U.S. FOOD & DRUG ADMINISTRATION

FY 2016

PERFORMANCE REPORT TO CONGRESS

for the

Generic Drug User Fee Amendments

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Acting Commissioner's Report

I am pleased to present to Congress the Food and Drug Administration's (FDA) annual performance report on the Generic Drug User Fee Amendments of 2012 (GDUFA). This report details FDA's preliminary accomplishments in fiscal year (FY) 2016 (October 1, 2015, through September 30, 2016) and updates FDA's performance for the previous years of GDUFA. This report marks the fourth year of GDUFA.

The procedural and processing goals agreed upon in the GDUFA Program Performance Goals and Procedures (GDUFA Commitment Letter)[1] helped FDA to safeguard the nation's generic drug supply while also ensuring the American public has access to safe, effective, and high-quality generic drugs. In the initial stages of the program, FDA underwent a major restructuring effort that considered the challenges of advancements in medical technology and prescription drug therapies and embraced the growing complexity and magnitude of FDA's responsibilities. FDA employed a meticulous approach to managing and achieving the GDUFA performance goals. Consequently, early investments in process improvement, infrastructure, and staff development have yielded significant benefits.

Before GDUFA goal dates went into effect in FY 2015, FDA improved the efficiency of the generic drug review program by:

- Hiring and training many additional FDA staff
- Reorganizing the Office of Generic Drugs (OGD) into a Center for Drug Evaluation and Research (CDER) "Super Office"
- Establishing a new Office of Pharmaceutical Quality
- Replacing fragmented information technology systems with a new integrated system (i.e., CDER Informatics Platform) that has enhanced database capacity and performance

Due to FDA's restructuring and commitment to building a robust, modern generic drug review program, FDA has not only met every GDUFA commitment to date, but exceeded them. In many ways, FDA's commitment to building a sustainable and predictable program has gone above and beyond the GDUFA Commitment Letter goals. Some examples include:

- Significantly reduced the number of human generic drug applications pending with the Agency and met the GDUFA backlog commitment 15 months ahead of schedule
  - Worked collaboratively with industry to reduce the frequency of multi-cycle approvals
  - Published guidance documents for industry in order to clarify Agency recommendations for submissions
  - Increased reporting on status of GDUFA goals to increase transparency on performance
  - Established and implemented a risk-based model to promote equivalency in scheduling of facility inspections between domestic and foreign manufacturers of human generic drug products

[1] www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf

I am excited about FDA's significant progress in meeting the challenges and responsibilities of the generic drug program. We look forward to continued success in the future.

Stephen M. Ostroff, M.D.
Commissioner of Food and Drugs

Acronyms

ANDA – Abbreviated New Drug Application

API – Active Pharmaceutical Ingredient

BE – Bioequivalence

CA – Completeness Assessments

CC – Controlled Correspondence

CBER – Center for Biologics Evaluation and Research

CDER – Center for Drug Evaluation and Research

CR – Complete Response

CGMP – Current Good Manufacturing Practices

DMF – Drug Master File

ECD – Easily Correctable Deficiency

eCTD – Electronic Common Technical Document

FDA – Food and Drug Administration

FDASIA – Food and Drug Administration Safety and Innovation Act

FD&C Act – Federal Food, Drug, and Cosmetic Act

FDF – Finished Dosage Form

FTE – Full-Time Equivalent

FY – Fiscal Year (October 1 – September 30)

GDUFA – Generic Drug User Fee Amendments of 2012

IR – Information Request

IT – Information Technology

MAPP – Manual of Policies and Procedures

OGD – Office of Generic Drugs

OIP – Office of International Programs

ORA – Office of Regulatory Affairs

PAS – Prior Approval Supplement

PDUFA – Prescription Drug User Fee Act

RLD – Reference Listed Drug

RPM – Regulatory Project Manager

RTR – Refuse to Receive

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Executive Summary

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA),[2] which included the authorization of the Generic Drug User Fee Act (GDUFA). GDUFA authorizes the Food and Drug Administration (FDA) to collect user fees for human generic drug activities and enables FDA to advance a safer, more efficient, and more affordable human generic drug review program. Furthermore, GDUFA enhances FDA's ability to protect Americans in the complex global supply environment by requiring the self-identification of facilities involved in the manufacture of generic drugs and associated active pharmaceutical ingredients (API). GDUFA also allows FDA to ensure that foreign and domestic industry participants in the U.S. generic drug system are held to consistent, high-quality standards and are inspected with comparable rigor and frequency, using a risk-based approach. This self-identification requirement allows FDA to create an accurate inventory of facilities and organizations involved in the manufacture of human generic drugs.

FDA has made noteworthy advancements in the implementation of GDUFA. This annual report presents preliminary data on FDA's success in meeting FY 2016 review performance goals and commitments, and updates the review goals performance for FYs 2013 through 2015.

FY 2016 GDUFA Performance

FDA's efforts to lay the foundation for a modern generic drug program have positioned the Agency to meet the FY 2016 GDUFA goals, which were agreed upon in the GDUFA Commitment Letter.[3] However, it is too soon to determine whether FDA will meet all the GDUFA review goals for FY 2016. For example, the goal date for review of an abbreviated new drug application (ANDA) that arrived on the last day of FY 2016, September 30, 2016, is December 29, 2017. However, FDA is confident that, given the Agency's efforts to transform the generic drug program, the GDUFA goals agreed to in the Commitment Letter will be met.

During FY 2016, FDA accomplished the following:

- FDA exceeded the commitment to respond to 70 percent of GDUFA Year 4 Controlled Correspondence (CC) within 2 months of submission (if the CC requires input from the clinical division, 1 additional month is added to the goal, making them due within 3 months of the submission). FDA has responded to 96 percent or more of CC within goal for those submitted through September 2016.
- FDA committed to review and act on 90 percent of all ANDAs, Prior Approval Supplements (PASs), and amendments that were pending on October 1, 2012 (i.e., backlog), by the end of FY 2017 (i.e., September 30, 2017). As of September 30, 2016,

[2] www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf
[3] www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf

FDA has taken action on 93 percent of the backlog. FDA met the backlog goal in June 2016, 15 months ahead of schedule.

- FDA committed to review and act on 75 percent of Year 4 (i.e., FY 2016) PASs requiring inspection within 10 months of submission. The Agency has not missed a goal date for such FY 2016 PAS submissions, and as of the end of Year 4, FDA is 100 percent on time.
- As of September 30, 2016, the average time to approval for the FY 2016 PAS cohort is 99 calendar days. As more PASs in each cohort are approved, the average number of calendar days is expected to increase. The cohort numbers for each fiscal year will be updated and reported in future GDUFA Performance Reports.
- FDA completed 890 Type II API Drug Master File (DMF) Completeness Assessments (CA).
- FDA continued to maintain the "Available for Reference Type II DMFs for APIs for Generic Drug Applications" list, containing more than 3,000 Type II API DMFs that passed the CA and are available for reference. This list is publicly available.[4]
- FDA continued to advance scientific efforts under the regulatory research science program through a collaborative partnership with the regulated industry. FDA's efforts included holding an annual Regulatory Science Part 15 hearing to provide an opportunity for industry and other stakeholders to provide input on developing the annual list of regulatory science initiatives specific to generic drugs for the FY 2016 Regulatory Science Plan.
- FDA engaged in other outreach efforts to educate and inform industry participants and other stakeholders about GDUFA. For example:

    - In November 2015, FDA speakers, along with industry, addressed a number of key current regulatory and technical issues impacting the generic drug industry at the Generic Pharmaceutical Association (GPhA) Fall Technical Conference.
    - In February 2016, FDA discussed GDUFA and the generic drug program at GPhA's annual meeting.
    - In April 2016, FDA staff discussed communication with industry, current trends in labeling and best practices, and GDUFA regulatory science with small businesses and others at the Regulatory Education for Industry (REdI) Generic Drugs Forum.
    - In May 2016, FDA speakers provided their insights on GDUFA and generic drug quality issues during the Chemistry, Manufacturing, and Controls (CMC) workshop hosted by GPhA.

[4] www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM332875.xls

- In July 2016, FDA discussed a range of important quality issues with small businesses and others at the REdI Pharmaceutical Quality Symposium.

