

**FY 2013 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) to report annually on the financial aspects of its implementation. Required under GDUFA, this report covers activities for fiscal year (FY) 2013.

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 provided in appropriation acts, or otherwise made available for obligation for such fiscal year.
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.

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

In FY 2013, FDA collected \$297.7 million in human generic user drug fees, spent \$121.3 million of fee revenue on human generic drug activities, and carried a balance of \$176.4 million forward for human generic drug activities in future fiscal years.

GDUFA fees and appropriations in FY 2013 supported 852 full-time equivalents (FTEs), including salaries and operational expenses to support human generic drug activities.

In FY 2014, FDA will spend user fees to continue enhancing the program, as agreed to in the commitment letter, while focusing on improving the efficiency, quality, and predictability of human generic drug activities.

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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 augment appropriations spent on FDA's human generic drug activities. FDA spends user fee revenues and appropriations to hire, support, and maintain resources allocated for human generic drug activities 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 certain applications and supplements for human generic drug products, on applications in the backlog as of October 1, 2012 (only applicable to FY 2013), on facilities, and on Type II active pharmaceutical ingredient (API) drug master files (DMF) to be made available for reference.

In FY 2013, fees were assessed on the following: (1) certain abbreviated new drug applications (ANDAs) in the backlog as of October 1, 2012; (2) certain types of ANDAs and prior approval supplements (PAS) for human generic drug products; (3) certain generic drug finished dosage form (FDF) and API facilities; and (4) certain DMFs associated with human generic drug products (section 744B(a) of the FD&C Act). Under GDUFA, the revenue amount for FY 2013 was \$299,000,000, as set in the statute. \$50,000,000 of the FY 2013 target revenue amount was to be derived from the backlog fee, while all other fee categories accounted for the remainder of the annual fee revenue.

GDUFA requires FDA to submit a performance report and a financial report to Congress no later than 120 days after the end of each fiscal year. The FY 2013 GDUFA Performance Report that describes FDA's progress in meeting the performance goals referred to in section 301(b) of GDUFA was transmitted to Congress on January 30, 2014. This report is the FY 2013 GDUFA Financial Report which addresses the implementation and use of human generic drug user fees by FDA during the period of October 1, 2012, through September 30, 2013.

As required by GDUFA, 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 2013 fee collections, carryover balances and obligations, as well as the total costs of human generic drug activities paid from both user fees and appropriations.

MEETING THE LEGAL CONDITIONS FOR HUMAN GENERIC DRUG USER FEES IN FY 2013

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 2013 is shown below. Detailed explanations and calculations are described in Appendix A.

First legal condition: 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 2013 total appropriation for salaries and expenses (excluding user fees) was \$2,504,774,000 whereas the FY 2009 salaries and expenses appropriation (excluding user fees) was \$2,038,964,000 after applying the adjustment factor. Thus, the first legal condition was satisfied.

Second legal condition: Fees authorized under GDUFA shall be collected and available in each fiscal year in an amount not to exceed that specified in appropriation acts, or otherwise made available for obligation for such fiscal year. Section 744B(i)(2)(C) of the FD&C Act, as added by GDUFA, made available for obligation GDUFA fees collected for FY 2013, beginning on October 1, 2012, and continuing until the date of enactment of an Act making appropriations through September 30, 2013, for the salaries and expenses account of FDA. The Consolidated and Further Continuing Appropriations Act, 2013 (Public Law 113-6), which the President signed on March 26, 2013, made appropriations through September 30, 2013, for the salaries and expenses account of FDA. It specified that \$299,000,000 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.

The third legal condition: 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. In FY 2013, FDA obligated \$145,603,996, exclusive of user fees, for human generic drug activities. As FDA spent more than the specified minimum amount in FY 2013, the third legal condition was satisfied.

USER FEE COLLECTIONS

GDUFA specifies that user fees shall be collected for certain: pending applications, ANDAs, DMFs, and 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.¹

Table 1 provides a breakout of FY 2013 GDUFA human generic drug user fees collected and the receivables by fee type.

