CDER: Ensuring the highest standards for the safety and effectiveness of drugs and therapeutic biologic products

The Center for Drug Evaluation and Research (CDER) is the Food and Drug Administration's line organization for setting and ensuring the highest standards for the safety and effectiveness of drugs and certain therapeutic biologic products.

In 2005, CDER once again exceeded its performance goals for reviewing new drug applications (NDAs) and biologic license applications (BLAs). The center accomplished these goals while advancing innovative programs for protecting patients and while pioneering a program to modernize and stimulate development of drugs and other medical products. Center productivity continued even while more than 100 CDER Commissioned Corps officers were deployed to aid the disaster response after Hurricanes Katrina and Rita.

NEW DRUG AND BIOLOGICS APPROVALS

In 2005, CDER approved 78 NDAs and two BLAs. Of these 80 approvals, 20 were for New Molecular Entities (NMEs), products that have not previously been marketed. While this represents a relatively low number of NME approvals historically, 15 of these approvals were designated for priority reviews, which represent promising significant health benefits over existing products. CDER also approved 13 orphan-designated products for the treatment of rare diseases. Significant CDER approvals in calendar year 2005 include

- Baraclude (entecavir) for the treatment of chronic hepatitis B virus infection.
- Increlex (mecasermin) and IPLEX (mecasermin rinfabate) for the long-term treatment of growth failure in children with severe primary growth-factor deficiency.
- Aptivus (tipranivir), in combination with ritonavir, for the anti-retroviral treatment of HIV-1-infected adult patients with evidence of viral replication. These patients had already used many HIV medicines, and had a type of virus resistant to currently available HIV therapy. This new combination therapy provides a new treatment option for patients with limited options.

CDER Approval Times for Priority and Standard NMEs and New BLAs

Calendar Year	Priority Review		Standard Review	
	Number Approved	Median Total Approval Time (months)	Number Approved	Median Total Approval Time (months)
1996	18	9.6	35	15.1
1997	9	6.7	30	15.0
1998	16	6.2	14	13.4
1999	19	6.9	16	16.3
2000	9	6.0	18	19.9
2001	7	6.0	17	19.0
2002	7	16.3	10	15.9
2003	9	6.7	12	23.1
2004*	21	6.0	15	24.7
2005*	15	6.0	5	23.0

*Includes the therapeutic biologic products transferred from CBER to CDER

- Orencia (abatacept) for reducing signs and symptoms, inducing major clinical response, slowing the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis.
- Nexavar (sorafenib) for the treatment of patients with advanced renal cell carcinoma.

In addition, CDER approved 452 generic medications that cost a fraction of their brand-name counterparts and help reduce health care costs. Generic products approved in 2005 include 13 treatments for HIV/AIDS that will be available for purchase abroad as part of the President's Emergency Plan for AIDS Relief in 15 hardest-affected countries, mostly in Africa.

PATIENT SAFETY

CDER's 2005 activities were especially focused on strengthening safeguards for patients. The most significant actions included

- appointment of 31 experts to an independent Drug Safety Oversight Board to enhance internal deliberations regarding the performance of approved drugs in wide use, and to increase the transparency of important drug issues
- sponsorship of a study by the Institute of Medicine to examine the role of the FDA within the health care delivery system and to make recommendations to provide Americans the greatest level of confidence in the safety and effectiveness of the drugs they use
- leadership and technical support for risk-oriented drug facility inspections that increased 23 percent over 2004
- continued development of an electronic system for providing prescribers with up-to-date medication information, and implementation of a new system for standardizing and improving drug labels.

NEW TECHNOLOGY

CDER also advanced its activities related to the agency's Critical Path initiative, a novel program that seeks to dramatically energize the development of new medical products. The goal is to facilitate the creation and use of novel tools—such as biomarkers, innovative clinical trial designs, and simulation models—that would enable sponsors to assess the safety and effectiveness of their products before heavily investing—and potentially wasting—funds in their development.

As part of this initiative, the FDA conducted a workshop with the Drug Information Association and the Biotechnology Industry Association to discuss ways of routinely using new imaging techniques in product development. The agency also created a nonregulatory pathway for discussions with sponsors of certain issues involving submission and use of pharmacogenomic data, and published a final guidance on the development of pharmacogenomic data that can help predict the optimum treatment for each individual patient.

MOVE TO WHITE OAK

CDER achieved outstanding results in 2005 while also coordinating the move of more than 1,500 drug reviewers and support staff to the new FDA White Oak facility. Unprecedented in its size and complexity for the center because of moving staff from 15 buildings into one, this move signifies that the center is moving forward toward its vision of operating in a more cohesive, connected, and efficient manner. The move also represents historic change as the FDA begins achieving economies of scale and providing a world-class workspace that more efficiently supports the vital mission of the agency.