

# **FY 2014 GDUFA FINANCIAL REPORT**

**REQUIRED BY THE**

## **GENERIC DRUG USER FEE AMENDMENTS OF 2012**

**FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**



## EXECUTIVE SUMMARY

The Generic Drug User Fee Amendments (GDUFA) of 2012 requires the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of its implementation. Required under GDUFA, this report covers activities for fiscal year (FY) 2014. This is the second GDUFA Financial Report.

GDUFA specifies that the following three legal conditions must be satisfied each fiscal year in order for FDA to collect and spend human generic drug user fees:

1. FDA's total appropriations for salaries and expenses (excluding user fees) must be equal to, or greater than, FDA's FY 2009 appropriations for salaries and expenses (excluding user fees) multiplied by the adjustment factor.
2. The fee amounts FDA may collect must be specified in appropriation acts.
3. FDA must allocate a minimum of \$97,000,000 of appropriations (excluding user fees) multiplied by the adjustment factor, and these funds shall be available to defray the costs of human generic drug activities.

As it did in 2013, FDA met these three legal conditions, and this report explains how these legal conditions were satisfied. The statements and tables in the report also provide data on FY 2014 human generic drug user fee collections, expenditures, and carryover balances.

In FY 2014, FDA had net collections of \$327.2 million in human generic drug user fees, spent \$226.1 million of fee revenue on human generic drug activities, and carried a balance of \$277.5 million forward for human generic drug activities in future fiscal years.

GDUFA fees and non-user fee appropriations in FY 2014 supported 1,224 full-time equivalents (FTEs), including salaries and operational expenses to support human generic drug activities.

In FY 2015, FDA will spend user fees to continue enhancing the program, as agreed to in the GDUFA Commitment Letter<sup>1</sup>, while focusing on improving the efficiency, quality, and predictability of human generic drug activities.

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<sup>1</sup> <http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf>

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## **1: BACKGROUND**

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by GDUFA, authorizes FDA to collect user fees from the human generic drug industry to supplement non-user fee appropriations spent on FDA's human generic drug activities. FDA spends user fee revenues and non-user fee appropriations to hire, support, and maintain resources allocated for the GDUFA program to ensure that safe and effective human generic drug products reach the American public more quickly.

GDUFA (Public Law 112-144, Title III) was authorized for 5 years, through FY 2017. It established fees for: (1) abbreviated new drug applications (ANDAs) in the backlog as of October 1, 2012 (assessed in FY 2013 only); (2) certain types of ANDAs and prior approval supplements (PASs) for human generic drug products; (3) generic drug finished dosage form (FDF) and active pharmaceutical ingredient (API) facilities; and (4) drug master files (DMFs) for APIs associated with human generic drug products (section 744B(a) of the FD&C Act).

GDUFA requires FDA to submit a financial report to Congress no later than 120 days after the end of each fiscal year. The financial report addresses the implementation and use of human generic drug user fees by FDA during the period of October 1, 2013, through September 30, 2014. This report discusses the legal conditions that must be satisfied for FDA to collect and spend human generic drug user fees each year. In addition, this report presents statements of FY 2014 fee collections, carryover balances and obligations, as well as the total costs of the GDUFA program paid from both user fees and non-user fee appropriations.

## **2: LEGAL CONDITIONS**

GDUFA imposes three legal conditions that must be satisfied for FDA to collect and spend human generic drug user fees. A summary of how each of these legal conditions was satisfied in FY 2014 is shown below.

**Legal Condition 1** – FDA’s total appropriations for salaries and expenses (excluding user fees) must be equal to or greater than FDA’s FY 2009 appropriations for salaries and expenses (excluding user fees) multiplied by the adjustment factor. FDA’s FY 2014 total appropriation for salaries and expenses (excluding user fees) was \$2,551,905,000 whereas the FY 2009 salaries and expenses appropriation (excluding user fees) was \$2,083,052,519 after applying the adjustment factor. Thus, the first legal condition was satisfied.

**Legal Condition 2** – Fees authorized under GDUFA shall be collected and available in each fiscal year in an amount not to exceed that specified in appropriation acts for such fiscal year. The Consolidated Appropriations Act, 2014 (Public Law 113-76), which the President signed on January 17, 2014, made appropriations through September 30, 2014, for the salaries and expenses account of FDA. It specified that \$305,996,000 shall be derived from human generic drug user fees, and that human generic drug user fees collected in excess of this amount, if any, are appropriated for FDA. Thus, the second legal condition was satisfied.

**Legal Condition 3** – FDA must allocate a minimum of \$97,000,000 of appropriations (excluding user fees) multiplied by the adjustment factor; and these funds shall be available to defray the costs of the GDUFA program. The specified minimum level for FY 2014 is \$99,097,431. In FY 2014, FDA obligated \$160,952,419, exclusive of user fees, for the GDUFA program. As FDA spent more than the specified minimum amount in FY 2014, the third legal condition was satisfied.

### **References**

Detailed explanations and calculations of how each of these legal conditions was satisfied in FY 2014 are described in section 5.1 – Appendix A.

### 3: FINANCIAL INFORMATION

#### 3.1 – USER FEE COLLECTIONS

##### Introduction

GDUFA specifies that user fees shall be collected for certain pending applications in the backlog as of October 1, 2012, ANDAs, PASs, DMFs, and FDF and API facilities. The statute also specifies the amount FDA is allowed to collect each fiscal year and how the fee rates should be adjusted in subsequent fiscal years.