**TABLE 1: HUMAN GENERIC DRUG USER FEE COLLECTIONS
AND RECEIVABLES BY FEE TYPE AS OF SEPTEMBER 30, 2013**

FEES COLLECTED	FY 2013
Backlog Fee	\$49,673,479
DMF Fee	\$38,497,708
Application Filing Fee	\$63,398,167
Facility Fee	\$144,802,925
TOTAL COLLECTIONS	\$296,372,279
FEES RECEIVABLE	FY 2013
Backlog Fee	\$0
DMF Fee	\$64,123
Application Filing Fee	\$253,476
Facility Fee	\$337,236
TOTAL RECEIVABLES	\$654,835

Numbers may not total precisely due to rounding to the nearest dollar.

Totals reported are net of any refunds for the cohort year. In order to ensure the quality of the information provided in this fiscal report, FDA updates prior year numbers annually.

¹ Section 744B(c) of the FD&C Act states FY 2014-2017 fee adjustments shall be calculated based on inflation. In FY 2017, an additional adjustment may be applied if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carry-over user fees for human generic drug activities for the first 3 months of FY 2018 (Public Law 113-76).

COLLECTIONS REALIZED

Under GDUFA, the total amount of user fees collected for a cohort year must be provided in appropriation acts, or otherwise made available for obligation. In FY 2013, the appropriations language enacted in Public Law 113-6 appropriated all GDUFA fees collected for FY 2013; therefore the second legal condition was met. Accordingly, because the first legal condition and the third legal condition described on page 2 of this report were also met, the total amount of GDUFA fees collected for FY 2013 is available for allocation for human generic drug activities.

USER FEE OBLIGATIONS

User fees are expended only for costs necessary to support human generic drug activities as defined in GDUFA. Included and excluded costs for this function are described in Appendix D of this report.

In FY 2013, FDA obligated \$121,280,100 from human generic drug user fees. Table 2 provides a breakout of user fee obligations by expense category during FY 2013.

**TABLE 2: HUMAN GENERIC DRUG USER FEE
OBLIGATIONS BY EXPENSE CATEGORY AS OF SEPTEMBER 30, 2013**

EXPENSE CATEGORY	FY 2013
Personnel Compensation and Benefits	\$17,521,912
Travel and Transportation	\$300,651
Rent	\$5,006,000
Communications	\$1,150,752
Contract Services	\$80,516,066
Equipment and Supplies	\$8,125,627
Other ²	\$8,659,092
TOTAL OBLIGATIONS	\$121,280,100

² Other includes expenses from categories such as rent payments to others, printing & reproduction, and other miscellaneous expenses.

In FY 2013, FDA initiated many new contract initiatives in order to implement the new GDUFA organizational structure and program. These initiatives included developing advanced statistical methods for pharmacy compounding and new pharmacokinetic drug products, business process improvements, purchase of specialized lab equipment, program management, and other program start-up costs.

CARRYOVER BALANCES

Under GDUFA, fees collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA in future fiscal years. They are referred to as carryover balances.

Table 3 captures FDA's FY 2013 carryover balances for GDUFA.

TABLE 3: HUMAN GENERIC DRUG USER FEE COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES AS OF SEPTEMBER 30, 2013

FISCAL YEAR	BEGINNING CARRYOVER	NET COLLECTIONS	OBLIGATIONS	YEAR-END CARRYOVER
2013	N/A	\$297,722,245	\$121,280,100	\$176,442,145

The balances in Table 3 reflect the carryover balance from the beginning to the end of the fiscal year, the net amount collected, and any refunds or other adjustments that occurred. The collections in Table 3 include fees that had not been applied to a particular fee type at the end of the fiscal year. As a result, the amounts in Table 3 differ from the amounts in Table 1. These numbers are exclusive of any accounts receivable.

RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

At the end of FY 2013, there were several claims on the carryover balance. FDA holds a reserve of \$5,000,000 for potential refunds in future years. In addition, \$14,700,076 of collections appropriated for FY 2013, but sequestered under the Balanced Budget and Emergency Deficit Control Act of 1985, as amended by the Budget Control Act of 2011, is not available for obligation¹¹.

Table 4 provides a summary of carryover balances as of September 30, 2013. The FY 2013 carryover balance \$176,442,145 and the amount available inclusive of anticipated claims is \$156,742,069.