- FDA published multiple guidances and Manuals of Policies and Procedures (MAPPs) to clarify policies and procedures, including MAPP 5200.7: "Review of ANDAs, Amendments, and Supplements by the Division of Filing Review;" MAPP 5240.3 Rev 2: "Prioritization of the Review of Original ANDAs, Amendments, and Supplements" and MAPP 5241.2: "Consolidation of ANDAs by OGD."[5]

[5] www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf

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Introduction

Millions of Americans use generic drugs to treat a wide variety of medical conditions.[6] The Food and Drug Administration (FDA) helps ensure that human generic drug products are thoroughly tested and shown to meet the statutory standards for approval, in most cases by proof that they contain the same active ingredients, are identical in strength and dosage-form, deliver the same amount of active ingredients to the site of action, and maintain the same strict standards of good manufacturing practice regulations as their brand-name counterparts.[7]

On July 9, 2012, the President signed the Food and Drug Administration Safety and Innovation Act (FDASIA) into law, which included the authorization of the Generic Drug User Fee Act (GDUFA) for 5 years (FY 2013 through FY 2017). GDUFA authorizes FDA to collect user fees to support the review of human generic drug activities.

GDUFA provides FDA with supplemental funds to hire and train additional reviewers, investigators, and support staff, and to upgrade its information technology (IT) systems. GDUFA empowers FDA to better serve and protect public health by implementing management initiatives that are designed to increase the efficiency of the human generic drug program and improve the predictability of review processes. The GDUFA hiring initiative is a critical component to achieving GDUFA performance goals.

Historically, globalization of the human generic pharmaceutical industry challenged FDA's limited resources and impacted FDA's oversight of domestic and foreign facilities and their supply chain entities. GDUFA's authorization of additional resources, as described above, allowed FDA to increase oversight of foreign and domestic facilities and commit to achieving risk-adjusted parity in inspections of foreign and domestic facilities.

GDUFA requires that human generic drug facilities and sites submit, update, or reconfirm their identification information on an annual basis. Self-identification is a key element in FDA's ability to deliver health safety and security. It is crucial in understanding the scope of the global supply chain for human generic drugs and in allowing FDA to determine the universe of facilities required to pay user fees. FDA uses the information obtained through the self-identification process to facilitate inspections and compliance. Enhanced safety of the supply chain ultimately reduces risk.

[6] According to a GPhA report, generic drugs have saved the American health care system over $1.46 trillion over the 10-year period from 2006 through 2015—with over $227 billion saved in 2015 alone—under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act (www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg1585.pdf).

[7] Some generic drugs are permitted, after grant of a suitability petition, to deviate in minor ways from the innovator they copy. See section 505(j)(2)(C) of the FD&C Act.

Performance Presented in This Report

GDUFA performance goals cover a wide range of improvements including, enhancing the efficiency of the review process; increasing and expediting hiring and training; decreasing the backlog of applications that were pending FDA decisions as of October 1, 2012; ensuring consistency and frequency of inspections for domestic and foreign sites; improving transparency; establishing databases and IT systems; and advancing regulatory science initiatives. This report details FDA's performance in the fourth year of GDUFA and presents the Agency's progress in accomplishing the program goals and enhancements detailed in the GDUFA Commitment Letter. Unless otherwise noted, all data are as of September 30, 2016.

The information below applies to FDA's implementation of GDUFA and its performance goals and provides some key terms and concepts used in this report.

- Several of the GDUFA performance goals are scheduled to be implemented incrementally from FY 2015 through FY 2017. Therefore, this report will include information on goals not discussed in previous reports.
- FDA will annually report GDUFA performance data for each fiscal year receipt cohort (defined as submissions received from October 1 to September 30). Some submissions received in one fiscal year may have associated goals requiring completion in subsequent fiscal years. In these cases, FDA's performance will be reported in subsequent fiscal year reports either after FDA takes an action or when the action required by a goal becomes overdue, whichever comes first.
- In order for a performance goal to be met, FDA must review the specified percentage of submissions within the review-time goal. For example, in FY 2016, in order to meet the goal for original ANDAs, FDA will need to review and act on 75 percent of original ANDAs within 15 months.
- To "act on an application" means that FDA will issue a complete response (CR) letter, an approval letter, a tentative approval letter, or a refuse to receive (RTR) letter.
- FDA may close out a request for a first cycle review teleconference by (1) holding the teleconference or (2) responding to questions in the applicant's teleconference request in writing in lieu of holding the teleconference.
- For applications and supplements submitted in response to an RTR action, the applicable performance goal is determined by the fiscal year in which the response is received, rather than the fiscal year in which the initial application or supplement that was designated as RTR was submitted.
- Submission types with shorter review-time goals (e.g., PASs with 6-month goal dates in FY 2016, CC with 24-month goal dates in FY 2016) tend to have a larger percentage of reviews completed by the end of the fiscal year, and their preliminary performance is a more reliable indicator of their final performance. However, submission types (e.g., original ANDA submissions) with longer review-time goals (e.g., 15-month goal date in FY 2016) tend to have a smaller percentage of reviews completed, and their preliminary performance is a less reliable indicator of their final performance.

- Definitions of key terms used throughout this report can be found in Appendix A.

GDUFA Performance Goals and Commitments

The table below reflects the percentage of submissions that FDA must act on in order to meet the goal for that particular fiscal year. Goals are phased in incrementally over the 5-year authorization period, with most goals beginning in FY 2015. Definitions of submission types can be found in Appendix A.

GDUFA Goals/Commitment Type	Review-Time Goal	FY 13	FY 14	FY 15	FY 16	FY 17
Original ANDA Review						
Original ANDA Submissions	15 months	--	--	60%	75%	--
Original ANDA Submissions	10 months	--	--	--	--	90%*
Amendment Review[†]						
Tier 1 - First Major Amendment	10 months	--	--	60%	75%	90%
Tier 1 - First through Third Minor Amendment	3 months	--	--	60%	75%	90%
Tier 1 - First through Third Minor Amendment Requiring an Inspection	10 months	--	--	60%	75%	90%
Tier 1 - Fourth through Fifth Minor Amendment	6 months	--	--	60%	75%	90%
Tier 1 - Fourth through Fifth Minor Amendments Requiring an Inspection	10 months	--	--	60%	75%	90%
Tier 2 Amendments	12 months	--	--	60%	75%	90%
PAS Review Time						
PASs Not Requiring Inspections	6 months	--	--	60%	75%	90%
PASs Requiring Inspections	10 months	--	--	60%	75%	90%
Controlled Correspondence						
Controlled Correspondence	4 months	--	--	70%	--	--
Controlled Correspondence	2 months	--	--	--	70%	90%
Controlled Correspondence Requiring Input from Clinical Division	5 months	--	--	70%	--	--
Controlled Correspondence Requiring Input from Clinical Division	3 months	--	--	--	70%	90%
ANDA Review Efficiency						
30-Minute Teleconference	10 business days	--	--	200	250	300
DMF Review Efficiency						
30-Minute Teleconference	10 business days	--	--	[§]	[§]	[§]
Backlog						
Review and Act on ANDAs, ANDA Amendments, and ANDA PASs That Are Pending on October 1, 2012	60 months	--	--	--	--	90%
Human Resources						
Incremental Staffing	Staff/Train	25%	50%	25%	--	--

* Ten-month review cycle for 90 percent of applications submitted in year 5.
[†] Amendments may be submitted to either Original ANDAs or PASs.
[§] One teleconference per DMF holder per month, with the number of teleconferences not to exceed the number of teleconferences for ANDAs.

GDUFA Preliminary and Updated Performance Summary

The table below presents GDUFA preliminary performance data for FY 2016. Based on preliminary performance for FY 2016, FDA has not missed a goal, has already met the two CC goals, and has the potential to meet all goals. The percentage on time to date is 97 percent or higher for all goals. FDA will be able to report final performance for FY 2016 as goal dates for each category come to fruition. However, final performance will depend on the outcome of pending submissions and is presented as a potential range.

