# FDA Authorizing Legislation

The Administration is requesting that Congress authorize four 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 the review of new animal generic drug applications. The third authorizes FDA to collect user fees for Export Certificates for foods and animal feeds. The fourth 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 Animal Drug User Fee Act (ADUFA). 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 (FD&C 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 FD&C 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and annually for all drug products approved under an abbreviated new drug application (ANDA) (not voluntarily withdrawn) and listed in the FDA's publication *Approved Drug Products With Therapeutic Equivalence Evaluations* (also known as the Orange Book) maintained by the FDA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 2008** | | **FY 2009** | |
|---|---|---|---|---|
| | FTE | $ | FTE | $ |
| Human Drugs | 0 | $0 | 28 | $12,242,000 |
| Human Drugs Field | 0 | $0 | 6 | $2,792,000 |
| Headquarters and Office of the Commissioner | 0 | $0 | 0 | $549,000 |
| GSA Rent | 0 | $0 | 0 | $1,045,000 |
| **Total** | **0** | **$0** | **34** | **$16,628,000** |

**2. Authorize the Collection of User Fees for Animal Generic Drugs**

Current Law: The FD&C Act does not authorize FDA to collect user fees for generics animal drugs approved under the Abbreviated New Animal Drugs Application process established by section 512(j) (2) of the FD&C Act.

Proposal: Modify the Act to establish user fees for the review of Abbreviated New Animal Drug (ANADA). The additional resources generated by the proposed animal generic drug user fees allow FDA to reduce the time to conduct reviews of ANADAs and generic investigational new animal drug study submissions, and respond to the growing number of generic drug applications.

**Table: Estimated User Fee Collections for Animal Generic Drugs**

| Program | FY 2008 | | FY 2009 | |
|---|---|---|---|---|
| | FTE | $ | FTE | $ |
| Animal Drugs and Feeds – Center | 0 | $0 | 20 | $4,118,000 |
| Animal Drugs and Feeds – Field | 0 | $0 | 1 | $143,000 |
| Headquarters and Office of the Commissioner | 0 | $0 | 1 | $193,000 |
| GSA Rent | 0 | $0 | 0 | $305,000 |
| Other Rent and Rent-Related Activities | 0 | $0 | 0 | $72,000 |
| **Total** | **0** | **$0** | **22** | **$4,831,000** |

### 3. 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 2009 Discretionary Budget Authority | | FY 2009 Mandatory User Fee[1] | |
|---|---|---|---|---|
| | 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** |

**4. 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.

[1] The FY 2009 Budget includes $3,741,000 in discretionary budget authority for reinspection activities. Once authorizing legislation is enacted, the Administration will work with Congress to reclassify the user fees as discretionary.

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

| Program | FY 2009 Discretionary Budget Authority | | FY 2009 Mandatory User Fee[2] | |
|---|---|---|---|---|
| | 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 |
| Headquarters and Office of the Commissioner | 0 | $0 | 16 | $7,512,000 |
| Other Rent Related Activities | 0 | 0 | 0 | $846,000 |
| GSA Rent and Other Rent Related | 0 | $0 | 0 | $1,904,000 |
| **Total** | **0** | **$0** | **118** | **$23,276,000** |

**5. Reauthorization of the Animal Drug User Fee Act (ADUFA)**

Current Law: The Animal Drug User Fee Act (ADUFA), P.L. 108-130, which amended subchapter C of Chapter VII of the FD&C Act, expires at the end the FY 2008. This law authorizes FDA to assess user fees against new animal drug applications and supplements, certain drug products and establishments. It does not apply to generic animal drugs approved under the ANADA process, section 512(b(2)) of the Act.

Proposal: Reauthorize ADUFA through FY 2013, following discussions with various stakeholders, industry, consumers, and Congress. Reauthorizing ADUFA will increase the number of available and affordable new veterinary medicines intended for both companion animals and animals intended for food consumption.

**Table: Estimated User Fee Collections for ADUFA**
(dollars in $000)

| Program | FY 2009 | | FY 2010 | | FY 2011 | | FY 2012 | | FY 2013 | |
|---|---|---|---|---|---|---|---|---|---|---|
| | FTE | $ | FTE | $ | FTE | $ | FTE | $ | FTE | $ |
| ADUFA | 62 | $13,698 * | 62 | * | 62 | * | 62 | * | 62 | * |

* Repeat in subsequent fiscal years, plus cost-of-living.

[2] The FY 2009 Budget includes $23,276,000 in discretionary budget authority for reinspection activities. When Congress enacts authorizing legislation for the Reinspection User Fee, the Administration will work with Congress to reclassify the user fees as discretionary.