User fee collections are reported in the year the fee was originally due – referred to as the cohort year. For example, a fee originally due in FY 2013, even if the fee is received in FY 2014, is attributed to FY 2013 collections. Totals reported for each fiscal year are net of any refunds for the cohort year. To ensure the quality of the information provided in this financial report, FDA updates prior year numbers annually.

##### Data

Table 1 provides totals of user fees collected during the past two fiscal years and reflects the amount of open receivables.

**TABLE 1: HUMAN GENERIC DRUG USER FEE COLLECTIONS AND RECEIVABLES BY FEE SOURCE  
AS OF SEPTEMBER 30, 2014**

<b>Fees Collected</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>Notes</b>
Backlog Fees	\$49,708,347	\$0	A
DMF Fees	\$38,573,051	\$25,102,494	
Application Filing Fees	\$59,006,239	\$112,082,598	
Facility Fees	\$150,966,411	\$187,443,056	
<b>Total Collections</b>	<b>\$298,254,048</b>	<b>\$324,628,148</b>	
<b>Fees Receivable</b>			
Backlog Fees	\$209,208	\$0	A
DMF Fees	\$0	\$31,490	
Application Filing Fees	\$175,900	\$63,860	
Facility Fees	\$2,008,081	\$3,884,873	
<b>Total Receivables</b>	<b>\$2,393,189</b>	<b>\$3,980,223</b>	B

Numbers may not add due to rounding to the nearest dollar

##### Notes

- A. By statute, all backlog fees were only assessed for FY 2013 and are associated with FY 2013.
- B. The receivables for FY 2013 and FY 2014 are from uncollected backlog, DMF, application filing, and facility fees. After 90 days of attempting to collect the delinquent

debt, FDA turns these receivables over to the Program Support Center (PSC), Department of Health and Human Services, for further attempts at collection. After 180 days of the debt being outstanding, PSC turns the debt over to the United States Treasury for further collection efforts.

## **References**

The balances carried over from year to year are described in section 3.3 - Carryover Balances.

Trending of historical fees paid and user fee rates are provided in section 5.2 - Appendix B.

## 3.2 – USER FEE OBLIGATIONS

### Introduction

GDUFA fees may be expended only for costs necessary to support “human generic drug activities” as defined in GDUFA. For ease of reference, “human generic drug activities” are referred to as “the GDUFA program” in this report. For more information on the allowable and excluded costs, see section 5.3 – Appendix C.

### Data

Table 2 provides a breakout of user fee obligations by expense category during the past two fiscal years.

**TABLE 2: HUMAN GENERIC DRUG USER FEE OBLIGATIONS BY OBJECT CLASS EXPENSE CATEGORY  
BREAKDOWN AS OF SEPTEMBER 30, 2013 AND 2014**

Object Class Expense Category	FY 2013	FY 2014	Notes
<b>Personnel Compensation Benefits</b>			
Full-time permanent	\$10,576,100	\$45,211,273	
Other than full-time permanent	\$1,305,100	\$4,822,788	
Other personnel compensation	\$614,000	\$2,583,453	
Military personnel <sup>2</sup>	\$831,100	\$2,620,374	
Special personnel services payments	\$8,600	\$9,471	
Civilian personnel benefits	\$3,753,212	\$15,652,601	
Military personnel benefits	\$433,800	\$1,369,333	
Benefits former personnel	\$0	\$32,064	
<b>Total Personnel Compensation and Benefits</b>	<b>\$17,521,912</b>	<b>\$72,301,358</b>	A
<b>Non-Pay Costs</b>			
Travel & transportation of persons	\$280,538	\$2,793,299	
Transportation of things	\$20,113	\$231,174	
Rent payments to GSA	\$5,006,000	\$7,817,760	
Rent payments to others	\$158,046	\$174,270	
Communications, utilities & miscellaneous	\$1,150,752	\$1,498,292	

<sup>2</sup> The “military personnel” and “military personnel benefits” object class codes refer to FDA’s uniformed officers of the Commissioned Corps of the Public Health Service.



Object Class Expense Category	FY 2013	FY 2014	Notes
Printing & reproduction	\$43,486	\$113,612	
Other contractual services:			
Consulting services	\$33,442,614	\$20,099,686	
Other services	\$22,309,329	\$51,946,039	
Purchases of goods & services from government accounts	\$9,705,535	\$24,458,329	
Operations & maintenance of facilities	\$9,584,198	\$4,531,545	
Research & development contracts	\$4,199,407	\$7,290,128	
Operations & maintenance of equipment	\$1,274,983	\$7,477,355	
Subsistence and support of persons	\$0	\$0	
Supplies & materials	\$1,000,488	\$2,866,679	
Equipment	\$7,125,139	\$1,051,915	
Land & structure	\$0	\$0	
Grants, subsidies, & contributions	\$8,405,859	\$21,384,729	
Insurance claims & indemnities	\$51,276	\$90,972	
Interest account	\$425	\$1,703	
Receivables collected	\$0	\$16	
<b>Total Non-Pay Costs</b>	<b>\$103,758,188</b>	<b>\$153,827,502</b>	B
<b>Total Obligations</b>	<b>\$121,280,100</b>	<b>\$226,128,860</b>	

Numbers may not add due to rounding to the nearest dollar

## Notes

- A. Employee salaries and benefits accounted for 32 percent of FY 2014 human generic drug user fee obligations, which was an increase of over 14 percent from FY 2013. This is a direct result of significant hiring that occurred to meet GDUFA goals.
- B. Total non-pay costs increased over FY 2013 due to the growth of the GDUFA program. A large portion of these non-pay costs were associated with IT improvements, business process improvements and increased operations and maintenance of equipment.