GDUFA FY 2016 Preliminary Performance	Review-Time Goal	Goal	Actions* Completed	Percent on Time[†]	Potential Range[‡]
I. Original ANDA Review-Time Goals					
Original ANDA Applications	15 months	75%	224 of 835	100%	27% to 100%
II. Amendment Review-Time Goals[§]					
Tier 1 - First Major Amendment	10 months	75%	--	--	--
Tier 1 - First through Third Minor Amendment	3 months	75%	--	--	--
Tier 1 - First through Third Minor Amendment Requiring an Inspection	10 months	75%	--	--	--
Tier 1 - Fourth through Fifth Minor Amendment	6 months	75%	--	--	--
Tier 1 - Fourth through Fifth Minor Amendments Requiring an Inspection	10 months	75%	--	--	--
Tier 1 - Unsolicited Delaying Amendment	3 month	75%	1 of 5	100%	20% to 100%
Tier 2 Amendments	12 months	75%	2 of 12	100%	17% to 100%
Tier 3 Amendments	--	--	--	--	--
III. PAS Review-Time Goals					
PASs Not Requiring Inspections	6 months	75%	257 of 428	99%	60% to 100%
PASs Requiring Inspections	10 months	75%	15 of 25	100%	60% to 100%
IV. PAS Amendment Review-Time Goals[§]					
Tier 1 - First Major Amendment	10 months	75%	1 of 2	100%	50% to 100%
Tier 1 - First through Third Minor Amendment	3 months	75%	10 of 17	100%	59% to 100%
Tier 1 - First through Third Minor Amendment Requiring an Inspection	10 months	75%	--	--	--
Tier 1 - Fourth through Fifth Minor Amendment	6 months	75%	1 of 1	100%	100% of 100%
Tier 1 - Fourth through Fifth Minor Amendments Requiring an Inspection	10 months	75%	--	--	--
Tier 1 - Unsolicited Delaying Amendment	3 months	75%	5 of 7	100%	71% to 100%
Tier 2 Amendments	12 months	75%	5 of 8	100%	63% to 100%
Tier 3 Amendments	--	--	--	--	--
V. Controlled Correspondence					
Controlled Correspondence	2 months	70%	1543 of 1802	97%	83% to 98%
Controlled Correspondence Requiring Input from Clinical Division	3 months	70%	72 of 80	99%	89% to 99%

* Actions completed include any action taken regardless of whether or not it met the review-time goal.
[†] Percent on time represents the current percentage of actions FDA completed within the review-time goal.
[‡] Range represents the minimum (all pending become late) and maximum (all pending reviewed on time) performance.
§ Amendments are a work in progress. The dataset is preliminary and immature; we expect more robust reporting in future reports.

The following table shows the progress of the FY 2015 cohort. FDA continues to meet all of the review goals. FDA has already met 12 goals and has the potential to meet the goal for all the remaining milestones

GDUFA FY 2015 Updated Performance	Review-Time Goal	Goal	Actions* Completed	Percent on time†	Potential Range‡
I. Original ANDA Review-Time Goals					
Original ANDA Applications	15 months	60%	405 of 505	98%	79% to 98%
II. Amendment Review-Time Goals§					
Tier 1 - First Major Amendment	10 months	60%	0 of 17	--	0% to 100%
Tier 1 - First through Third Minor Amendment	3 months	60%	27 of 59	96%	44% to 98%
Tier 1 - First through Third Minor Amendment Requiring an Inspection	10 months	60%	0 of 4	--	0% to 100%
Tier 1 - Fourth through Fifth Minor Amendment	6 months	60%	--	--	--
Tier 1 - Fourth through Fifth Minor Amendments Requiring an Inspection	10 months	60%	--	--	--
Tier 1 - Unsolicited Delaying Amendment	3 month	60%	25 of 28	92%	86% to 93%
Tier 2 Amendments	12 months	60%	117 of 133	96%	85% to 96%
Tier 3 Amendments	--	--	--	--	--
III. PAS Review-Time Goals					
PASs Not Requiring Inspections	6 months	60%	344 of 347	98%	98% of 98%
PASs Requiring Inspections	10 months	60%	69 of 69	96%	96% of 96%
IV. PAS Amendment Review-Time Goals§					
Tier 1 - First Major Amendment	10 months	60%	2 of 5	100%	40% to 100%
Tier 1 - First through Third Minor Amendment	3 months	60%	66 of 70	100%	94% to 100%
Tier 1 - First through Third Minor Amendment requiring an Inspection	10 months	60%	2 of 2	100%	100% of 100%
Tier 1 - Fourth through Fifth Minor Amendment	6 months	60%	1 of 1	100%	100% of 100%
Tier 1 - Fourth through Fifth Minor Amendments Requiring an Inspection	10 months	60%	--	--	--
Tier 1 - Unsolicited Delaying Amendment	3 month	60%	6 of 6	100%	100% of 100%
Tier 2 Amendments	12 months	60%	16 of 16	100%	100% of 100%
Tier 3 Amendments	--	--	--	--	--
V. Controlled Correspondence					
Controlled Correspondence	4 months	70%	1183 of 1197	98%	97% to 98%
Controlled Correspondence Requiring Input from Clinical Division	5 months	70%	322 of 322	100%	100% of 100%

* Actions completed include any action taken regardless of whether or not it met the review-time goal.
† Percent on time represents the current percentage of actions FDA completed within the review-time goal.
‡ Range represents the minimum (all pending become late) and maximum (all pending reviewed on time) performance.
§ Amendments are a work in progress. The dataset is preliminary and immature; we expect more robust reporting in future reports.

For the receipts in FY 2013 and FY 2014, the GDUFA Commitment Letter does not require FDA to report on any performance goals. The table below presents GDUFA's performance in terms of completed actions for cohort years of receipt FY 2013, FY 2014, and FY 2015, as well as preliminary FY 2016 performance.

GDUFA Performance	FY 13*	FY 14*	FY 15*	FY 16
Refuse to Receive for Failure to Pay Fees	62	38	7	16
Refuse to Receive for Technical Reasons	147	157	94	198
Number of CR Letters with Inspection Recommendations	704	722	281	7
Number of CR Letters without Inspection Recommendations	137	63	3	--
Number of Tentative Approvals	86	45	24	--
Number of Approvals	171	158	23	--
Number of PAS CR Letters	105	54	135	63
Number of PAS Approvals	248	192	339	226

* These figures represent the updated FY 2013, FY 2014, and FY 2015 GDUFA performance data, as well as preliminary FY 2016 GDUFA performance data.

GDUFA Workload: Applications and Submissions Received

Under GDUFA, FDA agreed to issue timely CR letters generally reflecting full division-level reviews of all deficiencies (including inspections and consults) noted by relevant review disciplines. FDA also agreed to make every reasonable effort to communicate promptly with applicants to facilitate the timely revision of easily correctable deficiencies (ECDs) found in ANDAs and PASs and to clarify issues and answer questions on deficiencies used in the first cycle CR letter. FDA's communications are further discussed in the ANDA and DMF Review Efficiency Enhancements section of this report. These commitments are intended to reduce the number of ANDA review cycles.

The following table summarizes GDUFA workload for FY 2013 through FY 2016. The GDUFA application figures represent submissions that are subject to the review metrics. Submissions to FDA are tracked according to the fiscal year in which they are submitted. Since GDUFA afforded FDA a 2-year implementation period (i.e., FY 2013 and FY 2014) to hire and train new staff and establish the necessary infrastructure, FDA had no review-time goals for ANDAs, PASs, or amendments in FY 2013 or FY 2014. The performance of the GDUFA review time is measured against a goal for the first time in FY 2015; however, FDA did monitor the performance during the first 2 years to identify any areas where improvements were needed.

When GDUFA was negotiated, the average number of ANDAs and PASs expected was approximately 750 each annually. As is reflected below, receipts for ANDAs significantly exceeded that expectation in FY 2013, FY 2014, and FY 2016 but fell below expectations in FY 2015. Regardless of the lower number of receipts in FY 2015, FDA received more than 5 years of projected ANDA receipts in the first 4 years of GDUFA. Also it is important to note that the table below shows a significant increase in PAS receipts and CC.

GDUFA Workload	FY 2013*	FY 2014*	FY 2015*	FY 2016
Original ANDAs				
Total Original ANDAs Submitted	1,055	1,583	505	836
ANDAs Submitted after RTR for Failure to Pay User Fees	44	36	19	12
ANDAs Submitted after RTR for Technical Reasons	75	99	95	187
ANDA Solicited Amendments				
Total Solicited ANDA Amendments Submitted	527	317	80	0
PASs				
Total PAS Submissions with Inspection Status Undetermined	323[†]	256[†]	416	453
PAS Solicited Amendments				
Total Solicited PAS Amendments Submitted	87	40	78	21
CC				
Total CC Submitted	953	1,087	1,197	1,802
Total CC Requiring Input from Clinical Division	36	26	322	80

* Numbers for prior fiscal years are updated annually.
[†] Inspection status for PASs submitted in FYs 2013 and 2014 was not established because there were no PAS review goals in those fiscal years.

Management Priorities and Accomplishments

GDUFA includes several management and statutory requirements that are critical to enabling progress toward performance goals for the human generic drug program. These priorities include enhancing the efficiency of the review process, increased and expedited hiring, decreasing the backlog of applications, ensuring consistency and frequency of inspections for domestic and foreign sites, improving transparency, establishing databases and IT systems, and advancing regulatory science initiatives. This section details the status of these requirements.

Human Resources

FDA committed to hiring and training the staff necessary to achieve GDUFA program goals with incremental hiring goals established for FY 2013 and FY 2014. In FY 2015, FDA met the mandated human resources goal by hiring the final 25 percent of overall GDUFA program hires nearly 11 months ahead of schedule. FDA has continued to add resources to the GDUFA program with a total of 1,192 hires by the end of FY 2015.

The following table shows how FDA met the GDUFA human resource goals.

