DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Room 352-G
200 Independence Avenue, SW
Washington, DC 20201
Office of Media Affairs
FDA NEWS RELEASE

For Immediate Release: Oct. 7, 2011
Media Inquiries: FDA – Karen Riley, 301-796-4674, karen.riley@fda.hhs.gov;
CMS – Media Relations Group, 202-690-6145, OEABox@cms.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA, CMS launch pilot program for voluntary parallel review of innovative devices

Aim is to reduce time between FDA approval and CMS national coverage determinations

The U.S. Food and Drug Administration and the Centers for Medicare & Medicaid Services (CMS) today launched a "parallel review" pilot program for concurrent review of medical devices for FDA approval and Medicare coverage.

The FDA and CMS, which will begin accepting submissions today, issued procedures for voluntary participation and guiding principles that the agencies will follow during product review. The FDA and CMS anticipate that parallel review will facilitate the development of innovative new products and increase the efficiency of the review processes for both agencies.

"The pilot program will help the FDA and CMS streamline the parallel review process so that it works efficiently for expedient patient access to safe and effective medical devices," said Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health.

Often, device sponsors focus solely on obtaining FDA approval, only to find that Medicare coverage is not automatically forthcoming. Both agencies rely on clinical data in reaching their decisions, and while the two agencies have distinctly different regulatory responsibilities, parallel review can reduce time between FDA approval and Medicare national coverage determinations.

"The parallel review program has the potential to increase patient access to innovative devices that improve clinical outcomes. Our goal is to reduce regulatory burden and improve patient outcomes," said Patrick Conway, M.D., CMS chief medical officer.

The pilot program, announced in a Federal Register notice posted for advanced viewing today, is voluntary and will not change the existing separate and distinct review standards for FDA device approval and CMS coverage determination. It is only available for qualifying new medical device technologies.

The Federal Register notice also outlines the agencies' commitment to ensuring that submitted data is confidential and highlights when sponsors can opt-out of the parallel review program.

The pilot program, which will last for up to two years with the possibility for extension, will focus on innovative technologies that can benefit from the efficiencies of parallel review. The pilot program will accept no more than three to five submissions per year.

In September 2010, the FDA and CMS announced their intention to implement a parallel review process, and received 37 public comments, which can be found in the public docket.

For more information and to read the Federal Register notice:

FDA-CMS Premarket Review
http://www.fda.gov/parallel-review.

Medicare Coverage Center
http://www.cms.gov/center/coverage.asp

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

#