FDA Authorizing Legislation

The Administration is requesting that Congress authorize three new user fees. The first authorizes FDA to collect user fees for each new generic drug application and annual fees for all approved generic drugs. The second authorizes FDA to collect user fees for Export Certificates for foods and animal feeds. The third authorizes FDA to collect user fees for re-inspections and follow-up work when a regulated firm fails to meet good manufacturing practices or other regulatory requirements.

The Administration is also requesting that Congress reauthorize the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFMA). These authorities expire on September 30, 2007.

1. Authorize the Collection of User Fees for Generic Drugs

Current Law: The Federal Food, Drug, and Cosmetic Act (the Act) does not authorize FDA to collect user fees for generics approved under the ANDA process established by section 505(j) of the Act.

Proposal: Modify the Act to establish user fees for user fees for each new application and annually for all drug products approved under an abbreviated new drug application (ANDA) (not voluntarily withdrawn) and listed in the FDA's publication *Approved Drug Products With Therapeutic Equivalence Evaluations* (also known as the Orange Book) maintained by the FDA Office of Generic Drugs (OGD). The additional resources generated by the proposed generic drug user fees allow FDA to reduce the time to conduct reviews of ANDAs and respond to the growing number of generic drug applications.

Table: Estimated User Fee Collections for Generic Drugs

Program	FY 2007		FY 2008	
	FTE	$	FTE	$
Human Drugs	0	$0	28	$11,560,000
Human Drugs Field	0	$0	6	$2,636,000
Headquarters and Office of the Commissioner	0	$0	0	$518,000
GSA Rent	0	$0	0	$987,000
Total	**0**	**$0**	**34**	**$15,701,000**

2. Authorize the Collection of User Fees for Export Certificates for Foods and Animal Feed

Current Law: FDA collects user fees of up to $175 per certificate issued for export certificates for drugs, animal drugs and devices as authorized by Section 801 (e)(4)(B) of

the Act. However, there is no similar authority for collecting user fees for export certificates for foods and animal feed.

Proposal: Amend the Act to authorize the Secretary to recover costs of food and animal feed export certificate-related activities through user fees and to use the fees to hire staff (above normal FTE ceiling) for these activities. The Administration proposes the following legislative language: Amend Section 801(e)(4)(A) by inserting "food and animal feed," before each appearance of the words "drug, animal drug, or device."

Table: Estimated User Fee Collection for Food and Animal Feed Export Certificates

Program	FY 2007		FY 2008	
	FTE	$	FTE	$
Foods Center	0	$0	6	$958,000
Foods Field	0	$0	17	$2,716,000
Animal Drugs and Feeds Center	0	$0	0	$67,000
Total	**0**	**$0**	**23**	**$3,741,000**

3. Authorization of User Fees for re-inspections and follow-up work due to failure to meet Good Manufacturing Practice regulations and other requirements

Current Law: Reinspections of FDA-regulated firms are currently funded from appropriations.

Proposal: Amend the Act to permit FDA to collect and retain fees to recover from the inspected firm the full cost of reinspections that FDA performs to ensure that their products and facilities comply with current FDA regulations. FDA conducts follow-up inspection to verify that a firm implements action to correct violations discovered during an inspection or when we issue a warning letter. When FDA finds violations during an inspection, the agency conducts a follow-up inspection to ensure the firm has corrected the violation. When FDA issues warning letters, the FDA usually conducts follow-up inspections within 90 days.

Table: Estimated User Fee Collections for Re-Inspections and Follow-Up Work

Program	FY 2006		FY 2007	
	FTE	$	FTE	$
Foods Field	0	$0	44	$5,517,000
Human Drugs Field	0	$0	16	$2,126,000
Biologics Field	0	$0	3	$434,000
Animal Drugs and Feeds Field	0	$0	17	$2,169,000
Devices and Radiological Health Field	0	$0	22	$2,768,000
Office of the Commissioner	0	$0	16	$7,512,000
GSA Rent and Other Rent Related	0	$0	0	$2,750,000
Total	**0**	**$0**	**118**	**$23,276,000**

4. Reauthorization of the Prescription Drug User Fee Act (PDUFA)

Current Law: The Prescription Drug User Fee Act (PDUFA), P.L. 107-188, which amended sections 735 and 736 of the Act, expires at the end the FY 2007. This law authorizes FDA to assess user fees against new drug applications and supplements, certain drug products and establishments. It does not apply to generic drugs approved under the ANDA process, section 505(j) of the Act.

Proposal: Reauthorize PDUFA through FY 2012, following discussions with various stakeholders, industry, consumers, and Congress. Reauthorizing PDUFA will increase the number of available and affordable new medicines for Americans in the coming years.

Table: Estimated User Fee Collections for PDUFA

Program	FY 2008		FY 2009		FY 2010		FY 2011		FY 2012	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
PDUFA	1,519	$339,195,000 [1]	1,519	[1]	1,519	[1]	1,519	[1]	1,519	[1]

[1]Repeat in subsequent fiscal years, plus cost-of-living

5. Reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA)

Current Law: The Medical Device User Fee Modernization Act (MDUFMA), P.L. 107-250, which amended sections 737 and 738 of the FD&C Act, expires at the end the FY 2007. The law authorizes FDA to assess user fees against device premarket applications, premarket reports, supplements, and premarket notification submissions

Proposal: Reauthorize MDUFMA through FY 2012, following discussions with various stakeholders, industry, consumers, and Congress.

Table: Estimated User Fee Collections for MDUFMA

Program	FY 2008		FY 2009		FY 2010		FY 2011		FY 2012	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
MDUFMA	200	$47,500,000 [1]	200	[1]	200	[1]	200	[1]	200	[1]

[1]Repeat in subsequent fiscal years, plus cost-of-living