

Report to Congress

Strategic Integrated Management Plan for the  
Center for Drug Evaluation and Research (CDER), the  
Center for Biologics Evaluation and Research (CBER), and the  
Center for Devices and Radiological Health (CDRH)

Food and Drug Administration Safety and Innovation Act of 2012  
Section 1131

U.S. Department of Health and Human Services

Food and Drug Administration

## **Executive Summary**

The Food and Drug Administration's (FDA's) mission is to protect and promote the health and safety of all Americans by assuring the availability of safe and effective medical products, the safety of the supply chain, and supporting science and innovation. FDA's responsibilities have increased significantly over the past several years, most recently with the enactment of the FDA Safety and Innovation Act (FDASIA) of 2012. Among other important provisions, FDASIA reauthorized two successful user fee programs for drugs, biologics and devices, and created two new user fee programs for generic drugs and biosimilars.

The user fee programs play an important role in providing FDA with the necessary resources and experienced scientific staff to efficiently review applications for medical products, thereby providing patients and health care providers with timely access to medical products, including breakthrough treatments. The user fee programs involve multiple FDA organizational units. For instance, the Prescription Drug User Fee Act (PDUFA V) is implemented by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), with support from the Office of Regulatory Affairs (ORA), the Office of Operations (OO), and the Office of the Commissioner (OC). Similarly, the Medical Device User Fee Amendments (MDUFA III) are implemented by the Center for Devices and Radiological Health (CDRH) and CBER, with support from ORA, OO, and OC. This Strategic Integrated Management Plan reflects the coordination and cooperation among these organizational units to address the specific needs of their respective medical product review programs while sharing best practices and common solutions.

FDA is committed to the highest standards of transparency and accountability in assuring that its resources are managed as efficiently and effectively as possible. In that spirit, and in response to Section 1131 of FDASIA, the agency has developed an integrated strategic management plan for the medical product centers that:

- 1) Identifies strategic institutional goals, priorities, and mechanisms to improve efficiency for CDER, CBER, and CDRH;
- 2) Describes the actions FDA will take to recruit, retain, train, and continue to develop the workforce at CDER, CBER, and CDRH, in order to fulfill FDA's public health mission; and
- 3) Identifies results-oriented, outcome-based measures that the agency will use to assess the progress of achieving the efficiency improvement efforts (under 1), and the effectiveness of the actions taken to recruit, retain, train and continue to develop the workforce at CDER, CBER, and CDRH (under 2). This includes ensuring that center managers and reviewers are familiar with and appropriately and consistently apply the requirements under the Federal Food, Drug, and Cosmetic Act, including new statutory requirements added by PDUFA, MDUFA, GDUFA, and BsUFA.

While each of FDA's three medical product centers must address a different portfolio of products and associated challenges, the strategic goals and priorities that CDER, CBER, and CDRH are

pursuing to improve efficiency have three common and important themes: 1) smarter regulation, 2) process improvement, and 3) business modernization.

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## **Introduction**

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA). Among other important provisions, this new law reauthorized the Prescription Drug User Fee Act (PDUFA V) and the Medical Device User Fee Amendments (MDUFA III). It also authorized two new user fee programs for FDA, the Generic Drug User Fee Amendments (GDUFA) and the Biosimilar User Fee Act (BsUFA), which allow FDA to collect user fees for the review of generic drugs and biosimilar biological products, respectively.

These four user fee programs directly impact the core activities of FDA's medical product centers—the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH). Section 1131 of FDASIA requires FDA to submit an integrated strategic management plan to Congress that:

- 1) Identifies strategic institutional goals, priorities, and mechanisms to improve efficiency for CDER, CBER, and CDRH;
- 2) Describes the actions FDA will take to recruit, retain, train, and continue to develop the workforce at CDER, CBER, and CDRH, in order to fulfill FDA's public health mission; and
- 3) Identifies results-oriented, outcome-based measures that the agency will use to measure the progress of achieving the efficiency improvement efforts (under 1), and the effectiveness of the actions taken to recruit, retain, train and continue to develop the workforce at CDER, CBER, and CDRH (under 2). This includes ensuring that center managers and reviewers are familiar with and appropriately and consistently apply the requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act), including new statutory requirements added by PDUFA V, MDUFA III, GDUFA and BsUFA.

This document satisfies the requirements of Section 1131. The sections that follow address each of these three components of the medical product centers' plan.

## **Section 1: Strategic Institutional Goals, Priorities and Mechanisms for Improving Efficiency.**

While each of FDA's three medical product centers must address a different portfolio of products and associated challenges, the strategic goals and priorities that CDER, CBER, and CDRH are pursuing to improve efficiency have three common and important themes: 1) smarter regulation, 2) process improvement, and 3) business modernization.

***1.1 Smarter Regulation:*** FDA's efforts to achieve smarter regulation are expected to result in regulatory activities and decision processes that feature greater predictability, transparency, efficiency and effectiveness. Smarter regulation will also result in the identification and adoption of regulatory requirements that increase clarity about FDA expectations, and reduce the burden and cost to external stakeholders to achieve the required level of public health protection.

*Key plans and initiatives in the next several years include the following:*

### **New Drugs and Biologics**

#### *New review program for the most innovative new drugs and biologics*

A key feature of PDUFA V is a new review model (Program) for the most innovative new drug and biological product applications that FDA reviews. The Program builds in new opportunities for FDA and applicants to meet during FDA's review of the application as well as additional time for FDA to complete its review of these complex applications. These modifications are designed to promote greater transparency and improve communication between the FDA review team and the applicant with the goal of improving the efficiency and effectiveness of the first cycle review process. For an application that otherwise meets FDA's high standards for approval, an optimal review allows for resolution of all review issues on or before the original PDUFA goal date. Subsequent review cycles are sometimes necessary for applications that contain outstanding deficiencies or require additional discussions between FDA and the applicant. This represents an inefficient use of FDA and applicant resources if resolution of these issues could have been achieved prior to the first cycle PDUFA goal date. The targeted enhancements of the Program should lead to improvements in the quality and completeness of submissions, the resolution of review issues that can be addressed in the first review cycle, a more predictable and transparent FDA review process, and ultimately more timely patient access to safe, effective, and high quality new drugs and biologics.

More information about the Program can be found here:

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327030.htm>

#### *Enhancing benefit-risk assessment in regulatory decision making*

The FDA's regulatory decisions in the pre-market and post-market settings are based on an assessment of the benefits and risks of the product under review. This assessment is informed by science, medicine, policy, and judgment, and it is an increasingly complex task that takes into account the extensive evidence of safety and effectiveness submitted by a sponsor in the marketing application, as well as many other factors affecting the benefit-risk assessment. These

other factors include the nature and severity of the condition that the drug is intended to treat or prevent, the benefits and risks of other available therapies for the condition, and the risk management that might be necessary to ensure that the benefits of the drug outweigh its risks. Over the past several years, FDA has developed a structured framework for benefit-risk assessment in regulatory decision-making for human drug and biological products that can serve as a template for product reviews, as well as a vehicle for explaining the basis for FDA's regulatory decisions in drug approvals.