## References

Additional information on GDUFA program costs can be found in section 3.6 – Total GDUFA Program Costs.

### 3.3 – CARRYOVER BALANCES

#### Introduction

GDUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to FDA in future fiscal years. These funds are referred to as carryover balances, and are available solely for the GDUFA program. The operations in FY 2014 resulted in a net increase of the carryover balance of \$101,090,633 from \$176,442,145 to \$277,532,778.

#### Data

Table 3 captures FDA's carryover balances since the enactment of GDUFA in FY 2013.

**TABLE 3: HUMAN GENERIC DRUG USER FEE COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR**

Program	Fiscal Year	Beginning Carryover	Net Collection	Obligations	Year-End Carryover	Notes
GDUFA	2013	N/A	\$297,722,245	\$121,280,100	\$176,442,145	
	2014	\$176,442,145	\$327,219,493	\$226,128,860	\$277,532,778	A

Numbers may not add due to rounding to the nearest dollar

#### Notes

- A. Table 3 also reflects the amount of fees collected net of any refunds or other adjustments that occurred during each fiscal year, for all cohort years combined, and the amount obligated during the fiscal year. The numbers do not include any accounts receivable. Therefore the numbers for FY 2013 and FY 2014 are different from the numbers in Table 1 in section 3.1 – User Fee Collections, which reflect the total net collections for the cohort years only.

### 3.4 – COLLECTIONS REALIZED

#### Introduction

Under GDUFA, the total amount of user fees collected for a cohort year must be provided in appropriations acts. In FY 2014, the appropriations language enacted in Public Law 113-76 specified that \$305,996,000 shall be derived from human generic drug user fees, and that human generic drug user fees collected in excess of this amount are also appropriated for FDA. The total amount of GDUFA fees collected for FY 2014 is available for allocation for the GDUFA program.

#### Data

Table 4 depicts fee collections realized in FY 2013 and FY 2014, collection amounts specified in the appropriations act, and any amounts in excess of collection amount specified in the appropriations act.

**TABLE 4: GENERIC DRUG USER FEES COLLECTED, COLLECTION AMOUNTS SPECIFIED IN APPROPRIATIONS ACTS, AND EXCESS AMOUNTS  
AS OF SEPTEMBER 30, 2014**

FISCAL YEAR	COLLECTIONS REALIZED	COLLECTION AMOUNT SPECIFIED IN APPROPRIATIONS ACT	AMOUNT IN EXCESS OF COLLECTION AMOUNT SPECIFIED IN APPROPRIATIONS ACT	Notes
2013	\$298,254,048	\$299,000,000	-	
2014	\$324,628,148	\$305,996,000	\$18,632,148	A

Numbers may not add due to rounding to the nearest dollar

#### Notes

- A. FDA received more applications than expected, which resulted in excess collections. By statute, there is no offset provision and these funds are available to support the GDUFA program.

### 3.5 – RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

#### Introduction

GDUFA's carryover balance in FY 2014 is \$277,532,778. There are anticipated claims on this balance that are described below. After subtracting these claims, FDA's total remaining carryover balance is \$272,532,778.

#### Data

Table 5 provides a summary of carryover balances as of September 30, 2014, and anticipated claims on those balances.

**TABLE 5: SUMMARY STATEMENT OF HUMAN GENERIC DRUG USER FEE CARRYOVER BALANCE  
AS OF SEPTEMBER 30, 2014**

Status of Carryover Funds	Amount	Notes
Total Carryover Balance	\$277,532,778	
Reserve for Refunds	(\$5,000,000)	A
<b>Remaining Carryover Balance</b>	<b>\$272,532,778</b>	

Numbers may not add due to rounding to the nearest dollar

#### Notes

- A. Prudent operations require that a reserve be kept aside for potential refunds. For that purpose a total of \$5,000,000 is being set aside.

## 3.6 – TOTAL GDUFA PROGRAM COSTS

### Introduction

There are four organizations that support the GDUFA program: Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Office of Regulatory Affairs (ORA), and FDA Headquarters (HQ). The GDUFA program is supported by both user fees and non-user fee appropriations.

### Data

Table 6 shows the full cost (non-user fee appropriations and user fees) for the GDUFA program during the past two fiscal years by FDA organizational components (CDER, CBER, ORA, and HQ). The percentages spent in the various FDA components have remained essentially stable over time, with CDER at about 82%, and ORA at about 12%.

**TABLE 6: GDUFA PROGRAM – HISTORICAL TREND OF TOTAL COSTS BY ORGANIZATION  
AS OF SEPTEMBER 30 OF EACH FISCAL YEAR**

Fiscal Year	Total Spent	Spent by CDER	CDER %	Spent by CBER	CBER %	Spent by ORA	ORA %	Spent by HQ	HQ %
2013	\$266,884,096	\$215,983,391	81%	\$169,574	0%	\$33,801,677	13%	\$16,929,455	6%
2014	\$387,081,279	\$319,051,167	83%	\$737,326	0%	\$42,406,255	11%	\$24,886,531	6%

Numbers may not add due to rounding to the nearest dollar

Table 7 provides the total amount spent on the GDUFA program for the last two years, and the dollar amount and percentage derived from fees and non-user fee appropriations.

**TABLE 7: GDUFA PROGRAM - HISTORICAL TREND OF TOTAL COSTS BY FUNDING SOURCE  
AS OF SEPTEMBER 30 OF EACH FISCAL YEAR**

Fiscal Year	Total Spent	Spent from Appropriations	Appropriations Percent	Spent from GDUFA Fees	GDUFA Fee Percent
2013	\$266,884,096	\$145,603,996	55%	\$121,280,100	45%
2014	\$387,081,279	\$160,952,419	42%	\$226,128,860	58%

Numbers may not add due to rounding to the nearest dollar

### References

An expense category breakout of the FY 2013 and FY 2014 dollar amounts spent from GDUFA fees is provided in Table 2 in section 3.2 – User Fee Obligations.