Fiscal Year	New Full-Time Equivalent Count as of End of Fiscal Year	Incremental Hiring Goal	Percent of Incremental Staff Hired*	Cumulative Percent Hired	Goal Met
2013	291	25%	31%	25%	Yes
2014	591	50%	64%	96%	Yes
2015	310	25%	34%	129%	Yes
2016	There are no additional hiring goals for GDUFA				

* The percentage of incremental staff hires does not add up to 100 percent because FDA exceeded the GDUFA hiring goal.

Generic Industry Facility Self-Identification

To increase transparency into the complex, global, human generic drug industry and to enhance the safety of the supply chain, GDUFA requires facilities, sites, and organizations involved in the manufacturing of finished dosage forms (FDF) or API for human generic drugs to self-identify annually. This statutory requirement enables FDA to build an accurate inventory of facilities, sites, and organizations; improves the Agency's ability to target compliance issues and inspections; and expedites access to human generic drug products. In addition, facilities manufacturing FDFs and APIs for human generic drugs are required to pay an annual facility fee when the facility is referenced in a pending or approved human generic submission as of the fee due date of each applicable fiscal year.

The table below displays the number of facilities, sites, and organizations that submitted their self-identification information to FDA during the open periods for fiscal years 2013 through 2017. A detailed list of all GDUFA self-identified facilities, sites, and organizations is available on FDA's GDUFA website.[8] Across the 5-year initial reporting period, an average of 3,500 GDUFA facilities, sites, and organizations self-identified each fiscal year. On average there were 290 domestic FDF and 423 foreign FDF versus 112 domestic API and 728 foreign API.

Fiscal Year	Number of Facilities, Sites, and Organization	Self-Identification Open Period per FY	Business Operations Reported for User Fees			
			Domestic FDF	Foreign FDF	Domestic API	Foreign API
2013	3,334	Oct 02, 2012 - Dec 03, 2012*	325	433	122	763
2014	3,604	May 01, 2013 - Jun 01, 2013	315	433	128	775
2015	3,335	May 01, 2014 - Jun 01, 2014	271	410	103	692
2016	3,641	May 01, 2015 - Jun 01, 2015	283	422	105	721
2017	3,605	May 01, 2016 - Jun 01 2016	255	420	101	688

* For FY 2013, the open period was extended to allow generic manufacturers additional time to comply with self-identification requirements.

GDUFA Guidance and Procedural Development

FDA committed to increasing transparency in operations and enhancing communication on critical information for ANDA applicants and manufacturers. While not required by the GDUFA Commitment Letter, in FY 2016 FDA published many guidances and MAPPs, including:

- Draft Guidance for Industry: Acceptability of Draft Labeling to Support ANDA Approval, October 2015[9]
- Draft Guidance for Industry: Liposome Drug Products – Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation, October 2015[10]
- Final Guidance for Industry: Completeness Assessments for Type II API DMFs Under GDUFA, February 2016[11]
- Draft Guidance for Industry: General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products, March 2016[12]
- Final Guidance for Industry: Environmental Assessment: Questions & Answers Regarding Drugs With Estrogenic, Androgenic, or Thyroid Activity, March 2016[13]
- Draft Guidance for Industry: Comparability Protocols for Human Drugs and Biologics: CMC Information, April 2016[14]

[8] www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm
[9] www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM465628.pdf
[10] www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm070570.pdf
[11] www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM321884.pdf
[12] www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/UCM492172.pdf
[13] www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444658.pdf

- Draft Guidance for Industry: Assessing Adhesion with Transdermal Delivery Systems and Topical Patches for ANDAs, June 2016[15]
- Draft Guidance for Industry: Quality Attribute Considerations for Chewable Tablets, June 2016[16]
- Draft Guidance for Industry: Elemental Impurities in Drug Products, June 2016[17]
- Manual of Polices and Procedures 5241.2: Consolidation of ANDAs by the Office of Generic Drugs, October 2015[18]
- Manual of Polices and Procedures 5200.7: Review of ANDAs, Amendments, and Supplements by the Division of Filing Review, November 2015[19]
- Manual of Polices and Procedures 5240.3 Rev 2: Prioritization of the Review of Original ANDAs, Amendments, and Supplements, March 2016[20]

- FDA posted 128 new draft guidances and 74 revised draft guidances with product-specific recommendations in FY 2016. These guidances describe the Agency's current thinking and expectations on how to develop generic drug products therapeutically equivalent to specific reference-listed drugs.

	Total # of Guidances	New Draft Guidance	Revised Draft Guidance
Jan 2016 batch posting	46	35	11
April 2016 batch posting	44	38	6
June 2016 batch posting	38	19	19
Stand-alone postings	7	2	5
September 2016 batch posting	67	34	33
Total	202	128	74

[14] www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496611.pdf
[15] www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/UCM504157.pdf
[16] www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM507098.pdf
[17] www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM509432.pdf
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM509432.pdf
[18] www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM469249.pdf
[19] www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM471803.pdf
[20] www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf

Technology Enhancements

FDA employed a number of significant technology improvements aimed at: promoting the efficiency of the human generic drug review process, facilitating self-identification of generic manufacturers, strengthening surveillance and inspections, and managing user-fee collection. FDA continues to devote resources to IT enhancements that integrate human generic drug information across relevant Agency systems.

Subsequent to the initial pilot release of the CDER Informatics Platform in 2014, FDA has now implemented the modern informatics platform for the review of new and generic drugs while consolidating legacy systems and increasing operational efficiency. This platform further integrates 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. It also helps FDA track GDUFA review performance goals and commitments by managing work commitments throughout FDA in one place. Recent accomplishments of the new platform include the following:

- By November 18, 2015, FDA implemented enhancements to reduce the inbound data entry processing time and streamline review assignments for ANDA amendments.

- By June 26, 2016, FDA implemented significant improvements for sending information requests to industry as well as FDA-internal consults, and implemented immediate notification to the reviewer at the time of response. Other enhancements include advanced document management for uploading, routing, and electronically signing reviews and communications. This improves review efficiency and provides reviewers with faster access to relevant information.

Backlog Summary

FDA committed to reviewing and acting on 90 percent of the backlog of 2,866 original applications and 1,877[21] PAS submissions that were pending as of October 1, 2012, by the GDUFA-defined goal of September 30, 2017. By FY 2014, FDA had issued first regulatory actions on approximately 65 percent of the backlog. As of this October 2016, FDA had issued a first action on approximately 93 percent of the GDUFA backlog applications since program launch, meeting the GDUFA backlog commitment 15 months ahead of the goal. The table below shows FDA's progress toward meeting the backlog goal.

Cumulative Percent of Backlog Issued First Action

Submission Type	Backlog as of October 1, 2012	FY 2013	FY 2014	FY 2015	FY 2016
ANDA	2866	31%	60%	80%	94%
PAS	1877	40%	73%	86%	93%
Total	4743	34%	65%	82%	93%

Review Time

Because implementation of GDUFA involves improvements in many areas, the efficiency and performance goals are phased in over the 5-year GDUFA program period. FDASIA required FDA to report the following three metrics starting in FY 2013:

1. The average total time to full approval action of applications (original ANDAs and PASs) received in each fiscal year cohort.
2. The number of original ANDAs and PASs pending with FDA for more than 10 months on September 30, 2012.
3. Of these pending ANDAs and PASs, the number FDA has taken a final action on during the previous fiscal year.

The first metric requires FDA to report the average total time to full approval action for ANDAs and PASs[22] received during the respective fiscal year, including the number of calendar days spent during the review by FDA and the number of calendar days spent by the applicant responding to a CR letter(s). The figures represented under each cohort are revised annually to

[21] The FY 2014 GDUFA Performance Report noted there were 1,879 PAS submissions. This figure has been adjusted as a result of data validation and cleanup.

[22] Section 715(a)(2) of FDASIA requires FDA to report on the total time for "applications for approval of a generic drug under 505(j), amendments to such applications, and prior approval supplements…" Pursuant to 21 CFR 314.98, applicants may amend an ANDA not yet approved to revise existing information or provide additional information. Amendments are not submissions separate from an original ANDA or PAS. FDA does not take action on amendments and therefore cannot report on the time to approval for amendments received in any fiscal year.

incorporate updated results based on ANDAs and PASs approved in the previous fiscal year. The data are presented in the following two tables.

Average Calendar Days to Full Approval Action: Original ANDAs

	FY 2013	FY 2014	FY 2015*	FY 2016
First Cycle Approvals[†]				
Average Total Time to Approval	992	749	440	--
Multi-Cycle Approvals				
Average Total Time to Approval	1,019	773	541	--[‡]
Average Calendar Days Spent During Review by FDA	859	636	518	--[‡]
Average Calendar Days Spent by Applicant Responding to CR	160	137	24	--[‡]
Total Combined (First Cycle and Multi-Cycle)				
Combined Average Total Time to Approval	1,012	759	467	--

***** Given the substantial workload and the 15-month review goal for original ANDAs submitted in FY 2016, none of the original ANDAs submitted in FY 2016 were approved during FY 2016 and only one ANDA submitted in FY 2015 was approved during FY 2016.

