

FDA Report to PharmPAC
September 3, 2009
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On August 19, FDA launched the new Center for Tobacco Products in a historic effort to curb the hundreds of thousands of deaths caused by those products each year.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm179410.htm>

On August 12, FDA issued final rules to help patients gain access to investigational drugs. The new rule, "Expanded Access to Investigational Drugs for Treatment Use," makes investigational drugs more widely available to patients by clarifying procedures and standards. The other rule, "Charging for Investigational Drugs Under an Investigational New Drug Application," clarifies the specific circumstances and the types of costs for which a manufacturer can charge patients for an investigational drug when used as part of a clinical trial or when used outside the scope of a clinical trial.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm176526.htm>

On August 6, FDA Commissioner, Dr. Margaret Hamburg, set out vision on enforcement to support public health. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm176119.htm>

On August 3, FDA and the European Medicines Agency launched collaborative good clinical practices initiative aimed to ensure appropriate conduct of clinical trials.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm174983.htm>

Visit MedWatch: The FDA Safety Information and Adverse Event Reporting Program to get timely FDA safety and adverse event reporting information or to report safety problems.

<http://www.fda.gov/Safety/MedWatch/default.htm>

Visit FDA.gov for timely information on Drug Shortages or to sign-up for the Drug Shortages Email Alert.

<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>