The development of the costs associated with the GDUFA program is described in more detail in section 5.4 – Appendix D.

## 3.7 – FULL-TIME EQUIVALENT

### Introduction

FTE is a measure of paid staff years devoted to the programs or activities by FDA. One FTE is the work of 1 full-time employee for a full year.

From FY 2013 to FY 2014, the total FTEs for the GDUFA program increased by 372 (44%) reflecting FDA's commitment to meeting GDUFA hiring goals.

### Data

Table 8 presents total FTE levels that support the GDUFA program by FDA organizational components (CDER, CBER, ORA, and HQ) for the last two years, paid from both user fees and non-user fee appropriations. Staff in the consolidated shared services organization (facilities, procurement, Information Technology (IT) services, etc.) is included in the FTE levels for the various components.

**TABLE 8: HISTORICAL TREND OF TOTAL FTEs UTILIZED BY ORGANIZATION  
AS OF SEPTEMBER 30 OF EACH FISCAL YEAR**

Fiscal Year	CDER	CBER	ORA	HQ	Total
2013	623	1	170	58	852
2014	930	3	199	92	1,224

Numbers may not add due to rounding

### References

The development of the costs associated with the GDUFA program is described in more detail in section 5.4 – Appendix D.

## 4: PROGRAM MANAGEMENT INFORMATION

### Summary of Current Program

Beginning in FY 2015, FDA must review and act on a certain percentage of ANDA, supplement, and amendment submissions within a certain time period from the date of submission. An action on a submission may be issuance of a complete response letter, an approval letter, a tentative approval letter, or a refuse to receive letter. FDA's performance on meeting these performance goals for FY 2015 will be reported in subsequent fiscal years. To meet the required goals for FY 2015, FDA has prioritized enhancing the efficiency of the review process, hiring additional personnel, decreasing the backlog of applications, providing consistency and frequency of inspections for domestic and foreign sites, improving communication, establishing databases and IT systems, and advancing regulatory science initiatives.

The FY 2014 human resources goal was to hire 50 percent of overall GDUFA program FTEs. By the end of FY 2014, FDA had hired 64 percent of the overall GDUFA program hires, resulting in 591 Agency-wide user-fee funded FTEs. During FY 2015, FDA will strive to complete the GDUFA-funded human resources hiring goal as necessary to achieve the program performance metrics and goals.

FDA is dedicated to reviewing and acting on 90 percent of the backlog of 2,868 original ANDAs and 1,897 PAS submissions that were pending as of October 1, 2012, by the end of FY 2017, as defined in the GDUFA Commitment Letter. In FY 2014, FDA made significant progress toward eliminating the backlog of applications and achieving this performance goal. As of September 30, 2014, FDA had taken a first action on approximately 65 percent of the backlog through issuance of a complete response letter, an approval letter, or a tentative approval letter. In FY 2015, FDA anticipates making additional progress towards the 90 percent goal.

Under GDUFA, the Agency committed to increasing transparency in operations and enhancing communication with the human generic drug industry. During FY 2014, FDA held a Public Hearing on Policy Development on September 17, 2014, providing industry with an additional venue to provide feedback on the GDUFA program. FDA was particularly interested in receiving industry's input on guidances that were issued during FY 2014 and issues related to generic drug exclusivity and first generics. FDA is currently reviewing all comments received related to the Public Hearing and will use this information to develop the FY 2015 GDUFA priorities.

To further increase transparency in operations and enhance communications, the Agency has published several significant guidance documents on the review of human generic drug submissions including:

- *DRAFT Guidance for Industry Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules*, December 2013<sup>3</sup>
- *FINAL Guidance for Industry ANDAS: Stability Testing of Drug Substances and Products' Questions and Answers*, May 2014<sup>4</sup>

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3 <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377938.pdf>.

4 <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM366082.pdf>.

- DRAFT Guidance for Industry *ANDA Submissions — Content and Format of Abbreviated New Drug Applications*, June 2014<sup>5</sup>
- DRAFT Guidance for Industry *ANDA Submissions — Prior Approval Supplements Under GDUFA*, July 2014<sup>6</sup>
- DRAFT Guidance for Industry *ANDA Submissions — Amendments and Easily Correctable Deficiencies Under GDUFA*, July 2014<sup>7</sup>
- DRAFT Guidance for Industry *Controlled Correspondence related to Generic Drug Development*, September 2014<sup>8</sup>
- FINAL Guidance for Industry *ANDA Submissions — Refuse to Receive Standards*, September 2014<sup>9</sup>
- DRAFT Guidance for Industry *ANDA Submissions — Refuse to Receive for Lack of Proper Justification of Impurity Limits*, September 2014<sup>10</sup>
- Manual of Policies and Procedure (MAPP) 5200.4: Criteria and Procedures for Managing the Review of Original ANDAs, Amendments and Supplements, August 2014<sup>11</sup>
- MAPP 5240.3 Rev 1: Prioritization of the Review of Original ANDAs, Amendments, and Supplements, August 2014<sup>12</sup>

The Agency will devote resources to finalizing the draft guidance documents and developing additional policy documents during FY 2015.