Section 905 of FDASIA also requires FDA to implement a structured benefit-risk framework in the new drug and biologics approval process. In March 2013, FDA published a [draft implementation plan](#) for the benefit-risk framework. In compliance with FDASIA, throughout PDUFA V, FDA will implement the framework into the drug and biologics review process according to the finalized plan and any future revisions as necessary.

FDA has also begun implementation of a new initiative called Patient-Focused Drug Development with the goal of obtaining the patient perspective on certain disease areas during PDUFA V. Information regarding the severity of the condition treated and available therapies for the given disease is a critical aspect of FDA's decision-making, as it establishes the context in which the regulatory decision is made. FDA believes that drug development and FDA's review process, including the benefit-risk assessment framework, could benefit from a more systematic and expansive approach to obtaining the patient perspective on disease severity and current available options in a therapeutic area. FDA held a kick-off meeting for this initiative on October 25, 2012, and on April 11, 2013, the agency published 16 disease areas that will be the subject of patient-focused meetings in fiscal years (FY) 2013-2015. The first disease-specific meeting occurred on April 25, 2013, regarding chronic fatigue syndrome. Later in PDUFA V, FDA will initiate a second public process to identify the disease areas that will be addressed during FY 2016-2017.

More information about enhancing benefit-risk assessment in regulatory decision-making can be found here:

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>

#### *Enhanced communication with sponsors during drug development*

FDA's philosophy is that timely interactive communication with sponsors during drug development is a core activity that helps achieve our mission to facilitate the conduct of efficient and effective drug development programs. Such programs can enhance public health by making new safe and effective drugs available to the American public in a timely manner.

In PDUFA V, FDA committed to establish a mechanism for enhancing our communication with sponsors during drug development. Since the enactment of FDASIA, FDA has established these communication mechanisms. Specifically, FDA has developed enhanced communication teams to serve as points-of-contact for general questions about drug development, as well as a secondary contact for sponsors who may encounter challenges in communicating with the FDA review team regarding their drug development program. More information on FDA's enhanced

communication is available at

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327281.htm>.

As the added PDUFA V resources become available to FDA, this enhancement will also include a small staff that will focus on the identification, communication, and training of best practices in communicating between FDA and sponsors during drug development. FDA will provide this training to FDA staff and the agency will collaborate with the industry to develop and provide training to sponsors regarding best practices in communication. The work associated with this new program will lead to publication of a guidance during PDUFA V, resources permitting, for FDA review staff and industry that will articulate (1) FDA's philosophy regarding timely communication with sponsors as a core agency activity in drug development, (2) the scope of appropriate interactions between the review team and the sponsor, (3) the types of advice that are appropriate for sponsors to seek from FDA in pursuing their drug development program, (4) the general expectations for the timing of FDA response to sponsor inquiries involving simple and clarifying questions or referral of more complex questions to the formal meeting process, and (5) the best practices and communication methods (including the value of person-to-person scientific dialogue) to facilitate interactions between the FDA review team and the sponsor during drug development.

More information about this program can be found here:

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327281.htm>

### **Biosimilar Biological Products**

With the establishment of the new biosimilar products program, FDA expects sponsors to require significant advice and support throughout the biosimilar development phase. As a result, the BsUFA program established five meeting types specific for biosimilar development programs. These meetings provide targeted points of interaction to help maximize development program success. This approach facilitates biosimilar product development by providing advice and clarity regarding regulatory expectations throughout the development stage. Sponsors choose the meeting or combination of meetings matching their development needs. FDA considers the review of biosimilar products to be a high priority. These meetings enhance transparency and communication during biosimilar product development, and they facilitate the development of safe and effective biosimilar products for the American public.

More information about BsUFA is available at: [www.fda.gov/bsufa](http://www.fda.gov/bsufa).

### **Generic Drugs**

The Generic Drug User Fee Amendments of 2012 (GDUFA) are designed to speed access to safe and effective generic drugs to the public and reduce costs to industry. The law requires industry to pay user fees to support the costs of enhancements in the review of generic drug applications and inspection of generic drug facilities. Additional resources will enable the agency to reduce a current backlog of pending applications, cut the average time required to review generic drug applications, and increase risk-based inspections. GDUFA will also enhance global supply chain safety by requiring that generic drug facilities and sites around the world self-identify.



More information about GDUFA is available at:  
<http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm>

#### *Self-identification and registration of generic drug facilities*

GDUFA will significantly improve global supply chain transparency by requiring owners of facilities producing generic drug products and active pharmaceutical ingredients used in generic products and certain other sites and organizations that support the manufacture or approval of these products to electronically self-identify with FDA and update that information annually. Self-identification is a central component of an effort to promote global supply chain transparency. The information provided through self-identification enables quick, accurate, and reliable surveillance of generic drugs and facilitates inspections and compliance.

#### *Risk-based and parity of foreign and domestic inspection frequency*

During the 5-year period covered by the statute, FDA will leverage funding under GDUFA to achieve parity in the frequency of good manufacturing practice (GMP) inspections of foreign and domestic establishments; for both foreign and domestic establishments FDA will use a risk-based approach to prioritize inspections. In appropriate circumstances FDA can rely on a relatively recent routine surveillance inspection in lieu of an application-specific inspection as a basis for the approval of a drug application. Thus, the increased frequency of surveillance inspections is expected to speed approvals of generic drugs, as well as assure that generic products continue to be manufactured in compliance with applicable regulatory standards.

#### *Commitments, complete review, and easily correctable deficiencies*

Under GDUFA, FDA agreed to program enhancements and performance goals. This includes FDA's agreement to review and act on 90 percent of original unamended abbreviated new drug applications (ANDAs) within 10 months following the date of submission by year 5 of the program. Other program enhancements include an immediate commitment to provide timely and complete information to applicants by issuing complete response letters to all ANDAs that have deficiencies. These letters will reflect full division-level reviews of any deficiencies noted by relevant review disciplines. FDA has also agreed to make every reasonable effort to communicate promptly with applicants to facilitate the timely revision of easily correctable deficiencies found in ANDAs and to clarify issues and answer questions during first cycle meetings. Additional efficiency enhancements and goals will be phased in over the life of the program.