**TABLE 4: FY 2013 SUMMARY STATEMENT OF HUMAN GENERIC DRUG
USER FEES CARRYOVER BALANCE AS OF SEPTEMBER 30, 2013**

STATUS OF CARRYOVER FUNDS	AMOUNT
FY 2013 Carryover Balance	\$176,442,145
Reserve for Refunds	(\$5,000,000)
Reserve for FY 2013 Collections Sequestered	(\$14,700,076)
Remaining Carryover Balance	\$156,742,069

GDUFA authorizes FDA to have available up to 3 months of operating reserves of carryover user fees for human generic drug activities at the end of FY 2017. FDA currently estimates that such activities will require approximately \$84.6 million for the first 3 months of FY 2018, thus the carryover available could fund the first 3 months of operations in FY 2018.

¹ This report provides information on user fee balances as of the end of FY 2013. We note that, after the end of FY 2013, Congress enacted legislation that makes the FY 2013 sequestered user fees available for obligation by FDA. See section 747 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2014. (Public Law 113-76).

TOTAL COSTS ASSOCIATED WITH HUMAN GENERIC DRUG ACTIVITIES

Table 5 shows the costs associated with human generic drug activities during FY 2013 by FDA organizational component. It depicts the full costs of the human generic drug activities paid from appropriations and user fees. The table displays data for the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Office of Regulatory Affairs (ORA), and FDA Headquarters (HQ).

**TABLE 5: TOTAL COSTS ASSOCIATED WITH
HUMAN GENERIC DRUG ACTIVITIES AS OF SEPTEMBER 30, 2013**

FDA COMPONENT	FY 2013
CDER	\$215,983,391
CBER	\$169,574
ORA	\$33,801,676
HQ	\$16,929,455
TOTAL PROCESS COSTS	\$266,884,096
Obligations from Appropriations	\$145,603,996
Obligations from Generic Drug User Fees	\$121,280,100

Of the total of \$266,884,096 obligated in support of human generic drug review activities as defined in GDUFA, about 45 percent came from GDUFA fees and about 55 percent came from appropriations.

FDA strives to maintain a low overhead cost for human generic drug activities. For FY 2013, general and administrative costs are approximately 6 percent of costs associated with human generic drug activities. The development of these costs is described in Appendix D.

FULL-TIME EQUIVALENTS (FTEs)

FTE is a measure of paid staff years devoted to human generic drug activities. In FY 2013, GDUFA fees and appropriations expended for human generic drug activities accounted for 852 FTEs. Employee salaries and benefits accounted for just over 14 percent of FY 2013 human generic drug user fee obligations. FDA continues to secure additional resources for human generic drug activities to further reduce the backlog of pending applications, to strengthen and expand its capacity to conduct efficient and timely reviews, and to ensure the safety and effectiveness of human generic drugs.

Table 6 presents total FTE levels that support human generic drug activities by FDA organizational components for FY 2013, paid from both user fees and appropriations. Staff from the consolidated shared services organization (i.e. facilities, procurement, IT services, etc.) is included in the counts for the aforementioned components.

**TABLE 6: TOTAL FTEs UTILIZED FOR HUMAN
GENERIC DRUG ACTIVITIES AS OF SEPTEMBER 30, 2013**

ORGANIZATIONAL COMPONENT	FTEs UTILIZED
CDER	623
CBER	1
ORA	170
HQ	58
TOTAL FTEs	852

Numbers may not total precisely due to rounding to the nearest dollar

For additional information on the costs associated with human generic drug activities, refer to the Total Costs Associated with Human Generic Drug Activities section on page 8.

MANAGEMENT CHALLENGES FOR FY 2014

On July 9, 2012, the President signed Public Law 112-144, the Food and Drug Administration Safety and Innovation Act (FDASIA), Title III of which authorized GDUFA for 5 years.

To meet the goals established under GDUFA in FY 2014, FDA proposes to take the following actions:

- Hire and train at least 50 percent of GDUFA program hires by October 1, 2014, including reviewers, inspectors, communications staff, and key leadership positions across CDER.
- Develop IT systems to track, assign, and prioritize workload across the different cohort groups and the backlog.
- Collaborate with industry to increase communications and transparency.
- Implement policy and quality assurance organizations in the Office of Generic Drugs to write and communicate internal and external processes, procedures, and policies that need to be created, implemented, and monitored in order to meet GDUFA goals.
- 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;
 - Utilize telephone information requests to address easily correctable deficiencies 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 IV¹ submissions for cohorts 1 and 2; and
 - Strengthen filing requirements.
- Continue to review and act on applications and PAS identified for backlog review metrics.
- Convene a working group and consider suggestions from industry as well as other stakeholders to develop a list of FY 2015 regulatory science initiatives.

