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NEW REPORT REVEALS DRAMATIC DECLINE IN FDA ENFORCEMENT

WASHINGTON, D.C. — Today Rep. Henry A. Waxman (D-CA) released a new report that finds that FDA's enforcement of the nation's food and drug laws has dropped dramatically over the last five years and that FDA headquarters officials routinely reject the enforcement recommendations of career field staff.

"Americans have relied on FDA to ensure the safety of their food and drugs for 100 years," said Rep. Waxman. "But under the Bush Administration, enforcement efforts have plummeted and serious violations are ignored. FDA can't do its job when its enforcement arm is tied behind its back."

The report is being released just days before FDA — the first government agency established to protect consumers — celebrates its 100th anniversary. Key findings include:

- **FDA enforcement actions have declined under the Bush Administration.** The number of warning letters issued by FDA fell by over 50% between 2000 and 2005. Despite growing reports of defects in medical devices, such as pacemakers and defibrillators, the number of FDA warning letters involving medical devices has declined by 65%.
- **FDA headquarters officials routinely reject the enforcement recommendations of career field staff.** Internal agency documents show that FDA overruled field inspectors and failed to bring enforcement actions in cases involving death and serious injury.
- **FDA recordkeeping and case tracking practices are inadequate.** FDA is unable to track and maintain adequate records of agency enforcement decisions, an apparent violation of the Federal Records Act.

The complete report is available online at www.democrats.reform.house.gov.