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May 24, 2011

Dr. Margaret Hamburg, MD Commissioner Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

Re: Safety of Shrimp Imports from India

Dear Commissioner Hamburg,

Efforts by the U.S. Food and Drug Administration (FDA) to monitor potentially unsafe shrimp imports from India and the agency's detailed response to our previously stated concerns regarding oversight of such imports has been appreciated. The Southern Shrimp Alliance (SSA) has continued to monitor publicly available trade data and has observed a 300% increase in shipments of shrimp products by an Indian company currently subject to two separate Import Alerts. The surge in demand for shrimp exported by **GVR Exports Pvt. Ltd** and **Sagar Grandhi Exports (P) Ltd.**, which appear to be the same company, is inconsistent with expectations and appears to reflect weakness in the U.S. Food and Drug Administration's (FDA) enforcement efforts.

There are two Indian firms currently listed on Import Alert (IA) 16-129, "Detention without Physical Examination of Seafood Products Due to Nitrofurans": (1) GVR Exports Pvt. Ltd. (GVR Exports), 74, Venkatesan St, Chintadripet, Chennai, India; and (2) Sagar Grandhi Exports (P) Ltd. (Sagar Grandhi), 53, Venkateson Street, Chintadripet, Chennai, India. Both firms are listed on the Import Alert for shrimp products. The notes accompanying the Import Alert indicate that, for Sagar Grandi, the Detention without Physical Inspection (DWPE) date was June 11, 2009 and the date published was September 18, 2009. For GVR Exports, the date published was November 30, 2010. Similarly, neither GVR Exports nor Sagar Grandhi is listed as a firm that has "met the criteria for exclusion from Detention without Physical Examination (DWPE) under" Import Alert (IA) 16-35, "Detention without Physical Examination of Raw and Cooked Shrimp from India." Thus, shrimp imports from GVR Exports and Sagar Grandhi are subject to both Import Alert (IA) 16-129 (for nitrofuran contamination) and Import Alert (IA) 16-35 (for salmonella).

Publicly-available information indicates that GVR Exports and Sagar Grandhi are the same company. Sagar Grandhi's website is found at <u>http://www.gvrfoods.com/</u> and reports that the company is part of the "GVR Group." The Marine Products Export Development Authority (MPEDA), part of the Ministry of Commerce and Industry of the Government of India, maintains a directory of exporters on the agency's web-site. For Sagar Grandhi, MPEDA lists the company's contact information as follows (http://www.mpeda.com/exporters/directory/s.htm):

Sager Gandhi Exports Pvt. Ltd.

No. 53, Venkatesan Street, Chintadripet,Chennai - 600 002 Tel: 044-28456711, Fax: 44-28456707 e-mail: sgepl@vsnl.net Chief Executive:G. Chella RaoPlants:Andhra Pradesh.Capacity:33 tons per day

For GVR Exports, MPEDA lists the company's contact information as follows (http://www.mpeda.com/exporters/directory/g.htm):

GVR Exports Pvt.Ltd.

No. 53. Venkatesan Street, Chintadripet,Chennai Tel:044-28526711, Fax: 044-28526707 e-mail: gvr@md3.vsnl.net.in Chief Executive:G. Chella RaoPlants:Andhra PradeshCapacity:5 tons per day

As reported in MPEDA's directory, the address and Chief Executive of both firms are exactly the same.

Nevertheless, the two firms are listed separately in Import Alert (IA) 16-129. Moreover, a review of information available from Operational and Administrative System for Import Support (OASIS) indicates that the two firms have separately had shrimp imports recently refused by FDA. On May 28, 2010, OASIS reports that entry line AQZ-0283673-5/1/1, described as "FROZEN FRESH WATER IQF DEEP CUT SHRIMP 4/6" from GVR Exports Private Ltd. (Manufacturing ID# 3003960131), was refused for nitrofurans. Just two months ago, OASIS reports that on March 24, 2011, entry lines 814-0184229-9/1/1, 814-0184229-9/2/1, and 814-0184229-9/3/1 described as "Frozen Shrimps" from Sagar Grandhi Exports (P) Ltd. (Manufacturing ID# 3004278786), was refused for salmonella and "VETDRUGRES" ("The article appears to contain a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512.").

FDA's findings regarding the health risks posed by shrimp exported from Sagar Grandhi is seconded by the regulatory authorities of other shrimp importing countries. Specifically, the government of Switzerland publishes its "Stop & Test" list on the Federal Veterinary Office's website (<u>http://www.bvet.admin.ch/</u>). For the most recent list posted, dated May 1, 2011, Sagar Grandhi is included (along with twelve other Indian firms) for shrimp products because of

nitrofurans.¹ A document detailing actions catalogued by the European Union's Rapid Alert System for Food and Feed (RASSF) between September 2008 and October of 2009 indicates that two shipments of shrimp from Sagar Grandhi were found to be contaminated with nitrofurans by government authorities in the United Kingdom, one on December 1, 2008 (reported to be (8.9 μ g/kg - ppb)) and one on March 13, 2009 (reported to be (2.6 μ g/kg - ppb)).² In the latter case, the positive result led to the destruction of the shrimp at the border.