To increase transparency of the complex, global human generic drug industry and enhance safety of the supply chain, GDUFA requires facilities involved in the manufacture of FDF or API for human generic drugs to self-identify annually. This regulatory requirement enables FDA to build an accurate inventory of facilities, sites, and organizations involved in the manufacture of human generic drugs; improve the Agency's ability to target compliance issues and conduct inspections; and expedite access to safe and effective human generic drug products. For FY 2014, the self-identification reporting period began on May 1, 2013, and closed on May 31, 2013, and the FY 2015 self-identification was completed in May 2014. In FY 2014, more than 3,900 manufacturing and testing facilities submitted self-identification information to FDA. This list is available on FDA's GDUFA web page.<sup>13</sup>

5 <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400630.pdf>.

6 <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM404441.pdf>.

7 <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM404440.pdf>.

8 <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM411478.pdf>.

9 <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM370352.pdf>.

10 <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM414598.pdf>.

11

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407848.pdf>.

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<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf>.

13 <http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM330790.xls>.

<http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM330790.xls>



To provide consistency and frequency of inspections for domestic and foreign sites, FDA will employ a site selection surveillance inspection model that will run annually on all facilities in FDA's inventory. For purposes of risk ranking, this model will not distinguish if the site is foreign or domestic. Risk will be assessed consistent with the requirements of FDASIA section 705. This model will also drive inspection performance goals and inspection planning. Inspection parity will be achieved by following this risk-adjusted model that considers risk rather than location.

During FY 2014, FDA implemented several significant improvements to promote the efficiency of the human generic drug review process, facilitate self-identification of generic manufacturers, strengthen surveillance and inspections, and manage user fee collection. FDA developed the CDER Informatics Platform (the Platform) that integrates the drug review processes, institutes a managed inventory of facilities and sites, enables a more efficient facility inspection process, and supports the overall quality assessment of drug applications. The Platform is essential in helping FDA meet and track GDUFA review performance goals and commitments. FDA also is facilitating standardized electronic submissions by requiring electronic submissions for certain application types and publishing draft guidance on electronic submissions.<sup>14</sup> In support of Data Standards implementation, FDA published a draft guidance requiring electronic submission of standardized data and published the draft Data Standards Catalog.<sup>15</sup> Finally, FDA has collaborated with the European Union to implement the International Standards Organization Identification of Medicinal Products standards that define, characterize, and identify each regulated medicinal product for human use from approval through post-marketing. Establishing efficient databases and IT systems are an integral component of FDA meeting its GDUFA commitments, and the Agency is committed to maintaining strong support for IT infrastructure investment in FY 2015.

Another FDA commitment under GDUFA is the advancement of scientific efforts to develop new human generic drug products and novel dosage forms. An FDA Working Group was convened to develop the FY 2014 and FY 2015 GDUFA regulatory research priorities. FDA has held two Part 15 meetings to develop the FY 2014 and FY 2015 Regulatory Science Plans. The FY 2014 human generic drug regulatory science priorities identified were 1) post-market evaluation of generic drugs, 2) equivalence of complex products, 3) equivalence of locally acting products, 4) therapeutic equivalence evaluation and standards, and 5) computational and analytical tools.<sup>16</sup> The FY 2015 Regulatory Science Plan is currently under development.

FDA believes it has developed a strong framework to achieve FDA's performance goals under GDUFA and remains committed to evaluating, developing, and revising programs, policies, and initiatives to ensure the GDUFA program is successfully implemented. During FY 2015, the Agency will continue to work on hiring personnel, decreasing the backlog of applications, providing consistency and frequency of inspections for domestic and foreign sites, improving communication, establishing databases and IT systems, and advancing regulatory science initiatives.

## **Accomplishments**

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14 Draft Guidance for Industry Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications. This guidance is located at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf>.

15 Guidance for Industry Providing Regulatory Submissions In Electronic Format — Standardized Study Data. This guidance is located at <http://www.fda.gov/downloads/Drugs/Guidances/UCM292334.pdf>. The accompanying FDA Data Standards Catalog is located at <http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM340684.xlsx>.

16 A further description of the FY 2014 priorities can be found in the FY 2014 GDUFA Performance Report.

In FY 2014, FDA staff expended significant effort for the GDUFA program. Some of FDA's accomplishments are provided in the section above. A more detailed description of accomplishments can be found in the FY 2014 GDUFA Performance Report.

## Challenges

To meet the goals established under GDUFA in FY 2015, FDA proposes taking the following actions:

- Hire and train the remainder of GDUFA program FTEs by October 1, 2015, including reviewers, investigators, communications staff, and key leadership positions across FDA.
- Maintain strong support for IT infrastructure investment in FY 2015.
- Further develop and refine IT systems to track, assign, and prioritize workload across the different cohort groups and the backlog.
- Collaborate with industry to increase communications and transparency.
- Continue to refine and implement policy and quality assurance organizations in the Office of Generic Drugs to write and communicate, in coordination with CBER, as applicable, internal and external processes, procedures, and policies that need to be created, implemented, and monitored in order to meet GDUFA goals.
- Provide consistency and frequency of inspections for domestic and foreign sites.
- Continue to implement and staff regulatory science components to meet GDUFA goals.
- Continue to refine and implement efficiency enhancements for ANDAs and DMFs to meet GDUFA goals:
  - Issue complete response letters reflecting full division-level review of deficiencies from all relevant review disciplines;
  - Issue easily correctable deficiency (ECD) letters requesting information on ECDs identified during the review process;
  - Hold 30 minute post-complete response teleconferences to clarify issues and answer questions at a level similar to pre-GDUFA;
  - Expedite, review, and act on day-one (first to file) Paragraph IV<sup>17</sup> submissions for cohorts 1 and 2; and

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<sup>17</sup> Refers to a specific subset of ANDAs submitted on the first day that any valid Paragraph IV application is, or can be submitted. Detailed information on Paragraph IV certified ANDAs is available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm147166.htm>.  
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm147166.htm>

- Strengthen filing requirements through issuance of guidance for industry on enhanced refuse-to-receive standards.
- Continue to review and act on applications and PASs identified for backlog review metrics.
- Implement the FY 2015 GDUFA Regulatory Science priorities.<sup>18</sup>

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<sup>18</sup> The GDUFA Regulatory Science Priorities for FY 2015 can be found at:  
<http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM417234.pdf>.

