

## **Regulatory Compliance Services helps companies avoid regulatory problems**

*Seventy-five cents of every dollar spent on healthcare goods is FDA-regulated*

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By: MARIALBA MARTINEZ

Eric Olivieri, the former Johnson & Johnson PSGA director of compliance, is helping U.S. Food & Drug Administration (FDA)-regulated manufacturing companies meet quality control standards and avoid thousands of dollars in fines.

"I established Regulatory Compliance Services [ReComS] to help manufacturing companies in pharmaceutical, food, and cosmetics production avoid problems with federal regulatory agencies such as the FDA, Drug Enforcement Administration, Environmental Protection Agency, and Occupational Safety & Health Administration," said Olivieri, who has partnered with Lausell & Carlo Law Firm. "Few people know that seventy-five cents of every dollar consumed in the U.S. is spent on healthcare products regulated by the FDA. The U.S. government is very strict and audits these manufacturing sectors to assure compliance with federal laws."

ReComS will provide services such as training on current good manufacturing practices, audits of internal and external suppliers, pre- and post-approvals assessment, responses to FDA warning letters, consent decrees, and preparation of letters of understanding. In addition, Olivieri's office can act as a liaison between a company and a regulatory agency; can get involved in project management, proposal submittals, and negotiations; and can conduct analyses of due diligence.

"Between July 2002 and July 2003, the FDA's San Juan District Office has sent 18 warning letters to local manufacturing companies alerting them of violations to federal regulations and giving them to set time to work out the problems," said Olivieri. "Pharmaceutical companies such as Schering-Plough, Bristol-Myers Squibb, Pharmacia, Searle, and the former SmithKline Beecham [now GlaxoSmithKline] have been some of the companies cited."

To date, Schering-Plough has paid more than \$500 million in fines and still faces a criminal investigation. Medical device manufacturers such as Baxter Healthcare and Becton Dickinson & Co. and food producers Dulces De Aqui, La Hacienda Fruit, Tropical City Industries, and Requeson Cruz Pitre have also been found in violation of regulations related to food labeling, adulteration, and current good manufacturing practices.

Olivieri is working with Lausell & Carlo Law Firm in case a company should need legal advice or legal representation. ReComS is also setting up a regulatory / legal firm with offices in Washington, Atlanta, Houston, and Los Angeles to provide services.

"We are working with several professionals in different areas to give our clients more rounded services. For example, security issues are handled by former prosecutor Gary Montilla and Helaine Gregory is an expert in healthcare services," said Olivieri.

Olivieri is closely observing whether Puerto Rico's Legislature will approve Bill No. 2173, which grants a \$2-for-\$1 tax credit on research & development expenses. The bill was recalled in the past extraordinary session and is scheduled for discussion in the second extraordinary session, set to start on Aug. 1.

“Another issue is the Pharmacy Law for Puerto Rico [Bill No. 1278 of June 8, 2001], which calls for amendments to the law and will affect the licensing of any person that represents a pharmaceutical drug manufacturer or distributor,” said Olivieri. “In addition, licensed agents must present their renewal applications 45 days before the licenses expire. Many sales & marketing departments will be swamped trying to sort out who needs to apply, and will pay a license fee of between \$25 and \$500 for each representative.”