¹ Refers to a specific subset of ANDAs submitted on the first day that any valid P4 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>

APPENDIX A: CONDITIONS FOR ASSESSMENT AND USE OF FEES

The FD&C Act, as amended by GDUFA, specifies three legal conditions that must be satisfied each fiscal year for FDA to collect and spend human generic drug user fees. A summary of the legal conditions was presented on page 2 of this report. This appendix provides detailed descriptions of these conditions and explanations of how FDA met these conditions in FY 2013.

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 of the preceding fiscal year, i.e. October 2011, was 226.421. Since this number, 226.421, is both the numerator and the denominator of the adjustment factor for FY 2013, the first year of GDUFA, the applicable adjustment factor is 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 2013 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 equals \$2,038,964,000.

In FY 2013, Congress appropriated \$2,504,774,000 to FDA for salaries and expenses, (excluding user fees). Since the FY 2013 salaries and expenses appropriation is greater than the adjusted FY 2009 salaries and expenses appropriation of \$2,038,964,000, the first legal condition was satisfied

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.

Section 744B(i)(2)(C) of the FD&C Act, as added by GDUFA, made available for obligation GDUFA fees collected for FY 2013, beginning on October 1, 2012 and continuing until the date of enactment of an Act making appropriations through September 30, 2013, for the salaries and expenses account of FDA. The Consolidated and Further Continuing Appropriations Act, 2013 (Public Law 113-6), which the President signed on March 26, 2013, made appropriations through September 30, 2013, for the salaries and expenses account of FDA. It specified that \$299,000,000 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.

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.

The third condition requires a minimum spending from appropriations (excluding user fees) on human generic drug activities. For FY 2013, FDA's minimum spending from appropriations is set at \$97,000,000 multiplied by the adjustment factor of 1, which yields a minimum appropriation spending of \$97,000,000. 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 2013, FDA obligated \$145,603,996 from appropriations (excluding user fees) for the process of human generic drug activities, which exceeded the required minimum of \$97,000,000 by \$48,603,996. Thus, the third condition was satisfied.

APPENDIX B: GDUFA REVENUE AND NUMBER OF FEES PAID IN FY 2013

GDUFA established four fee categories and set fee revenues for each category. Based on the statutory revenues and estimated numbers of fees that would be paid in each category, FDA published the following FY 2013 fee rates:

TABLE 7: HUMAN GENERIC DRUG USER FEE CATEGORIES AND FEE RATES¹

USER FEE CATEGORY	FY 2013 RATE
Backlog Fee	\$17,434
Drug Master File Fee	\$21,340
Application Fee	
ANDA Fee	\$51,520
PAS Fee	\$25,760
Facility Fee	
Facility FDF Fee	DOMESTIC: \$175,389
	FOREIGN: \$190,389
Facility API Fee	DOMESTIC: \$26,458
	FOREIGN: \$41,458

¹ FDA published FY 2013 human generic drug user fee rates in the *Federal Register* –
 On October 25, 2012 (77 FR 65198): <http://www.gpo.gov/fdsys/pkg/FR-2012-10-25/html/2012-26256.htm>
 On October 25, 2012 (77 FR 65199): <http://www.gpo.gov/fdsys/pkg/FR-2012-10-25/pdf/2012-26257.pdf>
 On January 17, 2013 (78 FR 3900): <http://www.gpo.gov/fdsys/pkg/FR-2013-01-17/html/2013-00851.htm>

Table 8 represents the number of human generic drug user fees paid in FY 2013 for cohort year 2013 in comparison to what the FDA estimated when GDUFA fees were established.

**TABLE 8: NUMBER OF HUMAN GENERIC DRUG
USER FEES RECEIVED FOR COHORT YEAR 2013 AS OF SEPTEMBER 30, 2013**

USER FEE CATEGORY	FY 2013 FEES ESTIMATED	FY 2013 FEES COLLECTED
Backlog Fee	2868	2849
Drug Master File Fee	700	1804
ANDA and PAS Fee		
ANDA Fee	850	992
PAS Fee	576	412
Facility Fee		
Facility FDF Fee	758	640
Facility API Fee	885	806

APPENDIX C: INCLUDED AND EXCLUDED COSTS FOR HUMAN GENERIC DRUG ACTIVITIES

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

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-RELATED 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 process activities have been attributed to human generic drug activities:

- (A) All 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 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 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 submission and DMFs.
- (F) Post-market safety activities with respect to drugs approved under ANDAs 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 ANDAs.
- v. Carrying out section 505(k)(5)(relating to adverse-event reports and post-market 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.