[†] First cycle approvals may include applications for which ECDs and Information Requests (IRs) were issued in order to help applicants correct deficiencies in the current review cycle. This reduces the need for additional review cycles; however, it may add to the total review time for first cycle approvals.

[‡] There are no approvals to report yet for FY 2016, but as FY 2016 goal dates come to fruition, there may be first cycle approval numbers to report along with multi-cycle approval numbers in future reports.

Average Calendar Days to Full Approval Action: PASs

	FY 2013	FY 2014	FY 2015	FY2016
First Cycle Approvals*				
Average Total Time to Approval	327	269	111	94
Multi-Cycle Approvals				
Average Total Time to Approval	652	441	350	252
Average Calendar Days Spent During Review by FDA	523	310	236	222
Average Calendar Days Spent by Applicant Responding to CR	129	130	114	30
Total Combined (First Cycle and Multi-Cycle)				
Combined Average Total Time to Approval	401	290	147	99

*First cycle approvals may include supplements for which ECDs and IRs were issued in order to help applicants correct deficiencies in the current review cycle. This reduces the need for additional review cycles; however, it may add to the total review time for first cycle approvals.

The table below presents data on the third and fourth FDASIA metrics (the number of original ANDAs and PASs pending with FDA for more than 10 months on September 30, 2012, and the number of these with final regulatory action). A final regulatory action is either an approval by FDA or a withdrawal by the sponsor. FDA continues to make steady progress reducing the number of such applications.

Number of Pending Applications with Final Regulatory Action*

Submission Type	Applications Pending for Longer Than 10 Months as of September 30, 2012	Final Regulatory Actions Taken				Number Remaining
		FY 2013	FY 2014	FY 2015	FY 2016	
ANDA	1,854	383	371	315	239	546
PAS	943	301	284	159	87	112
Total	2,797	684	655	474	326	658

*Data in this table have been adjusted as a result of ongoing data validation.

Drug Safety and Inspections Performance

Many active ingredients that are used in human generic medicines that are marketed in the United States are manufactured in foreign countries. Prior to the passage of GDUFA, domestic facilities were routinely inspected about once every 2 years while their foreign counterparts were inspected about once every 7 to 13 years.[23] This regulatory disparity, combined with limited resources and the associated cost of inspecting foreign facilities, produced an increasing gap in the level of oversight that is needed to ensure the safety of the human generic drug supply. The Agency is addressing this regulatory disparity in part through a risk-adjusted inspection schedule further discussed in this section.

GDUFA Inspection Strategy

GDUFA requires FDA to leverage the information obtained through self-identification to conduct accurate and reliable surveillance of human generic drugs and to facilitate inspections.

FDA also committed to:

- Prioritize inspections of establishments not previously inspected and those that are associated with ANDAs that are otherwise approvable or eligible for tentative approval except for an outstanding inspection.

- Study foreign government regulatory inspections, report findings publicly, and develop a program to utilize foreign inspections classifications when and where appropriate.

- Make inspection classification results available to the public and industry. These can be found on the FDA website at www.accessdata.fda.gov/scripts/inspsearch/.

Risk-Adjusted Biennial Current Good Manufacturing Practices (CGMP) Surveillance Inspection

To ensure that foreign and domestic firms are held to consistent high-quality standards, FDA agreed to conduct risk-adjusted biennial CGMP surveillance inspections of human generic API and FDF manufacturers, with the goal of achieving risk-adjusted parity of inspection frequency between foreign and domestic establishments by FY 2017. Section 705 of FDASIA amended section 510(h) of the FD&C Act to require a risk-based schedule for inspections of

[23] FDA Fact Sheet: New User Fees for Generic Drugs Will Enhance Americans' Access to Less Expensive Drugs and Generate Major Cost Savings, www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDASIA/ucm310992.htm

establishments, whether they are located domestically or internationally.[24]

To accomplish this goal, FDA is employing a site selection surveillance inspection model that runs annually on all facilities in the FDA's inventory. The model does not distinguish – for purposes of risk ranking – if the site is foreign or domestic-based. Risk is assessed consistent with the requirements of FDASIA section 705.

Risk-adjusted parity between domestic and foreign drug inspection frequency is achieved by inspecting the highest-ranking facilities as determined by the site selection model each year.

In addition to achieving risk-adjusted parity in the frequency of inspections, FDA also committed to ensuring that domestic and foreign inspections are conducted with "comparable depth and rigor."[25] To accomplish this goal, FDA is:

- Continuing to ensure that domestic and foreign inspections are conducted according to one set of compliance programs.
- Continuing to ensure that the same trained FDA staff investigators generally conduct both domestic and foreign inspections. Under FDA's GDUFA hiring initiative, new investigators dedicated to the pharmaceutical program are expected to conduct both domestic and foreign generic drug inspections.[26]
- Prioritizing in the risk-based approach foreign establishments that have never been inspected. This will allow FDA to conduct more CGMP inspections of these establishments in future years that are classified as "abbreviated" pursuant to FDA Compliance Program 7356.002.[27]

[24] Section 705 of FDASIA amends section 510(h) of the FD&C Act to require FDA to establish a risk-based schedule for drug inspections. Section 510(h)(4) specifies that the risk-based schedule is based on the following factors: "(A) The compliance history of the establishment; (B) The records, history, and nature of recalls linked to the establishment; (C) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment; (D) The inspection frequency and history of the establishment, including whether the establishment has been inspected pursuant to section 704 within the last 4 years; (E) Whether the establishment has been inspected by a foreign government or an agency of a foreign government recognized under section 809; (F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources."

[25] GDUFA Commitment Letter, p.16: www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf.

[26] While the hiring initiative is intended to address the overall increase in the number of generic facility inspections needed, investigators hired separately from the GDUFA initiative also will be conducting generic facility inspections.

[27] See FDA Compliance Program Guidance Manual - 7356.002, Drug Manufacturing Inspections, p. 8, for a description of "Abbreviated" drug CGMP surveillance inspections www.fda.gov/downloads/ICECI/ComplianceManuals/CompliancePrograMManual/UCM125404.pdf

The table below shows numbers of inspections of generic drug establishments conducted by fiscal year. Overall, the number of domestic inspections has remained essentially stable, while the number of foreign inspections has generally increased. In all years, there have been somewhat more foreign inspections.

Location/Firm Type	FY 2013	FY 2014	FY 2015	FY 2016
Domestic Inspections*				
Generics Only†	198	213	187	201
Generic & Non-Generic	156	137	139	136
Total	**354**	**350**	**326**	**337**
Foreign Inspections*				
Generics Only†	291	379	440	377
Generic & Non-Generic	76	114	113	104
Total	**367**	**493**	**553**	**481**
Total Domestic and Foreign				
Generics Only†	489	592	627	578
Generic & Non-Generic	232	251	252	240
Total	**721**	**843**	**879**	**818**

*An inspection was characterized as "Generic" and GMP if the firm inspected registered with the CDER User Fee Facility Data Management (UFFDM) Self-Identification system in the appropriate fiscal year and the appropriate Program Assignment Code (PAC) (e.g., 56002) was reported in the Field Accomplishments and Compliance Tracking System (FACTS).

†A firm was characterized as "Generics Only" if it was not identified in the CDER Self-Identification system as "Manufactures Non-Generics."

ANDA and DMF Review Efficiency Enhancements

FDA committed to undertake various initiatives aimed at enhancing the premarket review of human generic drugs. This section provides the status of these initiatives.