Given these repeated findings of problems with GVR Exports/Sagar Grandhi's exports of shrimp, one would anticipate a sharp decline in the volume of shrimp exported from the company to the U.S. market. In fact, however, a review of ship manifest data indicates that there was a sharp increase in the volume of shrimp exported by Sagar Grandhi to the United States following the company's addition to Import Alert (IA) 16-129 and that between August of 2010 and January of 2011, Sagar Grandhi is reported to have shipped *over one million pounds* of shrimp to the U.S. market. This is three times the volume of shipments attributed to Sagar Grandhi in the ship manifest data for the period running between August of 2009 and January of 2010, nearly twice the volume tied to the company from August of 2008 through January of 2009, and double the amount reported to have been shipped by the company between August of 2007 and January 2008.

Moreover, this total likely understates the volume of shrimp exported by the company to the U.S. market as it encompasses only those shipments wherein Sagar Grandhi was identified as the exporter on the ship manifest. As the result of efforts to deprive competitors of information that might be used to gain a competitive advantage, a significant portion of shrimp exports to the United States from India are accompanied by ship manifests that do not identify the exporter of the product at the request of the importer. Thus, if Sagar Grandhi (or GVR Exports)³ makes shipments of shrimp to the United States but is not listed as the exporter on the ship manifest, these volumes would not be included in our analysis.

A substantial *increase* in the commercial shipments of shrimp from an exporter subject to not one but two Import Alerts would seem to be inconsistent with the FDA's model of regulatory oversight. Last week, the U.S. Government Accountability Office (GAO) made public a report

¹ The other twelve are: Elque & Co.; Haripriya Marine Export; ITC Limited, Secunderabad; Kader Exports, Bhimavaram; Kalyan Aqua and Marine Exports; M/S Avanthi Feeds Ltd, Mandal, Andhra Pradesh; M/S Jude Foods India Pvt. Ltd.; M/S Kader Exports Pvt. Ltd.; M/S Sai Marine Exports Pvt. Ltd.; M/S Sandhya Aqua Exports Pvt. Ltd.; and M/S Wellcome Fisheries Ltd. Additionally, M/S Forstar Frozen Food Private Limited is listed for chloramphenicol in shrimp products and M/S Sharat Industries Limited is listed for sulfites in shrimp products.

² A spreadsheet summarizing the RASSF notices is available from the Lithuanian government at: <u>http://vetlt1.vet.lt/kokybs/RASFF/RASFF_MP_P_visi.xls</u>.

³ According to the subscription commercial databases reviewed by SSA, GVR Exports is not listed as an exporter on any ship manifests after October of 2003. The May 2010 refusal action listed on OASIS attributed to GVR Exports, however, would appear to indicate that shipments of shrimp from that company have been made to this market, despite not being identified as the exporter in ship manifests.

critical of the FDA's oversight of imported seafood contaminated with drug residues ("<u>Seafood</u> <u>Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited</u> <u>Resources</u>," GAO-11-286 (Apr. 2011)). The report included an appendix listing the number of foreign facility inspections conducted by the FDA in various countries. According to the table (Appendix II), between fiscal years 2005 and 2010, the FDA has inspected 8 of the 477 processing facilities in India (1.7%), with seven of those inspections taking place in fiscal year 2006. These data would appear to indicate that repeated findings of problems with shrimp exports from GVR Exports/Sagar Grandhi are unlikely to have resulted in an on-site inspection of the company's processing facilities.

All of which leads to the following question: If GVR Exports'/Sagar Grandhi's shrimp exports have been deemed problematic enough to be listed on Import Alert (IA) 16-129 and not exempted from Import Alert (IA) 16-35, why are substantial quantities of shrimp from this company continuing to be shipped to the United States? Seafood, including shrimp, from the Gulf of Mexico has been subjected to rigorous testing to ensure the safety and wholesomeness of our product before it reaches American consumers. The domestic shrimp industry has welcomed this scrutiny. Yet, we continue to compete in the U.S. market with products that do not comply with our food safety laws and regulations and, in direct result, are available for sale at substantially lower prices.

Available data indicates that the FDA's publication of violations related to Sagar Grandhi's shipments of shrimp has not reduced demand for this exporter's product – indeed, that demand appears to have increased. To the extent that these data reflect weaknesses in FDA's approach, we ask that the agency urgently review its internal policies and procedures to ensure that product found to be unsafe is kept out of the U.S. market. Should you believe that our review of the available data has led to erroneous conclusions, we would be grateful for any clarification to assist in our understanding of the FDA's oversight of imported seafood.

Sincerely,

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John Williams Executive Director

 cc: Senator Tom Harkin, Chairman, Committee on Health, Education, Labor and Pensions Senator Michael B. Enzi, Ranking Minority Member, Committee on Health, Education, Labor and Pensions
Senator Kay R. Hagan, Member, Committee on Health, Education, Labor and Pensions Senator Richard Burr, Member, Committee on Health, Education, Labor and Pensions

> Senator Johnny Isakson, Member, Committee on Health, Education, Labor and Pensions Congressman Fred Upton, Chairman, Committee on Energy and Commerce Congressman Henry A. Waxman, Ranking Minority Member, Committee on Energy and Commerce Congressman Steve Scalise, Member, Committee on Energy and Commerce Congressman Bill Cassidy, Member, Committee on Energy and Commerce Congressman John Barrow, Member, Committee on Energy and Commerce Michael R. Taylor Donald W. Kraemer Melissa Ellwanger Stephen F. Sundlof Nega Beru Barbara Montwill