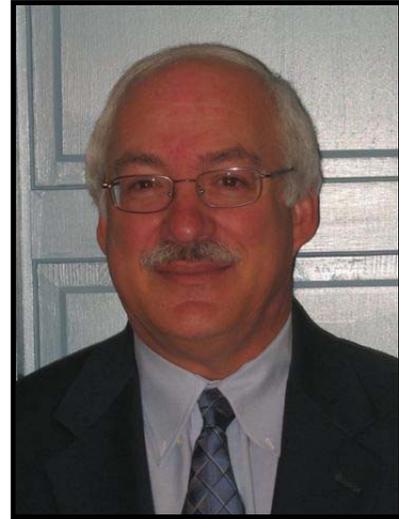


Foreword 2008 Enforcement Story

The actions in the FY08 Enforcement Story describe the FDA's activities related to all product areas over which FDA has jurisdiction. This year's Story highlights accounts of expanding international collaborations, and increased focus on global threats to domestic consumers but not to the exclusion of providing stories of critical domestic operations and collaborations in enforcement activities. FDA proactively monitors domestic firms and the foods, drugs, and medical devices that they produce, imported products and foreign firms exporting products to U.S. markets. Whether through research and methods development, inspection, sampling, recall, seizure, injunction, or criminal prosecution, FDA has acted over the last year to protect consumers from unsafe products. These domestic activities, combined with FDA's foreign initiatives, form an integrated, cohesive, and effective enforcement strategy.



On the foreign front, FDA recently celebrated the opening of its office in Beijing, China – the first in a series of foreign offices that will greatly enhance the Agency's ability to protect U.S. consumers from unsafe foreign-sourced products. The establishment of a foreign presence reflects the evolution of FDA's regulatory strategy and its responsiveness to U.S. consumers in meeting its mission of public health protection. To best protect Americans, FDA must operate in the global marketplace, in which many of the goods that we consume come from beyond our borders. And we must apply a lifecycle approach, overseeing regulated goods from their growth or production through their consumption.

FDA has moved to a risk-based lifecycle regulatory model through key initiatives introduced over the last year. This approach is perhaps most evident in the Agency's Food Protection Plan. New food sources, advances in production and distribution, and the growing volume of imported foods require new approaches to protect the food supply from unintended and deliberate contamination. The Food Protection Plan is designed to identify and counter hazards before consumers are harmed. The plan adopts measures to address risk throughout the product lifecycle, from the time a food is produced through its distribution and consumption. This relies on a three-pronged strategy that focuses on preventing problems before they occur, using risk-based intervention to assure that

preventive steps are properly implemented and risks are effectively mitigated, and rapidly responding when contamination occurs.

With over 17 million lines of regulated import entries reviewed at our borders in FY08, an increase of 83% over only five years ago, more products than ever are coming from abroad. FDA must join with its foreign counterparts and ask that industry ensures goods are safe where they are grown or manufactured, shipped, and consumed. This collaborative approach, which works in tandem with civil and criminal enforcement, is the guiding principal behind the multi-agency Action Plan for Import Safety. The Action Plan, introduced in November 2007, focuses on the most important safety considerations affecting imported goods throughout their lifecycle. Like the Food Protection Plan, the Action Plan emphasizes prevention and endorses public-private sector collaboration to identify and manage risks. This means building safety into manufacturing and distribution processes, preventing dangerous products from crossing our borders, and taking swift action to remove dangerous products from domestic commerce.

FDA's more global perspective and its use of a lifecycle model emerged in the Agency's management over the last year of significant cross-border public health crises. For example, beginning in November 2007 and continuing through February 2008, FDA noted an increase in reports of serious injuries and deaths for patients who were administered heparin, a blood-thinning drug. The active pharmaceutical ingredient (API) in the heparin was sourced from China.

FDA's scientists designed tests to identify the contaminant, investigators inspected both domestic facilities and international API suppliers to determine the presence and cause of the contamination, mapped out the supply route of contaminated products, and gauged the inspected firms' compliance with regulatory requirements. These inspections included a Chinese firm producing heparin API that was associated with patient injuries. FDA found significant violations of Current Good Manufacturing Practices, issued the firm a Warning Letter and placed the firm on import alert, preventing this product from entering the U.S. marketplace until the importer has provided proof that the product is free of impurities.

FDA also instituted industry-wide measures to prevent contaminated heparin from entering the U.S. drug supply. These included issuing a sampling assignment requiring shipments of heparin API to be sampled and tested using FDA-proven methods before being used in manufacturing. Shipments were also physically examined to verify their identity, security, and integrity.

Ultimately, FDA determined that the contaminated heparin was a worldwide problem; the tainted product was identified in more than ten countries. This global problem clearly demonstrated greater need for cross-border collaboration. In April, 2008, FDA hosted a meeting with international regulators, including representatives from China. The purpose of the meeting was to discuss the analytical testing and results related to the world heparin supply and to share inspectional findings and challenges.

FDA again applied cross-border strategies to a 2008 outbreak of salmonellosis (the illness caused by the *Salmonella* bacteria). In May of 2008, the Centers for Disease Control and Prevention (CDC) and State health authorities identified outbreaks of salmonellosis in New Mexico and Texas. This disease can cause serious infections in the young, the elderly, and persons with weakened immune systems. This outbreak – later identified as a rare serotype dubbed *Salmonella* Saintpaul – affected more than 1,400 people in 43 states, the District of Columbia, and Canada.

The CDC initially associated certain types of raw tomatoes as the source of the illnesses. Later CDC analysis associated illnesses with multiple food items, including jalapeño and Serrano peppers. FDA's investigation involved extensive sampling and traceback investigations often through complex distribution channels, throughout the U.S. and into Mexico. The Agency ultimately identified common distribution points in the U.S. and Mexico, and a common source in Mexico. FDA issued multiple public warnings, monitored recalls of contaminated product and issued import alerts to address the outbreak of this unusual *Salmonella* serotype. The Mexican government supported FDA's investigation and participated in FDA inspections of 11 Mexican firms and farms.

These and many other compelling stories describing FDA's FY08 activities are available in this year's Enforcement Story. This annual publication is a testament to the dedication of FDA's employees to its public health mission in an increasingly complex and global environment. These employees are working near our homes, at our borders, and now in foreign countries to protect you and your families' health in FDA's regulation of human and animal food, drugs, blood, human vaccines, and medical devices.

It is my pleasure to present the Enforcement Story of 2008.

Respectfully,

Steven Solomon
Deputy Associate Commissioner for Compliance Policy