Management Initiative	Performance Area	FY 2013	FY 2014	FY 2015*	FY 2016
CR Letters					
CR letters issued reflect full division-level reviews of deficiencies from relevant disciplines, including inspections and consults.	ANDA GDUFA CR letters issued	481[†]	589[‡]	816[§]	1,356**
	PAS GDUFA CR letters issued	315[†]	170[‡]	157[§]	186**
	DMF GDUFA CR letters issued	275	530	763	856
Inspections					
Inspection classification results, along with relevant information, are made public.	Inspections	Inspection classification results, along with relevant information, were made public and are available at: www.accessdata.fda.gov/scripts/inspsearch/			

* Data in this table have been adjusted as a result of ongoing data validation.
[†] CR totals include the backlog and the FY 2013 cohort. The FY 2013 report included backlog submissions only.
[‡] CR totals include FY 2014 CRs from the backlog and the FYs 2013 and 2014 cohorts.
[§] CR totals include FY 2015 CRs from the backlog, the FY 2013, and the FYs 2014 and 2015 cohorts.
** CR totals include FY 2016 CRs from the backlog, the FY 2013, the FY 2014, the FY 2015, and the FY 2016 cohorts

Management Initiative	Performance Area	FY 2013*	FY 2014*	FY 2015	FY 2016
RTR Standards					
FDA to develop enhanced RTR standards for ANDAs and other related submissions	RTR Standards	Draft guidance was published on October 1, 2012	Final guidance was published on September 16, 2014, and is available at: www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM370352.pdf. Draft Guidance on Refuse to Receive for Lack of Proper Justification of Impurity Limits was published on September 16, 2014, and is available at: www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM414598	Revised Final Guidance on Refuse-to-Receive Standards was published on May 26, 2015, and is available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM370352.pdf.	Final Guidance on Refuse to Receive for Lack of Justification of Impurity Limits was published on August 24, 2016, and is available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM414598.pdf

Management Initiative	Performance Area	FY 2013	FY 2014	FY 2015	FY 2016
Expedited Review of Paragraph IV Applications					
Expedite review of Paragraph IV applications that are submitted on the first day that any valid Paragraph IV application for the drug in question is submitted.	Expedited review of Paragraph IV applications	Expedited review was implemented consistent with existing procedure for expediting applications as set forth in CDER's MAPP 5240.3, Prioritization of the Review of Original ANDAs, Amendments, and Supplements, and also included those applications that became eligible for approval during the review period as a result of no blocking exclusivities, patent(s) and/or applicable stays based on appropriate documentation submitted.	Continued expedited review implemented in FY 2013 consistent with existing procedure for expediting applications as set forth in CDER's MAPP 5240.3 Rev 1, Prioritization of the Review of Original ANDAs, Amendments, and Supplements, and also included those applications that became eligible for approval during the review period as a result of no blocking exclusivities, patent(s) and/or applicable stays based on appropriate documentation submitted.	Continued expedited review implemented in FY 2013 consistent with existing procedure for expediting applications as set forth in CDER's MAPP 5240.3 Rev 1, Prioritization of the Review of Original ANDAs, Amendments, and Supplements, and also included those applications that became eligible for approval during the review period as a result of no blocking exclusivities, patent(s) and/or applicable stays based on appropriate documentation submitted.	Updated CDER's MAPP 5240.3 Rev 2,[28] Prioritization of the Review of Original ANDAs, Amendments, and Supplements, to include sole-source products category for expediting applications.
Type II API DMFs Available for Reference					
FDA will deem the DMF available for reference, placing the DMF number in a publicly available list of Type II API DMFs available for reference.	Type II API DMFs available for reference list	Published Type II DMF - Available for Reference List: www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM332875.xls			
FDA will conduct a completeness assessment of Type II API DMFs.	Type II API DMF CA	Final Guidance on Completeness Assessments for Type II API DMFs Under GDUFA published February 12, 2016, and is available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM321884.pdf			

[28] MAPP updated March 11, 2016: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf.

Management Initiative	Performance Area	FY 2013††	FY 2014††	FY 2015††	FY 2016
Type II API DMFs Available for Reference					
DMF workload	DMFs found complete	1,165	1,170	637	629
	Total CA review cycles performed (includes multiple cycles on the same DMF):	1,700	1,779	901	890
	DMF GDUFA incomplete letters issued	526	602	268	262
	DMF CR letters	275	530	763	856
	DMF no further comments letters	491	443	502	1,045
ANDA Teleconferences Workload					
When requested by the ANDA applicant within 10 business days of FDA issuing a first cycle CR letter, FDA will schedule a teleconference to clarify issues and answer questions.[29]	Teleconferences requested	23	64	52	36
	Teleconferences closed out	21	56	47	33
	Teleconferences denied	2	8	5	3
DMF Teleconferences Workload					
When requested by a DMF holder within 10 business days of FDA issuing a first cycle DMF deficiency letter, FDA will schedule a teleconference to clarify issues and answer questions. Priority for such teleconferences will be given to DMFs referenced in expedited and first major deficiency applications.	Teleconferences requested	10	9	5	5
	Teleconferences closed out	10	9	5	4
	Teleconferences denied	0	0	0	1

†† These figures represent the final FY 2013, FY 2014, and FY 2015 GDUFA teleconference data; prior years' numbers are updated annually.

[29] FDA may close out a request for a first cycle complete response teleconference by (1) holding the teleconference or (2) responding to questions in the sponsor's teleconference request in writing in lieu of holding the teleconference.

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Research Performance

Under GDUFA, FDA committed to advance scientific efforts to develop new human generic products and novel dosage forms. Through its regulatory science initiatives, FDA continues to work on developing tools, standards, and approaches to assess the safety, efficacy, and quality of these products and facilitate the path to market approval.

One example of FDA's commitment to this program has been through development of product-specific guidances and recommendations for regulatory submissions (e.g., ANDAs, pre-ANDA meeting requests, CCs). FDA has developed and published more than 100 product-specific guidances for complex drug products, including approximately 45 new complex drug product-specific guidances in FY 2016. The publication of these product-specific guidances on the design of bioequivalence studies has provided industry with sound scientific information that can be used in their development of new and novel generic drugs.

FDA's efforts have not gone unnoticed. The results of two post-approval bioequivalence studies in patients with epilepsy comparing generic versus brand-name lamotrigine were completely consistent with the healthy subject bioequivalence studies used for original approval of generic lamotrigine. These study results were published in a 2016 *Lancet Neurology* article and provide evidence to support successful generic substitution of anti-epileptic drugs.[30] These results convinced the American Epilepsy Society to revise their position statement on generic substitution of anti-epileptic drugs, which now supports the bioequivalence standards recommended by FDA.[31] The American Epilepsy Society's support demonstrates that FDA's efforts are making an impact and will help with the ultimate goal of GDUFA, which is to ensure the American public has access to safe, effective, and high-quality generic drugs.

FY 2016 Generic Drug Research Priorities

FDA agreed in the GDUFA Commitment Letter to immediately begin working on the FY 2013 Regulatory Science Plan and to consult with industry and the public to create an annual list of regulatory science initiatives specific to research on generic drugs for every year afterwards.

On June 5, 2015, FDA held the FY 2015 Regulatory Science Initiatives Part 15 public hearing, which provided an overview of the status of the human generic drug regulatory science program and an opportunity for public input in developing the FY 2016 research priorities. Information obtained during the public hearing, and other inputs, e.g., comments to the public docket, were considered in developing the FY 2016 Regulatory Science Plan.[32,33]

[30] Lancet Neurol. 2016 Apr;15(4):365-72.
[31] Epilepsy Curr. 2016 May-Jun; 16(3): 209–211.
[32] Similar activities were held to determine research priorities for FY 2014 and FY 2015
[33] The list of the FY 2016 research initiatives can be found at: www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM469453.pdf.

On May 20, 2016, FDA held the FY 2016 Regulatory Science Initiatives Part 15 public hearing which provided an overview of the status of the human generic drug regulatory science program and an opportunity for public input in developing the FY 2017 research priorities.

Information obtained during the public hearing, and other inputs, e.g., comments to the public docket, was considered in developing the FY 2017 Regulatory Science Plan.[34]

From FY 2014-2017, human generic drug regulatory science priorities identified were grouped into the follow topic areas:

- Topic 1: Post-market evaluation of generic drugs
- Topic 2: Equivalence of complex drug products
- Topic 3: Equivalence of locally acting products
- Topic 4: Therapeutic equivalence evaluation and standards
- Topic 5: Computational and analytical tools

A description of these priorities is provided in Appendix B.

A complete list of FY 2013 through FY 2016 awarded studies can be found at www.fda.gov/GDUFARegScience, and a summary is provided in the table below.

Fiscal Year	Number of External Research Projects Awarded using GDUFA Funds	
	New Projects	Ongoing Projects
2016	16	38
2015	22	41
2014	35	16
2013	29	--

[34] The list of the FY 2017 research initiatives can be found at: www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM526900.pdf

Appendices

Appendix A: Definitions of Key Terms

A. Act on an Application means that FDA will either issue a complete response letter, an approval letter, a tentative approval letter, or a refuse to receive action.

B. Active pharmaceutical ingredient (API) means:
(i) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended to be used as a component of a drug and intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or
(ii) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become the final active pharmaceutical ingredient as defined in paragraph (i).

C. Amendments to an ANDA - Amendments are classified as either major, minor, or telephone and assigned tiers (1, 2, 3, or unsolicited).[35]

- Major amendments contain a substantial amount of new data or new information not previously submitted to or reviewed by FDA, requiring, in FDA's judgment, a substantial expenditure of FDA resources.
- Minor amendments require, in FDA's judgment, fewer FDA resources than are necessary to review a major amendment, but more than are necessary to review the information submitted in response to an ECD.
- If an amendment would otherwise be classified as minor, but the deficiencies are of a limited number or complexity, it can be classified as a telephone amendment at the discretion of the reviewer's team leader. Telephone amendments represent the reviewer's highest priority work assignments.