### **Medical Devices**

#### *Improved review experience*

FDA recently improved its device review processes to increase predictability and transparency by providing more complete feedback to industry earlier in the regulatory process. These improvements include the implementation of a structured pre-submission process, submission acceptance reviews, and substantive interaction goals. To further provide clarity, FDA is

finalizing the medical devices [pre-submissions draft guidance](#), titled “The Pre-Submission Program and Meetings with FDA Staff.” This draft guidance document addresses FDA’s proposed implementation of the pre-submission processes outlined in the MDUFA III Commitment Letter. As proposed in this draft guidance, FDA intends that feedback provided to a sponsor in response to a pre-submission will not change, provided that the information submitted in a future submission is consistent with that provided in the pre-submission and that the data in the future submission do not raise any important new issues materially affecting safety or effectiveness. This draft guidance proposes that modifications to FDA’s feedback in a pre-submission will be limited to situations in which FDA concludes that the feedback given previously does not adequately address important new issues materially relevant to a determination of safety or effectiveness that have emerged since the time of the pre-submission. FDA conducts acceptance reviews within 15 days of receipt of most types of marketing applications based on objective screening checklists that were issued in final guidance documents. Upon accepting a marketing application, FDA conducts a complete review of the entire submission and communicates in a substantive interaction with a sponsor within 60/90 days of receipt for 510(k) submissions/premarket approval applications (PMAs). A more structured pre-submission process, earlier interactions between FDA and device applicants, and increased communication during the review process are expected to result in enhanced accountability, predictability, and transparency for the medical device industry.

#### *Establish a unique device identification (UDI) system*

Section 226 of the FDA Amendments Act (FDAAA) of 2007 and Section 614 of FDASIA require FDA to publish regulations establishing a unique device identification (UDI) system for medical devices. Incorporation of unique medical device identifiers into electronic health records (EHRs) would improve patient safety, make the conduct of postmarket surveillance more efficient, and make queries of and de-identified responses from EHRs more readily usable to support device approval or clearance (note this would not be required by the rule). Likewise, incorporation of UDIs into insurance claims data (also not required by the rule) would increase the utility of these data sources for medical device postmarket surveillance. These device identifiers may also help reduce medical errors by enabling health care professionals and others to rapidly and precisely identify a device, obtain important information concerning the device’s characteristics (e.g., whether it contains latex or is magnetic resonance imaging compatible), and improve the ability to track the device through the distribution chain to the point of patient use. FDA has worked for several years with stakeholders, healthcare providers, international regulators, and supply chain entities as well as patients and consumers to ensure that implementation of new requirements is done in a way that minimizes burden, helps ensure that appropriate exemptions and waivers are in place, and helps ensure that the regulation leverages existing business practices to the extent possible without compromising the critical public health goal of identification of medical devices throughout their distribution and use.

More information about UDI is available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm>.

#### *Implementing changes to the investigational device exemption (IDE) decision program*

Section 601 of FDASIA amended Section 520(g)(4)(C) of the FD&C Act to preclude FDA from disapproving an investigational device exemption (IDE) because, among other reasons, the study may not support clearance or approval of a future marketing submission. In light of these changes, FDA revised its IDE approvability decision policy and modified the IDE decision letters to better explain FDA's decisions, and the agency revised and re-issued the draft guidance, "FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations." This draft guidance identifies how FDA proposes to make approvability decisions and communicates those decisions. In addition, Section 606 of FDASIA gave FDA the authority to put a clinical investigation of a medical device on clinical hold. Under FDASIA, clinical hold authority is to be exercised when use of the device poses an unreasonable safety risk or for other reasons as may be established by regulation. FDA is drafting regulations to clarify how the clinical hold authority will be implemented and plans to publish the proposed rule in FY 2014.

### Regulatory framework for health information technology

Section 618 of FDASIA charges FDA in consultation with the National Coordinator for Health Information Technology (ONC) and the Chairman of the Federal Communications Commission (FCC) to publish a report by January 2014 that contains "a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications that promotes innovation, protects patient safety, and avoids regulatory duplication." A working group of stakeholders was formed to provide appropriate input on the strategy and recommendations required for this report. The Health IT Policy Committee (a federal advisory committee to ONC) will use the working group's input to develop recommendations. FDA, FCC, and ONC will review and consider the recommendations provided by the Health IT Policy Committee, as FDA in consultation with ONC and FCC writes the report. The working group meetings will provide opportunities for the public to comment. Documents discussed by the working group will be posted as they become available, at <http://www.healthit.gov/policy-researchers-implementers/federal-advisory-committees-facas/fdasia>. FDA expects this framework to appropriately focus the agencies' resources on the areas where oversight consistent with each agency's mandate will provide the greatest benefit to the public, innovators, and the healthcare sector.

**1.2 Process Improvement:** Efforts in this area will include review and evaluation of FDA's regulatory processes in terms of the outputs of these processes and the value they create for the agency's stakeholders. FDA will also work to eliminate unnecessary activities and thereby improve the efficiency of our regulatory operations. This work generally will employ a rigorous evidence-based approach to evaluating program operations, understanding how current programs actually work, and assessing the value added by each step in the process.

FDA notes that our process improvement efforts must strike a balance between standardization of operations to improve consistency and predictability, and customization to efficiently and effectively meet program-specific requirements. For example, both CBER and CDER review products under PDUFA by employing a quality systems approach to implementing good review management principles, yet they do so under different management procedures tailored to the specific requirements and circumstances of their respective product areas, regulatory

responsibilities, and organizational structures. CBER uses its Managed Review Process (MRP), which was developed to provide a common management approach to the review of drugs, biological products, and devices under different regulatory pathways using a consistent set of management procedures that are specifically designed for the types and volume of submissions it reviews. CDER uses its 21<sup>st</sup> Century Review Process, which employs cross-disciplinary teams and procedures tailored to the high volume of work to ensure that there is sufficient time to coordinate, consider, and address scientific and regulatory issues with a high degree of confidence within the standard review timelines. Despite the differences in the details, CDER and CBER share best practices and harmonize standards where possible and appropriate.

*Key plans and initiatives regarding process improvement in the next several years include the following:*

User Fee Council – FDA has the authority to collect fees to support or enhance various programs under a variety of statutes, including the Animal Drug User Fee Act, Animal Generic Drug User Fee Act, MDUFA, PDUFA, the Family Smoking Prevention and Tobacco Control Act, Food Safety Modernization Act (FSMA), and Mammography Quality Standards Act (MQSA). In addition, two new user fee programs, GDUFA and BsUFA are commencing in FY 2013. Collectively, these user fee programs represent an estimated \$2 billion, or nearly 45 percent of FDA’s total budget request in FY 2013. The expanding level of user fees across many of the agency’s program areas, the reporting of agency performance commitments associated with these fees, and the need for FDA to convey how these fees are executed call for strong financial governance. This requires a complete understanding of the design of these programs, clear financial plans, data-driven decisions on resource allocation, consistency and transparency about assumptions, and accountability for resources spent.

