DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

June 15, 2011

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

Dear Mr. Williams:

Thank you for your letter of May 24, 2011, addressed to Dr. Margaret Hamburg, the Commissioner of Food and Drugs, expressing concerns with imports of shrimp from India, particularly the shipments of shrimp products by GVR Exports Pvt. Ltd. and Sagar Grandhi Exports (P) Ltd.

The Food and Drug Administration (FDA) continues to share your concern regarding the unapproved use of nitrofurans in aquaculture and remains engaged in sampling, testing, and monitoring of imported products for these and other drug residues as well as other product defects that would cause the product to be unsuitable for use as human food.

We would like to take this opportunity to address the question you have posed, "If GVR Exports' /Sagar Grandhi's shrimp exports have been deemed problematic enough to be listed on Import Alert 16-129 and not exempted from Import Alert 16-35, why are substantial quantities of shrimp from this company continuing to be shipped to the US?

In order to address your question, we would like to explain FDA's import process and how an Import Alert (IA) affects shipments. IAs are used by the FDA to coordinate coverage of imports by FDA district offices. In most circumstances, firms and products that are identified on an FDA IA are detained by FDA upon entry based on past evidence of a violation. This action is referred to as Detention Without Physical Examination.

Please note that in addition to the IA described above there are different types of IAs, including the IA that identifies a specific manufacturer, shipper, grower, and product combination that FDA has documented to be violative. An example of this is IA #16-129, "Detention Without Physical Examination of Seafood Products Due to Nitrofurans." Some IAs list specific geographic areas that have been shown to be in violation of FDA rules and regulations. Depending upon the problem and the kind of evidence FDA has regarding imported products, the geographic region affected could be an entire country. This is referred to as a countrywide IA such as IA #16-35; "Detention Without Physical Examination of Raw and Cooked Shrimp from India."

Under Section 801(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the owner or consignee of the detained entry has the right to provide testimony that the subject shipment should be allowed entry into the U.S. A commonly used option is to hire a private laboratory to sample and test the commodity. If the analysis provides evidence that the entry is in compliance with U.S. laws and regulations, it may be released. For example, if a firm is on IA #16-129, the owner or consignee of the detained entry may collect a sample of the shrimp offered for entry into the U.S. and have the sample tested by a credible private laboratory. The test result must show that the consignment is free of nitrofuran before the shipment can be released and enter into U.S. commerce.

As part of this process, FDA reviews the analytical data submitted by private laboratories to determine whether import entries comply with the FD&C Act and can be released for sale. FDA needs to be assured that the scientific data presented is technically valid, has been obtained using sound methods of sampling and analysis, and has recognized quality assurance measures applied.

Therefore, while Sagar Grandhi Exports and GVR Exports are covered under IA #16-129, FDA may allow their shrimp to enter the U.S. market provided each shipment of shrimp is sampled and analyzed appropriately by a qualified laboratory and is shown to be free of nitrofuran and its metabolites.

This process also applies to regulated parties under IA #16-35. While Sagar Grandhi Exports is not on the exempt list for IA #16-35, FDA may allow their shrimp to enter the U.S. market provided each shipment of shrimp is sampled and analyzed appropriately by a qualified laboratory and is shown to be free of salmonella and filth, as well as not being decomposed.

We would like to also update you since our last correspondence on August 6, 2010, regarding FDA's efforts to assure imported aquaculture products are safe and free from unapproved or prohibited drug residues. In Fiscal Year 2010, FDA monitored the importation of more than 92,000 lines of shrimp and shrimp products from more than 67 countries, including over 4,400 entry lines from India. In conjunction with this monitoring, FDA sampled approximately 1,280 shrimp and shrimp products from more than 28 countries, including 77 samples from India. From these sampling efforts and IAs, more than 244 entries of imported shrimp and shrimp products were refused entry into the U.S., ten of which were refusals for shrimp and shrimp products imported from India. Refusals were based on findings and violations (or appearance of violations) including filth/decomposition, *Salmonella,* drug residues, unapproved food additives, and misbranding/mislabeling.

Since this time there has been one firm placed on IA for nitrofuran and one firm removed from the IA for nitrofuran. There has also been a reduction in the number of products from India found to contain nitrofuran and associated metabolites from 9.1 percent in 2009 to 2.6 percent in 2010.

In addition, in April 2010, the Agency sent a team of aquaculture experts to assess India's overall control of veterinary drug residues in products intended for the U.S. market. The Agency provided several recommendations to better assure the safety of the shrimp being exported to the U.S. India has implemented several of the recommendations, including a mandatory preharvest sample and testing program for unapproved residues for all shrimp exported to the U.S. This is one reason why we think samples of Indian shrimp have decreased from 9.1 percent violative in 2009 to 2.6 percent violative in 2010.

Thank you again for bringing your concerns regarding this issue to our attention. FDA relies on and appreciates input from its stakeholders as it continues to improve its programs to assure the safety of all imported seafood products and makes every effort to be as responsive as possible.

If you have subsequent inquiries regarding our progress in addressing this issue, please let me know or feel free to contact Ms. Melissa Ellwanger, Acting Director of our Division of Seafood Safety, at (240) 402-1401 or by email (melissa.ellwanger@fda.hhs.gov).

Sincerely,

William Jones
Acting Deputy Director
for Office of Food Safety
Center for Food Safety
and Applied Nutrition