The mission of the Food and Drug Administration (FDA) to protect the nation’s foods, drugs, biologics, medical devices, cosmetics, and veterinary products is even more critical today than in the past. In Fiscal Year 2002, FDA carried out its enforcement activities and accomplishments with renewed awareness, commitment, and determination to protect the American public from the new threat of bioterrorism.

Shortly after the events of September 11, 2001, Congress recognized the need to enhance the security of the United States and passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act). President George W. Bush signed the Act into law on June 12, 2002. Title III of the Act increases FDA’s authority regarding food by requiring:

- Registration of domestic or foreign facilities that manufacture, process, pack or hold food for consumption in the U.S.;
- Prior Notice of all imported food shipments;
- All businesses that manufacture, process, pack, transport, distribute, receive, hold or import food to create and maintain records that may be needed to determine the immediate previous sources and the immediate subsequent recipients of food.

In addition, the Bioterrorism Act authorizes FDA to detain a food if an FDA officer or qualified employee finds credible evidence or information that indicates that the food may pose a serious threat to humans or animals.

These new provisions will enable FDA to better protect the American food supply. FDA has intensified its efforts to monitor FDA-regulated products and, in particular, the nation’s food supply. For example, total food imports in Fiscal Year 2002 increased by only 10 percent over Fiscal Year 2001. However, FDA visual examinations of imported products tripled from Fiscal Year 2001 to Fiscal Year 2002, including examinations of imported seafood, vegetables, and some vegetable products. 1/

**Enforcement Highlights**

In addition to FDA’s work to protect the American food supply, FDA enforcement accomplishments included a broad range of activities in Fiscal Year 2002. FDA’s enforcement activities include the following highlights:

**Medical Devices:**

- A large medical device firm agrees to pay $7,000,000 to settle civil claims for submitting false and/or misleading claims to the United States.
- A clinical investigator is disqualified for submitting false information in reports to FDA for studies of investigational devices.
- A manufacturer of a “drug of abuse test” kit agrees to pay a $250,000 civil money penalty plus interest. The product had been cleared for professional use only but the firm was promoting the product over-the-counter.
- “Unsterile” obstetrical and gynecological devices labeled as “sterile” are seized.

**Foods:**

- Contaminated grape juice containing excessive amounts of lead is seized. The juice was intended to be used to manufacture juice for school lunch programs.
- Ephedrine HCl, claiming to be a dietary supplement, is seized because it was being promoted as a treatment for obesity.
- Four seafood firms sign Consent Decrees of Permanent Injunction for significant violations of the seafood regulations for Hazard Analysis and Critical Control Points.

**Drugs:**

- A large manufacturer of drugs and vaccines is notified by FDA of payments due under a Consent Decree of $1,655,000 and $2,520,000 for failure to complete various actions in accordance with the timetable in the Consent Decree.
- Under a Consent Decree a major pharmaceutical drug manufacturer is required to pay $500 million to the U.S. Treasury based on profits from the sale of drugs that were not manufactured in compliance with FDA regulations.

**Biologics:**

- FDA orders a recall of potentially contaminated tissue product used for transplantation.
Illegal Drug Residues:
- Livestock owner signs Consent Decree of Permanent Injunction for bringing 38 cattle to slaughter with illegal drug residues in edible tissues.

Criminal Prosecutions:
In fiscal year 2002, the efforts of FDA's Office of Criminal Investigations (OCI) resulted in 372 arrests and 317 convictions for violations of the Federal Food, Drug, and Cosmetic Act and related statutes. Additionally, these criminal investigations resulted in $24,027,549 in fines/restitution and $18,300,000 in forfeitures.

OCI reports enforcement activities that include:
- The conviction and sentencing of a physician for dilution of chemotherapy drugs. The defendant is sentenced to 30 years in prison, and required to pay a $25,000 fine as well as $10.4 million in restitution because of his sale of diluted drugs.
- The conviction and sentencing of a defendant who falsely claims to be a physician. The defendant is sentenced for the fraudulent promotion of a "promising new treatment for cancer." The sentence includes 121 months incarceration, followed by 3 years probation and payment of $1.5 million in restitution to his victims.

PURPOSE:
The Enforcement Story is devoted to practical presentation of actual FDA enforcement actions that impact on the development, manufacture, distribution, and marketing of foods, human and veterinary drugs, biologics, cosmetics, and medical devices. The Enforcement Story is intended as an internal publication to serve as an information source for the FDA's personnel. The statements made herein are not intended to create or confer any rights, privileges, or benefits on or for any private person, but are intended merely for internal information.

CONTENTS:
The information contained in this edition of The Enforcement Story publication was obtained from various sources within FDA throughout the course of the Fiscal Year 2002. While reasonable steps were taken to assure the information was correct at the time of publication, the statements in the publication may not contain all significant information on any cited account.

Further, this publication does not contain all enforcement actions undertaken by the FDA during the fiscal year. All items are presented in a summary form to convey the significance of the violation and/or court decision(s).

DISTRIBUTION WITHIN THE FDA:
FDA personnel may obtain copies of The Enforcement Story by contacting the Division of Compliance Policy (HFC-230) in the ORA's Office of Enforcement.

COMMENTS:
Any comments as to how this annual publication may be improved are welcomed. Please send your comments to the Director, Division of Compliance Policy (HFC-230), 5600 Fishers Lane, Rockville, MD 20857.

1/ Lester M. Crawford, D.V.M., Ph.D., Deputy Commissioner, FDA. Remarks at the National Association of State Departments of Agriculture (February 3, 2003)