In recognition of the need for comprehensive financial governance, FDA created the User Fee (UF) Council in 2013 to lead a variety of oversight and analysis activities, make recommendations, and convey decisions to the FDA Management Council regarding FDA-wide user fee management issues. The UF Council will help ensure the development of consistent data driven resource allocations, and will support compliance with statutory provisions and adherence to goals of negotiated agreements and commitments.

### **PDUFA Process Improvement Project Plans**

Meeting minutes - The advice that FDA provides sponsors on their drug development programs is a core drug review activity. This advice and the discussions that occur at FDA-sponsor meetings are documented in meeting minutes that are sent to sponsors. CDER is beginning a project to ensure the quality, consistency, and timeliness of these important records so that high quality minutes are distributed to sponsors within agreed upon PDUFA timelines. CDER recently completed an effort that examined existing approaches to the development of meeting minutes with the goal of identifying and adopting a standardized approach. Beginning in FY 2013 and continuing in FY 2014, CDER will apply process improvement methodology to test out a new streamlined approach for meeting minutes. Following this pilot, CDER will implement the identified appropriate improvements to the process that will result in the development of consistently high quality meeting minutes.

Warning letters - When FDA identifies compliance issues at a pharmaceutical manufacturing facility, the timely review and, if necessary, enforcement of good manufacturing practices is critical to protect public health. CDER recently initiated a process improvement effort pertaining to this aspect of FDA's enforcement efforts. A team comprised of staff from CDER and the Office of Regulatory Affairs will engage in a multi-month effort to streamline the process that will optimize the use of FDA resources.

Risk Evaluation Mitigation Strategies (REMS) review - When PDUFA was reauthorized as part of FDAAA in 2007, FDA received additional drug safety authorities that included the ability to require Risk Evaluation and Mitigation Strategies (REMS) if FDA concludes that additional risk management is necessary to ensure that the benefits of a drug outweigh its risks. In late FY 2013, CDER will begin a process improvement project to examine the REMS review process with the goal of improving the consistency, quality, and timeliness of that process and decision-making. As the process of determining that a REMS program is required involves the input of multiple offices in CDER, this effort will involve significant collaboration across the center.

Electronic review templates - CBER is currently finalizing and implementing electronic review templates for the various scientific disciplines involved in the review of biological product license applications. These templates will provide reviewers with links to relevant guidances and standard operating procedures to foster a more consistent approach to the analysis and documentation required for product reviews.

Quality system for CBER's MRP - Work is underway to develop and implement an overall quality system for CBER's review process. This will facilitate quality assurance audits of the review process which will be used to gauge compliance with established procedures and allow for refinements to procedures as appropriate. As part of the continual process improvement aspect of the MRP, an initiative is underway to evaluate specific sub-processes for their efficiency, relation to the overall plan, and consistent implementation. Introduction of the electronic managed review process tool should further expedite such continual process improvement.

Electronic managed review process tool - Ready access to the necessary job aids allows for greater efficiency in a reviewer's workflow. A tool is in development to provide this ready access to standard operating procedures, checklists, templates, and guidance to facilitate CBER's managed review process. When finalized, the electronic managed review process tool is expected to provide both workflow and workload information to individual staff and supervisors in order to maximize the efficiency of the review process.

### **MDUFA Process Improvement Project Plans**

510(k) triage - FDA has developed, piloted, and is in the process of deploying a Triage Program for the review of traditional and abbreviated 510(k) submissions. This program involves an initial screening according to "Quick Review Criteria" that identifies good quality 510(k) submissions and utilizes FDA experience with those devices. Accepted submissions are placed in a 30-day review track and reviewed using a "Quick Review Decision Memo." When this streamlined memo is used, greater emphasis is placed on the sponsor's comprehensive 510(k) Summary. Quality of the 510(k) review is maintained because all elements of the submission are

still reviewed. Faster review times are made possible by the high quality of accepted submissions, reviewers' experience which enables them to focus on key aspects of the submission, and less documentation needed from the reviewer because the sponsor has provided a comprehensive 510(k) Summary. An initial 6-month pilot demonstrated that the Triage Program is effective at identifying submissions that could be reviewed quickly, as evidenced by a reduction in the total time to decision for the top 20 percent of submissions from 51 to 32 days, and an increase in the percentage of submissions reviewed within 30 days from 4 percent (14/320) to 12 percent (43/349). A significant advantage of this program is the increased ability of reviewers to focus on more complex submissions sooner, which enhances the overall efficiency of the 510(k) review process.

More information about the initial 6-month pilot 510(k) Triage Program is available at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm300308.htm>.

*Parallel review pilot* - FDA is collaborating with the Centers for Medicare and Medicaid Services (CMS) on an innovative program designed to reduce the total time from investigation to marketing and reimbursement for devices with novel technologies. Under this voluntary program, developers of innovative devices can request parallel review by FDA for sponsors' premarket device submissions and by CMS for national coverage decisions. While the central objective of parallel review is a reduction in overall time by having the two agencies' review times partially overlap, collaboration between the agencies at the early stages of study design can also assist sponsors in developing a single data set to address review standards of both agencies. Experience from the pilot suggests this collaboration can lead to greater efficiencies. Feedback from participants in the pilot has been very positive. The pilot is in its second year and may be extended at the end of its 2-year term in October 2013.

More information about the Parallel Review Pilot is available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm255678.htm>.

*Medical Device Single Audit Program (MDSAP)* - FDA staff have been recruited and hired to facilitate the development of the Medical Device Single Audit Program (MDSAP). MDSAP will promote efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among regulators while respecting the independence of each regulatory authority. Project plans have been developed and implemented with a goal of piloting (starting January 1, 2014) a program that will allow a single audit of a medical device manufacturer's quality management system conducted by a "recognized" auditing organization to satisfy the needs of multiple regulatory jurisdictions (e.g., [Australia, Brazil, Canada, and the United States](#)).

*Signal management program* - Signal management is a set of activities to promptly and proactively identify, evaluate, and address new and unexpected risks associated with a marketed medical device or group of devices. Signal management is a core and critical component of CDRH's mission. Signal management provides a critical pathway through which new postmarket information regarding a medical device can be incorporated into the premarket review process. In late 2011, FDA re-assessed the way in which it handled safety signals for marketed devices, and in January 2012, began developing a new set of processes, policies, and

procedures that would govern this vital function and help ensure greater accountability, efficiency, transparency, and consistency in addressing such signals. In October 2012, FDA began piloting the new program. Discrete signal review teams, consisting of staff who reviewed the types of devices included in the pilot, were formed and began meeting regularly to prioritize, refine, and address new safety signals using a new set of milestones and timeframes. Since that time, several safety signals have been entered into the signal management program and addressed. FDA is evaluating the program roll-out with the goal of assessing best practices, and determining how the program might be modified for expansion to other product areas.

