



## *ORA: Maximizing compliance of FDA-regulated products and minimizing risk*

The principal mission of the Food and Drug Administration's Office of Regulatory Affairs (ORA) is to protect consumers and to enhance public health by maximizing compliance of FDA-regulated products and by minimizing the risk associated with those products. In 2005, several of the most important activities of ORA's 3,400 employees included responding to Hurricanes Katrina and Rita, ensuring the safety of imported drugs and food, and undertaking enforcement actions to protect consumers from illegal and unsafe regulated products.

### **HURRICANES KATRINA AND RITA**

There were about 1,700 FDA-regulated firms in the areas most heavily impacted by the hurricanes, and the storms' devastation created unprecedented public health hazards potentially affecting the products these firms manufactured, stored, or distributed. ORA took the lead in the agency's emergency response and revitalization efforts, although the hurricanes displaced many of its employees and caused extensive damage to the ORA District Office in New Orleans. Regardless of these hardships, ORA focused on

- assuring FDA's "continuity of operations" in the Gulf region by re-establishing the New Orleans District Office in Nashville, Tenn.
- deploying ORA personnel from other locations across the United States into the hurricane-impacted region to work with other federal, state, and local officials to
  - scrutinize more than 500 food service operations in schools, nursing homes, hospitals, shelters, and other establishments to make sure the food supply was safe
  - inspect 417 pharmacies to ensure that the drugs, medical devices, and biologics held and distributed by them continued to be safe and effective
  - supervise the reconditioning or destruction of regulated products that were no longer deemed suitable for consumption or for their intended use
  - identify and examine 53 shipments of humanitarian aid supplies donated by foreign relief agencies to make sure they met FDA requirements
  - dispatch two mobile laboratories to Thibodaux, La., to assist Louisiana health officials with the collection and analysis of 417 water samples so that the quality and safety of shellfish-growing waters could be assessed.

### **SURVEILLANCE OF IMPORTED DRUGS AND FOOD AND OTHER ENFORCEMENT ACTIONS**

ORA helps ensure the safety, quality, and security of the fast-growing number of imported, FDA-regulated products that enter the United States through more than 300 ports of entry and 14 international mail facilities. In 2005, ORA processed almost 7 times the number of import shipments it did in 1994.

In addition to these routine activities, last year ORA conducted "Operation Bait & Switch" at three airports around the country. During this operation, FDA personnel intercepted drugs that consumers believed they were importing from Canada to determine whether that was, in fact, the case. This effort revealed that 85 percent of the supposedly "Canadian" drugs actually came from 27 countries around the globe. ORA laboratories analyzed 487 samples of these drugs and found that many of them were not adequately labeled in English and that 32 were counterfeit.

ORA also has the primary responsibility for implementing the "Prior Notice" provision of the Bioterrorism Act. This provision requires advance notification of imported foods and animal feed to the FDA prior to their entry into the country and is designed to safeguard the food supply. For example, the FDA now knows, in advance,

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when and where specific human and animal food shipments will enter the United States, what those shipments will contain, the countries and entities from whom they originate, and the facility where the foods were manufactured. In 2005, ORA received and processed about 167,000 such notifications each week.

Last, ORA also protects consumers from fraudulent products. For example, ORA recently issued Warning Letters to nine firms marketing products with undocumented claims that they could prevent the spread of avian flu and other types of influenza. In addition, ORA's criminal investigators launched several official probes of companies and individuals involved in the manufacture, promotion, or distribution of illegal and potentially harmful products that allegedly were effective in preventing or treating avian flu or seasonal influenza.