D. ANDA (Abbreviated New Drug Application) is an application submitted under section 505(j) of the FD&C Act. It contains data which when submitted to FDA's CBER or CDER/OGD, provides for the review and, if adequate, ultimate approval of a generic drug product. Generic drug applications are called "abbreviated" because they are not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, a generic applicant must, in most cases, scientifically demonstrate that its product is pharmaceutically equivalent and bioequivalent to an innovator product that FDA has found to be safe and effective. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, quality alternative to the American public.

E. Backlog refers to the ANDAs and ANDA PASs that were pending as of October 1, 2012.

[35] See Draft Guidance for Industry *ANDA Submissions — Amendments and Easily Correctable Deficiencies*, July 2014, available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM404440.pdf.

F. Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.

G. Closing out a request for a first cycle review teleconference means:
(i) holding the teleconference; or
(ii) responding to questions in the sponsor's teleconference request in writing in lieu of holding the teleconference.

H. Cohort: The GDUFA program is structured based on five cohorts of submission dates (original ANDAs, PASs, and DMFs), corresponding to the five fiscal years to be covered by the program. The year 1 cohort refers to the dates of submissions made electronically in FY 2013 (October 1, 2012, to September 30, 2013). The year 2 cohort refers to the dates of submissions made electronically in FY 2014 (October 1, 2013, to September 30, 2014). The year 3 cohort refers to the dates of submissions made electronically in FY 2015 (October 1, 2014, to September 30, 2015). The year 4 cohort refers to submissions made electronically in FY 2016 (October 1, 2015, to September 30, 2016). The year 5 cohort refers to submissions made electronically in FY 2017 (October 1, 2016, to September 30, 2017).

I. Complete response (CR) letter refers to a written communication to an applicant or DMF holder from FDA usually describing all of the deficiencies that the agency has identified in an abbreviated application (including pending amendments) or a DMF that must be satisfactorily addressed before the ANDA can be approved. CR letters will reflect a complete review and will require a complete response from industry to restart the clock. Refer to 21 CFR 314.110 and www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084138.htm for additional details.

J. Complete review refers to a full division-level review from all relevant review disciplines, including inspections, and includes other matters relating to the ANDA and associated DMFs as well as consults with other agency components

K. Controlled Correspondence (CC) is a correspondence submitted to the Agency, by or on behalf of a generic drug manufacturer or related industry, requesting information on a specific element of generic drug product development. See http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm411478.pdf. CC does not include Citizen Petitions, petitions for reconsideration, or requests for stay.

L. Delaying Amendment refers to an amendment to an ANDA from the ANDA sponsor to address actions by a third party that would cause delay or impede application review or approval timing and that were not or may not have been initially recognized by FDA as necessary when the application was first submitted. FDA's Office of Generic Drugs shall have broad discretion to determine what constitutes a delaying event caused by actions generally outside of the applicants control taking into account facts and information supplied by the ANDA sponsor.

M. Type II API Drug Master File (DMF) is a confidential, detailed document submitted by API manufacturers to FDA. A DMF contains the chemistry, manufacturing and controls of a drug component and is submitted to FDA by a person that intends to authorize FDA to

reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.

N. Excipient is defined as an ingredient/component which is added to the drug product which is not the active pharmaceutical ingredient.

O. Expedited review of application: means that a submission will receive heightened review priority per MAPP 5240.3 Rev.1, Prioritization of the Review of Original ANDAs, Amendments, and Supplements.[36]

P. Facility is described as a business or other entity under one management either direct or indirect and at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form, but does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: repackaging, relabeling, or testing. For purposes of this definition, separate buildings within close proximity are considered to be at one geographic location or address if the activities in them are closely related to the same business enterprise, under the supervision of the same local management, and are capable of being inspected by FDA during a single inspection.

Q. Finished Dosage Form (FDF) means:
(i) a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;
(ii) a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or
(iii) any combination of an API with another component of a drug product for purposes of production of such a drug product.

R. First major deficiency application refers to an ANDA which has been issued its first complete response letter classified as having major deficiency(ies).

S. Generic drug is a drug product that is approved by FDA based in part on FDA's finding that an innovator product has been shown to be safe and effective. Generic drugs generally have the same conditions of use, route of administration, dosage form, strength, and labeling as the brand product they reference, and are bioequivalent to the brand product.

T. Generic Drug Program refers to all Agency activities related to the determination of approvability of an ANDA.

U. Major and minor amendments**:** All references to “major” and “minor” amendments in this document are intended to refer to the distinctions that FDA described in its Draft Guidance for Industry: *ANDA Submissions — Amendments and Easily Correctable Deficiencies Under GDUFA,* July 2014. See, www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM404440.pdf

[36] Available online at www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf.

V. Original ANDA - The initial submission to FDA's CDER OGD or CBER of an ANDA.

W. Parity as used in reference to parity in inspections between foreign and domestic facilities means inspection at an equal frequency plus or minus 20 percent with comparable depth and rigor of inspection.

X. Prior Approval Supplement (PAS) means a request to the Secretary to approve a change in the drug substance, drug product, production process, quality controls, equipment, or facilities covered by an approved abbreviated new drug application when that change has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.[37]

Y. Refuse to Receive (RTR) means refusal to receive an ANDA for review. See 21 CFR 314.101 and the Final Guidance for Industry *ANDA Submissions — Refuse-to-Receive Standards*, December 2016. www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm370352.pdf.

Z. Resubmission: A resubmitted original application is a response to a Refuse to Receive action letter addressing all identified user fee and/or technical deficiencies.

AA. Solicited amendment is an amendment to an ANDA submitted in response to a CR letter.

BB. Submission refers to an ANDA, an amendment to an ANDA, a PAS to an ANDA, or an amendment to a PAS.

CC. Submission date is the date an ANDA, ANDA amendment, ANDA supplement, or Type II active pharmaceutical DMF arrives in the appropriate electronic portal of FDA and the fees have been paid.

DD. Tentative Approval Letter - If a generic drug product is ready for approval but cannot be approved due to a patent or exclusivity related to the reference listed drug product, FDA issues a tentative approval letter to the applicant, and the tentative approval letter details the basis for the tentative approval. The FD&C Act delays final approval of the generic drug product until all patent or exclusivity issues have been resolved or, in some cases, until a 30-month stay associated with patent litigation has expired. A tentative approval does not allow the applicant to market the generic drug product.

EE. Tier 1 amendment refers to all solicited first major amendments and the first five minor amendments, as well as unsolicited amendments that OGD agrees, based on an indication by the applicant and taking into account information supplied by the applicant, either are the result of delaying actions by the innovator applicant or would eventually be solicited.

FF. Tier 2 amendment refers to all unsolicited amendments that are not submitted based on delaying actions as determined by the OGD, taking into account the facts and information

[37] Per section 744A(10) of the FD&C Act .

supplied by the ANDA applicant, with the exception of those amendments that only remove information for review.

GG. Tier 3 amendment is any solicited major amendment subsequent to the first major amendment and/or any minor amendment subsequent to the fifth minor amendment.

HH. Unsolicited amendment is an amendment with information that is not requested by FDA and is submitted on the applicant's own initiative. Unsolicited amendments are categorized as either delaying or nondelaying. For purposes of GDUFA commitments, FDA does not classify amendments that are routine or administrative in nature and that do not require scientific review (e.g., requests for final ANDA approval, patent amendments, general correspondence, and USP monograph updates) to be unsolicited amendments.

Appendix B: FY 2014-2017 Generic Drug Regulatory Science Priorities Topic Areas

Under GDUFA, FDA committed to develop an annual list of regulatory science priorities for generic drugs. From FYs 2014-2017 FDA organized its priorities into the following topic areas:

Topic 1: Post-market evaluation of generic drugs

Post-market evaluation of generic drugs includes research into monitoring methods, understanding patient perceptions of generic drug quality and effectiveness, and verifying therapeutic equivalence via patient brand-to-generic switching studies. These investigations provide additional data in therapeutic areas where concern exists about the substitutability of generic drugs and allow FDA to verify that generic drugs are fully interchangeable, safe, and effective in comparison to their reference listed drug (RLD).

Topic 2: Equivalence of complex drug products

Equivalence of complex drug products includes research into making generic versions available in all product categories, including complex drugs with unique characteristics. FDA spends an increasing amount of time reviewing and developing policy for complex drug products, and future generic products will need to demonstrate equivalence to increasingly complex RLDs. This scientific research supports the development of guidance and policy that clarifies the ANDA pathway for complex products, such as drug-device combinations, transdermal systems, implants and parenteral microspheres, nanomaterials (e.g. liposomes and iron colloids), and products that contain complex mixtures and peptides.

