. A total of 680 analyses for unapproved chemicals and animal drug residues were conducted on 428 shrimp samples. Shrimp samples from Vietnam comprised 16% of the total number of samples analyzed.

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 (IAs). 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 Web site 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, five firms, manufacturers/shippers of shrimp products, are listed on IA 16-124 for violative shrimp products. To gain entry of subsequent shipments, these firms must adequately demonstrate that the product offered into the U.S. complies with FDA laws and regulations and is not contaminated with unapproved animal drug residues.

Through these sampling efforts and Import Alerts, more than 550 entries of imported shrimp and shrimp products were refused entry into the United States in FY 2011, 52 of which were refusals for shrimp and shrimp products imported from Vietnam. Refusals were based on findings and violations (or appearance of violations) including filth/decomposition, *Salmonella*, drug residues, unapproved food additives, and misbranding/mislabeling.

In addition to wharf exams and importer inspections, routine FDA inspections of foreign processors are carried out to verify their compliance with the HACCP regulations. In the last two years, FDA completed 13 inspections at foreign seafood processors in Vietnam and has 28 inspections planned in FY 12. In addition, inspections at domestic sites that may receive imported products from Vietnam are conducted.

Since FDA's last assessment in 2008, Vietnam's competent authority underwent organizational changes. Consequently, a number of regulatory Directives and Decisions that are legally enforceable in Vietnam, including Ministry of Fisheries Decision No. 29/2005/QD-BTS (November 1, 2005) that required all consignments of basa, tra, shrimp and crabmeat to be tested before shipment to the U.S., has not been extended or has been revoked. In May 2012, the agency is planning to send a team of aquaculture experts to Vietnam to assess current programs and strategies the country's government and industry implement and their ability to institute adequate food safety measures to control animal drug and chemical residues in aquaculture products intended for the U.S. market.

The information collected during assessment trips, from on-going inspections, testing and information from our counterparts in Canada and the European Union, will be considered in discussions of any further appropriate course of action that may need to be taken to assure safe shrimp products from Vietnam.

Thank you for contacting us with regards to this matter.

Sincerely,

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