## **5: APPENDICES**

### **5.1 – APPENDIX A: CONDITIONS FOR ASSESSMENT AND USE OF FEES**

#### **Introduction**

The FD&C Act, as amended by GDUFA, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend human generic drug user fees. This appendix provides detailed descriptions of these conditions and explanations of how FDA met these conditions in FY 2014. A summary of the legal conditions is provided in section 2 – Legal Conditions.

#### **Adjustment Factor**

In order to compare and determine whether the legal conditions are satisfied, FDA must calculate and incorporate adjustment factors (defined in section 744A(3) of the FD&C Act, as amended by GDUFA) in the assessments of the first and third conditions. The FD&C Act states:

The term ‘adjustment factor’ means a factor applicable to a fiscal year that is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2011.

The Consumer Price Index (CPI) for October 2012, the October of the fiscal year preceding FY 2014, was 231.317. The CPI for October 2011 was 226.421. Dividing the CPI of October 2012 by the CPI of October 2011 yields an adjustment factor of 1.021623 (rounded to the sixth decimal place) for FY 2014.

#### **Legal Condition 1**

The first legal condition, defined in section 744B(h)(1) of the FD&C Act states that fees:

Shall be refunded for a fiscal year beginning after fiscal year 2012, unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for fiscal year 2009 (excluding the amount of fees appropriated for such a fiscal year) multiplied by the adjustment factor (as defined in section 744A) applicable to the fiscal year involved.

The first condition requires that FDA’s FY 2014 salaries and expenses appropriation (excluding user fees) be equal to or greater than FDA’s FY 2009 salaries and expenses appropriation (excluding user fees), multiplied by the adjustment factor. FDA’s FY 2009 salaries and expenses appropriation (excluding user fees) was \$2,038,964,000. Multiplying this amount by the adjustment factor of 1.021623 equals \$2,083,052,519.

In FY 2014, Congress appropriated \$2,551,905,000 to FDA for salaries and expenses, (excluding user fees). Since the FY 2014 salaries and expenses non-user fee appropriation is greater than the adjusted FY 2009 salaries and expenses appropriation of \$2,038,964,000, the first legal condition was satisfied.

## **Legal Condition 2**

The second legal condition, defined in section 744B(i)(2)(A)(i) of the FD&C Act, states that fees:

Shall be collected and available in each fiscal year, in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year.

The Consolidated Appropriations Act, 2014 (Public Law 113-76), which the President signed on January 17, 2014, made appropriations for FDA salaries and expenses, through September 30, 2014. It specified that \$305,996,000 shall be derived from human generic drug user fees, and that human generic drug user fees collected in excess of this amount are also appropriated for FDA. Thus, the second legal condition was satisfied.

## **Legal Condition 3**

The third legal condition, defined in section 744B(i)(2)(A)(ii) of the FD&C Act states that fees:

Shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of human generic drug activities (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activities), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than \$97,000,000 multiplied by the adjustment factor defined in section 744A(3) applicable to the fiscal year involved.

In other words, the third condition requires a minimum spending from appropriations (excluding user fees) on the GDUFA program. For FY 2014, FDA's minimum spending from appropriations (excluding user fees) is set at \$97,000,000 multiplied by the adjustment factor of 1.021623, which yields a minimum non-user fee appropriation spending of \$99,097,431. Further, FDA is considered to have met this spending requirement even if it underspends this amount by up to 10 percent without any financial penalty (see section 744B(i)(2)(B)).

In FY 2014, FDA obligated \$160,952,419 from appropriations (excluding user fees) for the GDUFA program, which exceeds the specified minimum appropriation spending level. Therefore, the third legal condition was met.

## **References**

A summary of the legal conditions is provided in section 2 – Legal Conditions.

## 5.2 – APPENDIX B: FEES RATES AND FEE PAYING SUBMISSION TRENDS

### GDUFA Fee History

GDUFA directs FDA to collect revenue from four fee categories: ANDAs in the backlog as of October 1, 2012; DMFs; facilities, and applications (ANDA and PAS). This requires FDA to establish user fee rates by fee category, application type, location and business operation as specified in the statute. FDA published the following fee rates based on statutory target revenues and estimates of fee-paying submissions.

**TABLE 9: TRENDS IN APPLICATION, DMF, AND FACILITY FEES<sup>19</sup>**

Fiscal Year	Backlog Fee	DMF Fee	Domestic FDF Facility Fee	Foreign FDF Facility Fee	Domestic API Facility Fee	Foreign API Facility Fee	ANDA Fee	PAS Fee
2013	\$17,434	\$21,340	\$175,389	\$190,389	\$26,458	\$41,458	\$51,520	\$25,760
2014	N/A	\$31,460	\$220,152	\$235,152	\$34,515	\$49,515	\$63,860	\$31,930

### GDUFA Forecasted Versus Actual Fee-Paying Submissions

Table 10 depicts FDA's estimates of fee-paying units used in the Federal Register (FR) notices for setting GDUFA fees prospectively versus the actual number of fee-paying units received each year.