**1.3 Business Modernization:** The medical product centers' regulatory business processes often rely on review of submitted, hard-copy information related to medical products and manufacturers. Much of this information is in paper or non-standardized electronic forms that impede the centers' review operations. The medical product centers recognize a major opportunity for efficiency improvements in the area of receiving and storing information electronically. These centers are developing and implementing plans for data standardization and integrated management that would ultimately include a range of marketing applications, safety reports, and other regulatory functions requiring data.

### **Electronic Submissions and Data Standardization**

*New authorities related to electronic submissions and data standardization* - Section 1136 of FDASIA provides FDA with the authority to require that certain types of submissions be submitted electronically, or include an electronic copy (for device submissions), using specified standards, as provided in guidance. This new authority also states that FDA may provide a timetable for the establishment of further standards for drugs-related electronic submissions. This authority will allow for steady and early progress towards a standards based end-to-end electronic receipt, review, and dissemination environment for regulatory activities.

*Data standards efforts jointly pursued by the medical product centers* - Though each FDA medical product center has unique requirements as defined by the products they regulate and statutory framework, there are several areas with respect to data standards where the centers collaborate. These areas include:

- *Governance* - Each center maintains a focused data standards program to oversee its standards' priorities and activities. The centers communicate and collaborate on these programs through shared initiatives and participation in one another's oversight functions. Representatives of the programs represent the centers' priorities at the FDA's Data Standards Council, tasked to coordinate the evaluation, development, maintenance, and adoption of health and regulatory data standards useful throughout the agency and to ensure that standards are consistent with those used outside the FDA. More information on activities and standards in use at FDA may be found at <http://www.fda.gov/ForIndustry/DataStandards/default.htm>.
- *Master data management* - The centers share an objective to ensure that a comprehensive, validated, accurate and up-to-date inventory of products and associated facilities is in place. The Master Data Management initiative is a group of efforts designed to identify and ensure the integrity of key data used in regulatory activities.

These data include unique substance identification, product identification, and facilities and manufacturing information. The centers collaborate on pilot efforts to ensure that centers' needs are met and that efficiencies in approaches (e.g., relating to tools, expertise) are achieved.

- *Electronic submissions and standardized data* - The centers are working to transition to an all-electronic submission receipt model. CDER and CBER currently receive certain standardized electronic submissions in the International Conference on Harmonization (ICH) Electronic Common Technical Document (eCTD) standard format for which draft guidance has recently been issued. In December 2012, CDRH issued final guidance that established the eCopy program that applies to certain device submission types. The eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or flash drive. In addition, CDRH is developing a media-less, electronic submission system that will increase the speed at which premarket reviews will be completed. The system will be piloted with volunteers from the medical device industry during FY 2014. All three centers are collaborating on the Health Level Seven (HL7) Regulated Product Submission (RPS) standard intended to be the "next generation" eCTD capable of supporting all medical products. The centers also jointly participate on several projects to enhance and implement open, consensus-based standards for clinical trials data in collaboration with Clinical Data Interchange Standards Consortium (CDISC) and HL7.

*PDUFA V data standards plan goals* - CDER and CBER share common goals in their standards efforts that function as guiding principles. These include:

- Supporting open, consensus-based data standards development;
- Maintaining and promoting a well-defined data standards governance function;
- Promoting the electronic submission of regulatory data using established standards; and
- Optimizing the regulatory review process to fully leverage data conformed to standards.

This incremental approach will be reflected in the PDUFA V Therapeutic Area Standards Initiatives Plan, a draft of which is anticipated to be published in FY 2013. This plan will describe the centers' intentions and approach to developing terminologies and content standards for clinical trials study data to support efficacy analyses of different disease and therapeutic areas. FDA has identified over 50 such areas through internal review and external input. To date, more than a dozen therapeutic area standards efforts have either resulted in published standards or are under development with the CDISC standards development organization. FDA, industry, and stakeholder organizations are participating in these efforts. As implied in the first principle above, the centers are committed to ensuring broad and relevant participation by stakeholders in an open, consensus-based process to develop these standards.

*CBER's move to FDA White Oak Headquarters* - CBER is preparing to move its personnel and equipment to the White Oak campus in FY 2014. This will centralize a staff that is currently located at several different sites and allow for standardization and modernization of business processes, such as document handling. It will also provide opportunities for CBER staff to more easily share data in order to collaborate with FDA counterparts in expediting the review process.



## **Modernization of Resource Tracking Systems**

*New approach to work tracking and time reporting in CDER* - In FY 2012, CDER commenced an initiative to modernize its workload tracking systems. This initiative seeks to integrate existing business applications into a central system that allows CDER to better plan, organize, and track work on regulatory activities. This new approach to workload management promises to increase collaboration across the center, streamline work process, and consolidate information into a central access point, ultimately resulting in more efficient operations. As part of this initiative, CDER updated its time reporting system to track the amount of effort expended on PDUFA, GDUFA, and BsUFA activities.

*New approach to time reporting in CBER* - CBER recently developed the Resource Reporting System (RRS) to track and report on level of work effort. CBER uses the RRS to analyze its workload based on periodic time reporting by CBER staff throughout each fiscal year. The RRS tracks staff work effort related to CBER's various work units, as well as how the work effort relates to the various types of products that CBER regulates. In FY 2012, CBER completed the modernization of the RRS from MS Access to Business Objects, giving CBER the ability to track and monitor the new biosimilar user fee level of work effort to be in place for FY 2013.

*Management of the premarket device review process and workload* - Under this initiative, CDRH is utilizing IT tools to facilitate efficient management of premarket reviews. CDRH developed a tool to monitor interim targets necessary to meet MDUFA III commitments for each submission type. Interim targets include steps such as assigning consulting reviews, due dates for consulting reviews, acceptance reviews, filing reviews, substantive interactions, final decisions, each level of managerial concurrence required at each step of the process, management briefings, and scheduling and holding panel meetings, when applicable. One important aspect of this tool is the automatic calculation of due dates for each interim target to facilitate timely management of the file by the lead reviewer. In addition, CDRH has revised the majority of its time reporting codes to better align with the new workload outlined in MDUFA III. The new codes reflect areas of interest to the device industry and other stakeholders.