Topic 3: Equivalence of locally-acting products

Equivalence of locally-acting products includes research into new bioequivalence methods and pathways for locally-acting drugs. To date, the lack of efficient bioequivalence pathways for locally-acting drug products has limited the availability of generic drugs in this category, which includes inhalation, topical dermatological, nasal, ophthalmic, gastrointestinal, and otic drug products. This research priority includes evaluating in vitro alternatives to clinical endpoint bioequivalence studies. Often these in vitro alternatives are based on microstructure characterization (Q3 equivalence) for products that are qualitatively (Q1) and quantitatively (Q2) similar in formulation.

Topic 4: Therapeutic equivalence evaluation and standards

Therapeutic equivalence evaluation and standards research supports the evolution of risk-based equivalence and product quality standards to ensure therapeutic equivalence across all dosage forms and routes of delivery.

Topic 5: Computational and analytical tools

Computational and analytical tools impact the other four GDUFA regulatory science priority areas and are essential to modernizing the ANDA review process. Modeling and simulation tools that FDA will investigate include physiologically-based pharmacokinetic or absorption models; pharmacodynamic models or clinical trial simulation; systems biology; and quantitative risk modeling. Advanced analytical methods include developing methods that characterize peptides and other complex mixtures and methods that evaluate particle size, surface chemistry, and gene expression for impurities or immunogenicity.

Appendix C: FY 2015-2016 Regulatory Science Progress Report Summary

FDA is charged with determining the safety, quality, and efficacy of new drugs, biologics, and medical devices[38] of increasing diversity and complexity. This responsibility shapes our scientific research portfolio, which seeks to develop the methods, tools, and standards needed to support evaluation of these products throughout their life cycle. Through guidance to industry, scientific publications, and open discussions at FDA-sponsored workshops and other forums, these methods, tools, and standards become valuable scientific resources in the public domain and furnish medical product developers with clear pathways and expectations as they generate the evidence to support their products. FDA is also responsible for the oversight of manufacturing quality throughout the lifecycle of medical products. In addition, the Agency plays a critical role in protecting the United States from emerging public health threats. These additional regulatory responsibilities are also important drivers of our research agenda. To address them, in fiscal years 2015 and 2016 we made significant progress in a number of areas:

Refining non-clinical predictive models to support the evaluation of medical products

FDA researchers developed and/or refined a wide variety of computational tools that now support nonclinical evaluation of medical products. These tools included sophisticated models to predict the carcinogenic effects of certain drug ingredients based on their structural attributes, computational phantoms[39] to evaluate medical imaging devices, and mechanistically informed pharmacokinetic models to help predict drug exposures in populations where clinical data is difficult to obtain. Genetic and transplantation approaches were used to create animal models that may more closely predict human response to medical products, and novel physical methods and procedures were developed to support the evaluation of bioequivalence[40] of generic versions of locally acting drugs, like those acting in the skin or airways.

Improving clinical evaluation

To support clinical evaluation of medical products, our statisticians helped design master protocols to efficiently evaluate therapies for treating defined subsets of cancer patients. Through a carefully designed pathway to foster biomarker development and adoption,[41] we have qualified new biomarkers to guide treatment decisions and to predict disease progression. A long-term research effort to improve prediction of cardiovascular risks contributed to the

[38] These products include generic drugs, and increasingly, combination products.
[39] Computational phantoms are mathematical representations of the human body that can be used to predict the effects of medical devices, such as exposure to radiation.
[40] Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. 21 CFR 314.3(b). One of the requirements for approval of a generic drug is that the generic drug must be bioequivalent to the innovator drug.
[41] The Biomarker Qualification Program.

recommendation by the International Conference on Harmonization[42] that the costly "thorough QT" clinical study (used to evaluate most drug candidates) could be replaced with electrocardiogram-based measurements performed during early-phase clinical studies.

Ensuring product quality

Our medical product centers continued to address scientific issues related to new technologies critical for product manufacturing, characterization of complex products, quality standards, post-approval monitoring of product quality, and understanding the complex interactions of regulated products with biological systems. We collaborated with the Biomedical Advanced Research and Development Authority (BARDA) to leverage continuous manufacturing to minimize domestic vulnerability to chemical, biologic, and radiologic threats, and we spearheaded creation of a 3-D printing facility to understand factors contributing to the quality and performance of implantable medical devices, drugs, and combination products made with this new technology. We developed automated approaches for predicting critical properties of human stem cell preparations, such as their ability to contribute to bone growth.

Advancing capabilities for the post-marketing surveillance of medical products

Exceeding our commitments to develop a national electronic system for active medical product surveillance, we expanded the Sentinel[43] system to include data from Medicare patients, and we developed new systems and tools for safety signal detection and interpretation. We worked with diverse stakeholders in the medical device ecosystem to further the development of a National Evaluation System for health Technology (NEST) that will increase access to and use of real-world evidence to support regulatory decisions.

Guidance to industry and promoting scientific collaboration

We shared our research with the medical product industry by publishing guidance documents[44] on a number of scientific topics—for example, how to test for Zika virus in blood and biologic products, how to formulate and validate reprocessing instructions for reusable medical devices, and how to evaluate abuse-deterrent properties of opioids. Our research contributed to the development of consensus standards, providing medical product developers with clearer pathways to developing evidence for product approval. We sponsored public workshops to foster scientific exchanges[45] with stakeholders representing industry, government, the academic community, and the public, and conducted or participated in numerous training activities, professional and scientific meetings, and workshops to help our staff integrate new scientific knowledge into review and regulatory practice. We expanded the number of our public-private partnerships to advance drug development, for example by inaugurating the International

[42] The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) was established to allow FDA and its counterparts in the European Union and Japan to achieve greater harmonization in the regulation of medical products.
[43] Launched as part of FDA's implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Sentinel is the FDA's national electronic system for monitoring of the safety of FDA-regulated medical products.
[44] www.fda.gov/RegulatoryInformation/Guidances/default.htm
[45] www.fda.gov/newsevents/meetingsconferencesworkshops/default.htm

Neonatal Consortium, whose purpose is to forge a predictable regulatory path for evaluating therapies for neonates.

Improving our readiness to respond to health crises

The medical product centers supported the regulatory public health response to the threats of Ebola virus and Zika virus through development of tools, reference materials, and publication of science-based guidance to support rapid development of new medical products to diagnose, treat, or prevent diseases caused by these pathogens. Research efforts on other threats, such as pandemic influenza virus, continued to advance.

Enhancing scientific infrastructure and coordination

In the past two years, we enhanced information technology tools that support scientific review of regulatory applications. Following the success of the award-winning JumpStart service that allows reviewers to organize, manage, and verify the quality of the clinical data in product applications, FDA initiated Kickstart, a service that delivers individual training and user-driven support and analysis for non-clinical data. To make possible the secure deposition, retrieval, and analysis of the vast next generation sequencing data that will support personalized medicine, we continued to enhance our high performance scientific computing environments, enabling storage of regulatory data. We extended our laboratory capabilities and facilities for mission-critical areas, including advanced manufacturing, analytical methodology, and emerging infectious diseases.

Through organizational and programmatic changes, we have enhanced our ability to identify regulatory science issues and provide critical information for decision making. Within the Center for Drug Evaluation and Research, we created the Office of Pharmaceutical Quality to better align product quality research with review and inspection. Our Center for Biologics Evaluation and Research established a regulatory science council to oversee research activities and revamped its peer review process. The Center for Devices and Radiologic Health piloted a Regulatory Science Research Program Review to facilitate a feedback loop between CDRH reviewers and bench scientists. New programs to enhance scientific interactions with stakeholders, such as the Critical Path Information meetings, saw a surge of interest from stakeholders.

The medical product centers also worked collaboratively to bring new efficiencies to research efforts by creating a unified program for animal research on the White Oak campus. A new shared resources program provided for multi-center funding and governance of large shared equipment and computing resources, [46] and our Challenge Grant programs continued to support innovative projects to advance regulatory science.

[46] One of the first shared resources under this initiative was a 3-D printing facility, jointly funded and managed by the medical product centers, which will allow researchers to better understand the application of this technology to new products and to more effectively develop standards and guidance to facilitate product development.

A full report, “Regulatory Science Progress Report for FY 2015 and FY 2016,”was completed in fulfillment of requirements under FDASIA Section 1124 and summarizes how FDA has advanced regulatory science to support medical product development in this time frame. The full report is available on the FDA website at: www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDASIA/ucm356316.htm.

Department of Health and Human Services
Food and Drug Administration

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