THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

APR 12 2005

The Honorable Richard Cheney
President of the Senate
United States Senate
Washington, D.C. 20510

Dear Mr. President:

Enclosed is the second annual financial report to Congress required by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). This report covers fiscal year (FY) 2004, documenting the extent to which the conditions specified in MDUFMA for the continued collection of medical-device user fees were met.

The report also presents the user fee revenues and related expenses for FY 2004 and details the amounts carried over at the end of the year that remain available. For FY 2004, FDA collected $27.2 million in user fees, and obligated $23.9 million. Over 65 percent of the fees were spent for staff salaries and benefits, and the remainder went toward increased support and infrastructure for the device review program. This infusion of resources is essential to enabling FDA to meet the performance goals associated with MDUFMA—goals that become increasingly more challenging each year.

Under current law, the program will end in October unless amendments are made to eliminate a statutory requirement for additional appropriations initially specified for FY 2003 and FY 2004. I urge Congress to modify MDUFMA quickly to assure continuation of this program through FY 2007.

I hope you will find this report informative.

Sincerely,

Michael O. Leavitt

Enclosure

Identical letters to:
Speaker of the House of Representatives
Chairman and Ranking Minority Member, Committee on Health, Education, Labor, and Pensions, United States Senate
Chairman and Ranking Minority Member, Committee on Energy and Commerce, House of Representatives