*Modernized infrastructure and processes for the review of premarket device applications* - At the start of FY 2013, CDRH implemented commercial-off-the-shelf and government-off-the-shelf solutions in order to modernize and drive consistency, efficiency, and cost reductions in the premarket device review program area. CDRH is now utilizing government PIV cards for digital signatures in concert with document management technology to eliminate printing and scanning. This effort has allowed increased telecommuting, as documents can be read and signatures applied from any location. In the future, the center plans to apply a standard electronic filing structure and taxonomy to lay the groundwork for compliance with records management requirements.

## **Section 2: Actions FDA will take to recruit, retain, train, and continue to develop the workforce at the medical product centers**

Regulatory review and other regulatory operations required to protect public health require FDA to hire and retain the best available scientific, medical, analytic, legal, and management talent. FDA's medical product centers are pursuing several key strategies to recruit, retain, train, and continually develop this essential workforce.

*These programs and initiatives include the following:*

### **FDA Recruitment Efforts**

*Insourcing of human resource functions at FDA* - FDA's Office of Human Resources (OHR) is working closely with all centers as well as the Office of Personnel Management to make the posting, selection, and hiring process as smooth as possible. The centers and OHR maintain close coordination through service representatives in OHR that serve as direct points of contact with hiring teams established within the centers. These teams also maintain close contact with hiring managers to ensure that their hiring needs are efficiently met.

*Hiring authorities* - FDA continues to use the government-wide direct hire authorities to fill important positions such as Medical Officers and Pharmacists. In addition, FDASIA provides streamlined hiring authority for a limited time to allow for the efficient hiring of any other job series needed to fulfill FDA's commitments and requirements related to MDUFA and GDUFA. The streamlined hiring authority for MDUFA and GDUFA expires in July 2015.

### **Center Specific Recruitment Initiatives**

*Blue Ribbon Executive Recruitment Program* - This CDER program is designed to manage progress in recruiting for positions at the Deputy Super Office Director level and above. A Blue Ribbon Executive Recruitment Steering Committee will oversee the executive recruitment process from the time a position is vacated to the time the position is filled with the new incumbent.

*Creation of an Alumni Network* - CDER is piloting an "Alumni Network" concept in four offices during calendar year 2013. The goal of this initiative is to develop contacts with several colleges and universities through current employees who are already connected to alumni organizations or career services centers. Alumni groups have been an informal resource in the past for CDER recruitment efforts. The new program formalizes this approach such that multiple offices in CDER can benefit from these connections. This year's pilot will focus on recruitment of positions in the Pathways Program as well as senior executives in the center at the Deputy Super Office Director level and above. CDER is also using social media as part of this pilot, including the creation of the @CDERStudents Twitter account to easily inform universities and interested students of available Pathways Program openings in CDER.

Corporate recruitment process - This CDER process was established to streamline recruitment efforts for GDUFA hiring. In collaboration with the National Institutes of Health, FDA developed a streamlined recruitment process that incorporates management meetings on job announcements to garner agreement and commitment around the specifics associated with advertising positions. In FY 2013, the corporate process includes positions where 10 or more positions must be filled, including chemists, computer scientists, chemical engineers, project managers, and management analysts. The positions are announced and open continuously for 90 days resulting in the hiring manager's ability to obtain a certificate of eligible candidates every 30 days without having to re-advertise. Selections from corporate certificates across CDER are returned on a pre-determined day which allows OHR to extend candidate offers within one to two days.

Comprehensive recruitment strategy - CBER HR specialists regularly target scientific, medical and technical candidates through outreach efforts that include local career fairs and postings in peer reviewed journals and their websites, as well as diversity-based job boards. CBER is also using open continuous announcements. CBER has evaluated the last 3 years of hiring and determined that open continuous announcements for biologist and consumer safety officers are most helpful in the recruitment efforts for those positions.

Strategic communication and outreach for recruitment - CDRH continues to develop strategic communications and outreach and recruitment activities to enable the development of solid partnerships with major institutions, associations, professional groups and universities to strengthen ongoing and future recruiting and hiring efforts. The approach consists of a variety of mechanisms and sourcing opportunities to reach a diverse population of medical officers, research scientists, and safety/regulatory professionals. The outreach tool kit includes: medical, engineering, and science-related career fairs, veteran and disability career fairs, job boards/newspaper/print ads, federal job sites, minority-oriented association meetings/career fairs, selected career search engines and resumes databases, other federal agencies, and current and former FDA employees.

Retention initiatives - As part of the MDUFA III negotiations, representatives from industry and FDA agreed that CDRH's attrition rate for employees and managers was unacceptably high. In the final commitment letter, CDRH committed to increase the number of staff in the review divisions and the number of managers. The expected outcome of this effort is to reduce the workload of staff, who often reported leaving the review offices due to unreasonable workloads. In addition, CDRH conducted an assessment of employee views with the goal of improving employee morale and finding ways to improve retention of highly skilled personnel. As a result of this strategic effort, a number of initiatives have been started to provide employees with a better work environment. These include providing supervisors and employees with better tools to conduct performance evaluations and exploring more meaningful ways to provide recognition.

## **Reviewer Training and Continuing Education Programs**

Comprehensive training program - CDER provides a wide range of recurring courses for all review staff, including the New Reviewer Blended Learning Program (NRBLP), a foundational learning opportunity that combines both on line and classroom instruction for new staff and serves as a review for all reviewers. The NRBLP has modules on the history of FDA and drug

regulation, the drug life cycle, the drug review process and review skills, pre-Investigational New Drug (IND) and IND review process, the New Drug Application (NDA)/Biologics License Application (BLA) review process, and post market activities; as well as courses in drug law; biologics law; basic and intermediate statistical methods; current good manufacturing practices; premarket safety review; postmarket drug safety; design and conduct of clinical trials and review of clinical trials; generic drug regulation and review; meetings management; conflict resolution; negotiation skills; technical writing; and a range of courses and lectures related to guidances and internal practices.

Continuing education program - CDER also provides continuing medical, pharmacy, and nursing education as a continuing education (CE) provider. The center is committed to providing high-quality, innovative continuing medical, pharmacy, and nursing educational programs to FDA employees and stakeholders by supporting and sustaining their scientific expertise and professional development. The overall goal of the FDA's CE program is to build a lifelong learning infrastructure that supports and strengthens the integrated scientific foundation of its regulatory mission. Through continuous professional development activities, FDA aims to address the scientific and professional development needs of its employees by improving professional competence, performance, and patient/public health outcomes.