**TABLE 10: TRENDS IN FORECASTED VS. ACTUAL FEE-PAYING APPLICATION, DMF, AND FACILITY FEES**

Fiscal Year	Forecasted vs. Actual	Backlog Applications	DMFs	Domestic FDF Facilities	Foreign FDF Facilities	Domestic API Facilities	Foreign API Facilities	Applications
2013	FR	2,868	700	325	433	122	763	1,160
	Actual	2,851	1,808	280	322	123	898	1,145
2014	FR	N/A	583	315	433	128	775	1,149
	Actual	N/A	798	286	366	125	689	1,755

<sup>19</sup> FDA published FY 2014 human generic drug user fee rates on August 2, 2013, in the Federal Register <http://www.gpo.gov/fdsys/pkg/FR-2013-08-02/pdf/2013-18625.pdf>

## **5.3 – APPENDIX C: INCLUDED AND EXCLUDED COSTS FOR THE GDUFA PROGRAM**

### **Introduction**

Section 744A of the FD&C Act, as amended by GDUFA, defines the term “human generic drug activities” and the costs that may be included in that process, collectively referred to as the GDUFA program in this document. Fees may only be spent for activities that are included in this definition. FDA identifies those activities and resources that are applicable to the GDUFA program in this appendix. In Appendix D, FDA describes how the costs for the GDUFA program are developed, based on the allowable activities identified below.

Because over 96 percent of the amounts obligated by FDA each year are expended within 2 years, obligations represent an accurate measure of costs.

### **GDUFA Program Costs**

#### **Included Activities**

Section 744A(8) of the FD&C Act defines in general, the term “human generic drug activities” as the activities associated with generic drugs and inspection of facilities associated with generic drugs. In summary, costs related to the following have been attributed to human generic drug activities:

- A. The activities necessary for the review of generic drug submissions, including review of DMFs referenced in such submissions.
- B. The issuance of—
  - i. approval letters which approve ANDAs or prior approval supplements to such applications.
  - ii. complete response letters which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.
- C. The issuance of letters related to Type II active pharmaceutical ingredient DMFs which:
  - i. set forth in detail, the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies; or
  - ii. document that no deficiencies need to be addressed.
- D. Inspections related to generic drugs.
- E. Monitoring of research conducted in connection with the review of generic drug submissions and DMFs.
- F. Postmarket safety activities with respect to drugs approved under abbreviated new drug applications or supplements, including the following activities:

- i. Collecting, developing, and reviewing safety information on approved drugs including adverse event reports.
- ii. Developing and using improved adverse-event data collection systems, including information technology systems.
- iii. Developing and using improved analytical tools to assess potential safety problems including access to external databases.
- iv. Implementing and enforcing section 505(o) (relating to post-approval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies) insofar as those activities relate to abbreviated new drug applications.
- v. Carrying out section 505(k)(5)(relating to adverse-event reports and postmarket safety activities).

G. Regulatory science activities related to generic drugs.

All user-fee-related costs represented by the above activities are collectively referred to in this report as human generic drug activities or the GDUFA program.

Section 744A(11) of the FD&C Act defines the term “resources allocated for human generic drug activities” as expenses for the following:

- A. Officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, committees, and to contracts with such contractors;
- B. Management of information, and the acquisition, maintenance, and repair of computer resources;
- C. Leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and
- D. Collecting user fees under subsection (a) and accounting for resources allocated for the review of abbreviated new drug applications and supplements and inspections related to the generic drugs.

**Excluded Activities**

The GDUFA Program excludes from the term “human generic drug activities” costs related to the following:

- A. All activities necessary for the review of new drug applications (NDAs), biologic license applications (BLAs), and investigational new drugs (INDs) for drugs that will not be approved under ANDAs.
- B. The issuance of correspondence unrelated to abbreviated new drug submissions or prior approval supplements.



- C. Inspections unrelated to human generic drugs.
- D. Monitoring of research unrelated to human generic drug submissions and DMFs.
- E. Post-market safety activities apart from those drugs approved under ANDAs or supplements.

## 5.4 – APPENDIX D: DEVELOPMENT OF COSTS FOR THE GDUFA PROGRAM

### General Methodology

The costs associated with the GDUFA program are based on obligations recorded within CDER, CBER, ORA, and HQ. These organizations correspond to the cost categories presented as follows:

Cost Category	FDA Organization
Costs for the Review of ANDA, PAS, and DMF submissions	CDER and CBER
Field Inspection and Investigation Costs	ORA
Agency General and Administrative Costs	HQ

The costs for each component are shown in table 6. They were derived using time-reporting systems in CDER, CBER, and ORA, and were calculated for HQ as described in more detail in this appendix. Using the definitions of costs and activities included in the GDUFA program, as explained in the discussion in Appendix C, the cost categories within each organization listed above were identified as parts of the generic human drug review process.

### Center Costs

Costs of the GDUFA program are tracked for each organizational component in CDER and CBER, usually at the division level. Most FDA components involved in the GDUFA program perform a mixture of activities – some within the scope of the GDUFA program, and some not. FDA groups its organizational components into three categories:

- direct review and laboratory
- indirect review and support
- Center-wide costs

The allocation of costs for each category is discussed below.