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

- (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 ANDAs and supplements and inspection related to the generic drugs.

Excluded Activities

The FD&C Act thus 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 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.

APPENDIX D: DEVELOPMENT OF COSTS ASSOCIATED WITH HUMAN GENERIC DRUG ACTIVITIES

GENERAL METHODOLOGY

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

<u>Cost Category</u>	<u>FDA Organization</u>
Costs for reviewing ANDA, PAS, and DMF submissions	CDER and CBER
Costs for Field Pre-Approval Inspection and Investigation	ORA
Costs for FDA General and Administrative Activities	HQ

The costs were derived utilizing 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 actions included in the human generic drug activities in GDUFA, as explained in the discussion in Appendix C, the cost categories within each organization listed above were identified as part of human generic drug activities.

CENTER COSTS

Costs of the human generic drug application review program are tracked for each organizational component in CDER and CBER, usually at the division level. Most FDA components involved in the process perform a mixture of activities – some within the definition of the process for the review of human generic drug activities, 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 8 weeks (2 weeks per quarter) each fiscal year in activity-based time reporting systems. The activities in the systems differentiate between time spent on the process for the review of human generic drug activities and all other time, so that time reported can be separated into allowable and excluded activities as defined by GDUFA.

FDA is a payroll-intensive organization – about 52 percent of all FDA funds pay for employee salaries and benefits, and almost all other costs are directly supporting these employees. Thus the average percentage of time reported on human generic drug review process activities 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 cost centers' costs incurred while conducting human generic drug review activities in FY 2013.

Indirect Review and Support

Indirect review and support components provide the infrastructure for the review process. In CDER, these components include portions of the Office of the Center Director, the Office of Strategic Programs, the Office of Management, the Office of Communications, and the Office of Executive 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 process for the review of human generic drug activities is equivalent to the proportion of time Center employees in direct review and laboratory components spend on human drug review process activities. Thus the average percentage of time expended on human drug review activities for all direct review and laboratory components in FY 2013 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 process for the review of human generic drug activities. 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.

Resources expended in FY 2013 by the Office of Shared Services in supporting the human generic drug application review process 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 review process for human generic drug activities.

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. The Agency then multiplies the total number of staff-years used in the process for the review of human generic drug activities by the average salary and benefits cost in ORA to arrive at ORA salary and benefit costs for work that is a part of the process for the review of human generic drug activities as defined in GDUFA. The final step is to allocate ORA obligations for operations and rent to the human generic drug review activities based upon the ratio of user fee related staff-years to total ORA staff-years.

Table 9 summarizes the calculation of ORA costs for the process for the review of human generic drug activities for FY 2012 and FY 2013.

TABLE 9: OFFICE OF REGULATORY AFFAIRS COSTS OF THE REVIEW PROCESS FOR HUMAN GENERIC DRUG ACTIVITIES AS OF SEPTEMBER 30, 2013

COST COMPONENT	FY 2013
FTEs Utilized	157
ORA Average Salary and Benefits	\$117,355
Total Salary and Benefits	\$18,424,735
Operating and Other Costs ¹	\$15,376,942
TOTAL	\$33,801,677

¹ Other costs are central, GSA rent, rent related, and Shared Services costs that are applicable to human generic drug activities.

ORA costs associated with human generic drug activities described above include costs paid from appropriations and costs paid from fee revenues. In FY 2013, ORA devoted 157 FTE to the review process for human generic drug activities.

FDA 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 Legislation
- Office of Policy and Planning
- 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 Operation
- 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 Device 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 process for the review of human generic drug activities 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 process for the review of human generic drug activities in CDER, CBER, and ORA to derive the applicable Agency general and administrative costs.

Using this methodology, FDA dedicated \$16,929,455 in general and administrative costs to human generic drug activities in FY 2013. The costs are total costs obligated from appropriations and user fees. FDA strives to maintain a low overhead cost for human generic drug activities. General and administrative costs are approximately 6 percent of FY 2013 costs associated with human generic drug activities.