Reviewer training and review management updates - On a regular basis, CBER provides new reviewer training, device reviewer training, and project management training. CBER also offers monthly "Review Management Updates" (RMU) that are required for all reviewers and staff involved in application reviews. CBER's RMUs regularly address:

- Content and implementation of new statutes, guidance documents, and policies;
- New or revised Standard Operating Procedures, job aids, and regulatory processes; and
- Refresher training on specific aspects of the regulatory process.

CBER's Office of Communication, Outreach and Development, in partnership with CBER's Review Management Staff, has developed a curriculum for all staff involved in reviews that includes instruction on key regulatory functions. This training has been updated to include the provisions of the new user fee programs.

Experiential Learning Program (ELP) - CDRH's ELP enhances premarket reviewer knowledge of medical device design, manufacturing, and utilization through real-world opportunities. The ELP is a collaborative approach geared to closing the knowledge gap between emerging and innovative technology and the premarket review of the resulting medical devices. It provides real-world knowledge of products that CDRH regulates, and fosters improvement of the premarket review process by allowing CDRH reviewers to learn from the medical device industry, the clinical community and academic stakeholders to improve the premarket review process. In FY 2012, a total of 112 CDRH employees participated in 16 ELP events at 8 sites. On April 2, 2013, CDRH published a [Federal Register notice](#) seeking sites to participate in the program in FY 2013.

Reviewer Certification Program (RCP) - CDRH's RCP requires new medical device reviewers to complete training that includes coursework on relevant laws and regulations, deficiency writing, and the conduct of quality reviews. Comprehensive knowledge assessment is conducted

upon completion of the coursework. In addition, an audit process, conducted by Master Reviewers, assesses new reviewers' work for a standardized approach to reviewing medical device submissions. This accelerated program equips the reviewers with the tools necessary to conduct successful reviews, and it promotes communication and collaboration among the review staff. Basic certification (Level 1) for the program is 10 months and Intermediate Certification is an additional 8 months.

*CDRH Leadership Readiness Program (LRP)* - LRP is a one-year professional development learning opportunity for employees interested in future leadership opportunities in CDRH. The program provides participants with experiences in mentoring, classroom-based learning, self-assessment, and experiential activities. The selection process is competitive and requires completion of an application, statement of interest and interviews of the most qualified candidates. Selected participants remain in their current position throughout the year and participate in the program as an additional activity. The program's goal is to provide staff with strong management and leadership skills, enabling them to be effective leaders and possible managerial candidates.

*Leadership Enhancement and Development Program (L.E.A.D.)* - L.E.A.D. provides effective leadership tools for CDRH managers and supervisors. L.E.A.D. is a mandatory supervisory training program targeting all CDRH supervisors, managers and non-bargaining unit team leaders. The L.E.A.D. curriculum supports CDRH management competencies and addresses the supervisory training requirements as mandated in 5 C.F.R. Part 412. CDRH has offered information sessions to allow managers and supervisors to gain a better understanding of the training requirements and how they can be met. A total of 32 courses were offered prior to the end of the 2012 calendar year. In FY 2013, courses will be offered dependent on budgetary constraints.

## **Specific Training Regarding the User Fee Programs**

### **PDUFA**

As the implementation planning for PDUFA V continued during FY 2012, FDA review staff received specific training in the new aspects and requirements of the Program highlighted in Section 1.1 of this report. This training focused on the aspects of the Program that required immediate implementation. An important feature of the Program is the Late Cycle Meeting where FDA and the applicant will discuss the status of and path forward for the application during the remainder of the review cycle. As these meetings began to occur during the second half of FY 2013, specific "just-in-time" training regarding these meetings was provided to individual review divisions. Additionally, there has been a recent focus in the pharmaceutical industry to develop drugs for rare diseases or those diseases that have a patient population of less than 200,000. A specific commitment in PDUFA V relates to training for FDA review staff on the development, review, and approval of drugs for rare diseases. In March 2013, FDA conducted a third annual two-day training for over 100 reviewers on "Meeting the Challenges of Rare Disease Drug Review." Such training on this topic will continue throughout PDUFA V. With respect to FDA's commitment on enhanced communication during drug development, the agency will develop and provide training to review staff during FY 2014 on best practices in communication with sponsors during drug development.

## **BsUFA**

FDA has developed targeted training and reference materials for the new BsUFA provisions and processes. FDA has delivered training to review staff and developed online training and reference materials for ongoing training. In addition, FDA has communicated the new BsUFA provisions and processes at industry association conferences, and developed a comprehensive BsUFA website of questions and answers, describing the new provisions and processes, and containing reference and resource materials. FDA has also revised over 60 letters to sponsors, and created 12 new letters to reflect novel components. These training and communication efforts will facilitate seamless transition to new processes, and successful implementation of BsUFA.

## **GDUFA**

The focus of the early years of GDUFA is on establishing the payment systems, hiring new staff, and establishing new processes that will facilitate FDA's ability to meet GDUFA performance goals that begin in FY 2015. As these tasks are accomplished, a robust training program will be implemented for existing and new review staff in preparation for FY 2015.

## **MDUFA**

Prior to implementation of MDUFA III, CDRH developed training modules that provided an overview of the MDUFA III program, explained improvements to electronic workload management made possible by FDASIA eCopy requirements, and outlined new processes and timeframes associated with review of pre-submissions, PMAs, 501(k)s, and Clinical Laboratory Improvement Amendments Waiver Applications. The 510(k) and PMA modules included training on Submission Acceptance Criteria and associated Refuse to Accept Policies and Interactive Review of such submissions. Training modules were offered twice—live and via webcast—with 99% participation across the Office of Device Evaluation and the Office of In Vitro Diagnostics and Radiological Health. The modules were recorded and can be viewed online by new staff or by experienced staff requiring refresher training. Since implementation of MDUFA III began, CDRH has been monitoring new processes and continues to streamline, document and communicate these processes to review staff, management, and program operations staff.

### **Section 3: Results-Oriented, Outcome-Based Measures of Centers' Progress**

FDA commits to various performance and procedural goals and reports on them annually as part of the agency's user fee programs. During FYs 2013-2017, FDA will report on its performance metrics for PDUFA, BsUFA, GDUFA, and MDUFA. This section highlights the key measures and milestones associated with each of the programs identified under Section 1 as well as other important metrics and evaluations over the next 5 years. FDA will use performance goal tracking and reviews, including evaluation studies, as tools to assess the knowledge and consistent application of the statutory requirements.