### Direct Review and Laboratory

Employees in all components of CDER and CBER, other than those noted below as Center indirect review and support components, are required to report their time for a total of eight weeks (two weeks per quarter) each fiscal year in activity-based time reporting systems. The activities in the systems differentiate between time spent on the GDUFA program and all other time, so that time reported can be separated into allowable and excluded activities as defined by GDUFA. The average percentage of time reported on the GDUFA program in CDER and CBER is applied to all costs incurred for the entire fiscal year in those Centers. This method provides an estimate of each centers' costs incurred while conducting the GDUFA program in FY 2014.

## **Indirect Review and Support**

Indirect review and support components provide the infrastructure for the human generic drug activities. In CDER, these components include the Office of the Center Director, the Office of Management, the Office of Communications, and portions of the Office of Executive Programs, and the Office of Strategic Programs. In CBER, these components include portions of the Office of the Center Director, Office of Management, and the Office of Communications, Outreach, and Development. Most employees of these components do not report their time.

FDA assumes the time of management and administrative personnel supporting the GDUFA program is equivalent to the proportion of time Center employees in direct review and laboratory components spend on the GDUFA program. Thus the average percentage of time expended on the GDUFA program for all direct review and laboratory components in FY 2014 was applied to all costs incurred for the entire fiscal year by the indirect review and support components.

## **Center-Wide Costs**

A number of Center-wide and Agency-wide expenses are paid from the central accounts of the Center or of FDA rather than from funds allocated to a specific Center or division or office within the Center. These costs include rent, telecommunications and utility costs, some computer equipment and support costs, and costs of the Office of Shared Services, which supports all FDA programs and activities. A percentage of these Center- and FDA-wide costs are chargeable to the GDUFA program. That percentage is either a specific amount that is supported by independent documentation or is the amount of time reported for allowable activities (direct and indirect) in the Center, as a percentage of total time reported for all Center direct and indirect activities.

As in FY 2013, resources expended in FY 2014 by the Office of Shared Services in supporting the GDUFA program are reported as if they were incurred in CDER, CBER, ORA, or HQ.

## **Field Inspection and Investigation Costs**

ORA incurs all field inspection, investigation, and laboratory analyses costs. ORA costs are incurred in both district offices (the “field”) and headquarters offices, which are tracked in the Field Accomplishment and Compliance Tracking System (FACTS). FACTS is a time and activity tracking system that captures time spent in a variety of categories, including pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples, which are all part of the GDUFA program.

Table 11 summarizes the calculation of ORA costs for the GDUFA program for FY 2013 and FY 2014.

**TABLE 11: ORA COSTS FOR THE GDUFA PROGRAM  
AS OF SEPTEMBER 30, 2013 AND 2014**

Cost Component	FY 2013	FY 2014	Notes
FTE Utilized	157	184	A
ORA Average Salary and Benefits	\$117,355	\$120,952	
Total Salary and Benefits	\$18,424,735	\$22,255,168	B
Operating and Other Costs <sup>20</sup>	\$15,376,942	\$20,151,087	C
<b>Total</b>	<b>\$33,801,677</b>	<b>\$42,406,255</b>	D

Numbers may not add due to rounding to the nearest dollar

## Notes

- A. Total direct hours reported in FACTS are used to calculate the total number of FTEs required by ORA to perform these activities. In addition to the direct time, an allocation of support time is also included to represent the work done by ORA administrative and management personnel.
- B. The Agency multiplies the total number of FTEs used in the GDUFA program by the average salary and benefits cost in ORA to arrive at ORA salary and benefit costs for work within the scope of the GDUFA program.
- C. The Agency then allocates ORA obligations for operations and other costs to the GDUFA program based upon the ratio of user fee related FTEs to total ORA FTEs.
- D. ORA costs for the GDUFA program described above include costs paid from non-user fee appropriations and costs paid from fee revenues.

<sup>20</sup> Other costs are central, GSA, rent, rent-related and Shared Services costs that are applicable to the GDUFA program.

## Agency General and Administrative Costs

The Agency general and administrative costs include all costs incurred in FDA's HQ that are attributable to the Office of the Commissioner and all other FDA headquarters components that are not Centers or ORA. For the purpose of these calculations, HQ is considered to comprise the following offices:

- Immediate Office of the Commissioner
- Office of the Counselor to the Commissioner
- Office of Policy, Planning, Legislation, and Analysis
- Office of External Affairs
- Office of the Executive Secretariat
- Office of the Chief Counsel
- Office of Minority Health
- Office of Women's Health
- Office of the Chief Scientist (excluding the National Center for Toxicological Research)
- Office of Operations
- Office of Foods and Veterinary Medicine (excluding the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine)
- Office of Medical Products and Tobacco (excluding CDER, CBER, the Center for Devices and Radiological Health, and the Center for Tobacco Products)
- Office of Global Regulatory Operations and Policy (excluding ORA)

In summary, the HQ costs include all of FDA except for the six product-oriented centers, ORA, and the National Center for Toxicological Research.

The HQ costs applicable to the GDUFA program were calculated using a method prescribed by the Division of Cost Determination Management, Office of Finance, Office of the Secretary, Department of Health and Human Services. The method uses the percentage derived by dividing total HQ costs by the total FDA salary expenses (excluding benefits) after subtracting the salary expense (excluding benefits) from HQ. That percentage is then multiplied by the total salaries (excluding benefits) applicable to the GDUFA program in CDER, CBER, and ORA to derive the applicable Agency general and administrative costs.

Using this methodology, FDA dedicated \$24,886,531 in general and administrative costs to the GDUFA program in FY 2014. The costs are total costs obligated from non-user fee appropriations and user fees. FDA strives to maintain a low overhead cost for the GDUFA program. General and administrative costs are approximately 6 percent of the FY 2014 GDUFA program costs.