#### **User Fee Program Performance Measures**

##### **PDUFA**

The recent authorization of PDUFA V largely carries forward the performance and procedural goals that have served the human drug review program well since PDUFA II. The new review model, discussed in Section 1.1 of this report modifies the review performance goals only for the most innovative new drug and biologic product reviews. These changes delay the start of FDA's review clock by 2 months (clock begins at the conclusion of the 60-day filing date), such that 90% of these applications should be reviewed and acted on within 8 and 12 months from the original submission for priority and standard applications, respectively. While a significant part of the drug review program involves FDA providing advice to sponsors on their drug development programs, this advice has typically occurred in formal meetings between the agency and the sponsor. In PDUFA V, for certain types of meeting requests, sponsors will have the opportunity to request, where appropriate, a written response to its questions, which could obviate the need for formal meetings under certain circumstances. As PDUFA V continues, FDA will gain an understanding for how this communication mechanism is used.

The progress of FDA in meeting the commitments associated with new PDUFA V enhancements (e.g., structured benefit-risk assessment in regulatory decision-making, patient-focused drug development, regulatory science, drugs for rare diseases, electronic submission and standardized data requirements, etc.) will be posted at this page on FDA.gov:

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm>.

Metrics to be posted will include trends in NDA and BLA submissions and approval times, PDUFA workloads by year, and key measures of review performance, such as on-time review statistics.

##### **BsUFA**

Under BsUFA, FDA committed to review performance goals for meetings with sponsors, application and supplement reviews, and other biosimilar review activities. The meeting goals include commitments for scheduling meetings within target timeframes depending on the type of meeting requested. The application review goals include a timeframe of 10 months for original biosimilar biological product applications and 6 months for resubmissions, with phased-in target performance levels of 70 percent in the first year, increasing to 90 percent by the fifth year of the program.

FDA will track and report its performance on scheduling meetings within target timeframes, as well as its performance on completion of application review within the target timeframe.

## **GDUFA**

FDA's review performance commitments for GDUFA take effect in FY 2015. As in the case of BsUFA, this is a brand new program. Accordingly, the performance goals are phased in throughout the FY 2015-2017 timeframe. In FY 2015, FDA committed to reviewing 60 percent of original ANDAs in 15 months, 60 percent of prior approval supplements (PAS) requiring inspection in 10 months, and 60 percent of PAS not requiring inspection in 6 months. By FY 2017, these goals increase to 90 percent in 10 months for ANDAs and PAS requiring inspection and 90 percent in 6 months for PAS not requiring inspection.

## **MDUFA**

[MDUFA III performance goals](#) represent a commitment between the U.S. medical device industry and FDA to increase the efficiency of regulatory processes in order to reduce the time it takes to bring safe and effective medical devices to the U.S. market. The performance goals will improve predictability and reduce the number of submissions for which a decision is not reached until well beyond the initial target deadline, which will help reduce total time to decision. Performance goals address the timeframes for FDA decision-making with respect to a variety of submission types. For example, under MDUFA III, the FDA will issue a decision about whether or not to clear a pre-market notification (510(k)) within 90 days of active FDA review for at least 91 percent of the submissions accepted in FY 2013. Certain performance goals will increase over the course of the MDUFA III program. Of note are the new "shared outcome" goals under which FDA and representatives of the medical device industry agreed to a joint commitment to reduce the total elapsed time (i.e., FDA and industry days) from FDA receipt of an accepted submission to an FDA decision on clearance of a 510(k) or approval of a PMA application (generally the path to market for a high-risk device).

MDUFA performance reports are available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109210.htm>.

## **Establishing and Developing Robust Workforces**

The commitments that FDA has made for FYs 2013-2017 for PDUFA, BsUFA, GDUFA, and MDUFA in many cases include reference to hiring and training of review staff. For example, PDUFA includes commitments that address the training of review staff in the development, review, and approval of drugs for rare diseases, communicating with sponsors during drug development, conducting a pharmacogenomics review of a new product application, and training on the implementation of structured benefit-risk assessment in FDA's drug review process. Furthermore, FDA committed to progress reporting on the new PDUFA V enhancements in terms of the hiring and placement of new staff and the use of PDUFA V resources to support the agreed upon enhancements. This information will either be reported in the [annual PDUFA performance reports](#) or in other annual reports that FDA posts on its website. Similarly, GDUFA includes commitments to hire and train at least 25 percent of the added GDUFA staff in FY



2013, 50 percent in FY 2014, with the goal of completing GDUFA hiring by FY 2015 as needed to achieve GDUFA performance goals. FDA's progress in meeting these goals will also be included in the annual GDUFA performance report. In MDUFA III, FDA is committed to adding 40 percent of the added MDUFA staff between FYs 2012/2013, 28 percent in FY 2014, and 25 percent in FY 2015 with the goal of completing hiring by 2017. The additional MDUFA funds will allow for an increase in the number of staff in the review divisions and the number of managers. A description of progress in meeting the MDUFA commitments associated with training of FDA staff is included as part of the [quarterly MDUFA performance reports](#).

### **Key Evaluation Studies in FY 2013-2017**

*PDUFA V new review "Program"* - The new PDUFA V review "Program" discussed in Section 1.1 of this report is being evaluated by an independent contractor over the duration of PDUFA V. This is the most extensive and in-depth evaluation of the new drug and biological product review process that has been conducted by the agency. Numerous aspects of the review process, with particular attention on new elements in the Program, will be examined to understand their impact on the efficiency of the first cycle review. An interim and final assessment will be delivered during PDUFA V with public meetings associated with each report. To improve the chances of the Program's success, any recommendation made by the contractor at the interim assessment may be implemented during the remainder of PDUFA V.

*Other PDUFA evaluations* - The PDUFA V commitments for CDER and CBER also include specific evaluations of FDA's implementation of a benefit-risk framework in regulatory decision-making and an evaluation of the activities associated with rare disease drug development, an evaluation of the impact of electronic submissions and data standards, and two evaluations of the review activity adjustment methodology (in FY 2013 and FY 2015).

*Device review process management* - MDUFA III includes FDA's commitment to participate with the medical device industry in a comprehensive independent assessment of the process for the review of medical device submissions. The two-phase assessment will be conducted under an FDA contract with a private, independent consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to objectively assess FDA's medical device premarket review processes. During the first phase, a comprehensive assessment of the process for the review of medical device submissions will be conducted. FDA will analyze the recommendations of the assessment and implement selected actions as appropriate. FDA also will incorporate the selected outcomes of the assessment into a Good Review Management Practices (GRMP) guidance document. FDA's implementation of the GRMP guidance will include initial and ongoing training of FDA staff and periodic audits of compliance with the guidance. In the second phase, the contractor will evaluate the implementation of recommendations adopted under phase one and publish a written assessment. The contract was awarded in June 2013.

The Independent Assessment Statement of Work is available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm314036.htm>.

Other BsUFA and GDUFA evaluations - CBER and CDER will use performance goal tracking and reviews to assess the knowledge and consistent application of the statutory requirements under BsUFA and GDUFA.