DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-3816

DEC 15 2014

Dear Mr. Chairman:

Thank you for providing the opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the November 15, 2013, hearing before the Subcommittee on Health, Committee on Energy and Commerce, entitled "Reviewing FDA's Implementation of FDASIA." We sent our first partial response for the record to questions posed by you and other Committee Members on September 9, 2014. This is our final response to the remaining questions, for the record.

If you have further questions, please let us know.

Sincerely,

Thomas A. Kraus
Associate Commissioner for Legislation

Enclosures

cc: The Honorable Frank Pallone, Jr.
Ranking member

We have restated your questions below in bold, followed by our responses.

The Honorable Joseph Pitts

9. **In your testimony, you note that you are making significant progress in implementing FDASIA and meeting most due dates. Which due dates are you missing and when does the Agency plan on completing them?**

Please refer to the FDASIA tracking spreadsheet, which was submitted with the first partial response to this letter, on September 9, 2014, and is enclosed. The "Targeted Completion Date" column lists the date by which the deliverable is to be completed and publicly available and includes FDA activity and external reviews and clearances. The "Date Completed" column lists the date by which the deliverable was actually completed and made public, including FDA activity and external review and clearances. Comparing the two dates will provide a snapshot of the due dates FDA missed, as of February 2014. More information about the deliverable and its status is listed in the "FDASIA TRACK Notes" column.

19. **How is interagency development of REMS for controlled substances coordinated? For example, how is DEA brought in to ensure that a REMS will not conflict with DEA's regulations? Does FDA consult with SAMHSA and/or the HHS-Office of Civil Rights on REMS compliance with HIPAA and other privacy laws regarding information about controlled substances? Finally, how is it ensured that controlled substance REMS do not put pharmacists in the untenable position where compliance with a REMS would require violating state controlled substance or state pharmacy laws?**

FDA takes into consideration input from various stakeholders in developing a REMS. For example, FDA has reached out to other Federal agencies during the development and evaluation process for certain REMS, e.g., FDA worked with the Office of National Drug Control Policy (ONDCP and DEA, as well as our sister HHS agencies, SAMHSA and NIDA, as we developed the extended-release, long-action (ER/LA) Opioid Analgesic REMS. The ER/LA Opioid Analgesic REMS requires that drug companies make training available, for health care professionals who prescribe ER/LA Opioid Analgesics, on proper prescribing practices and distribute educational materials to prescribers and patients on the safe use of these powerful pain medications.

Maximizing protection of patient privacy is of utmost importance to FDA. As necessary, FDA consults with other agencies with concerns regarding patient privacy.

20. **With recent reports of hackers gaining access to CBER's on-line submission systems compromising the information of approximately 14,000 current and past users, how has the FDA responded to this and similar attacks and what has been communicated to stakeholders?**

On October 15, 2013, an individual gained unauthorized network access to an online submission system of FDA's Center for Biologics Evaluation and Research (CBER). This system maintains the account information for the Electronic Biologic Product Deviation Reporting (eBPDR) System, the Electronic Blood Establishment Registration (eBER) System, and the Electronic Human Cell and Tissue Establishment Registration System (eHCTERS).

Anyone who had created a user account in the CBER On-Line system to access the eBPDR, eBER, or eHCTERs web applications was affected by this situation. The users of these systems are from regulated industry, including transfusion services and other manufacturers of blood and blood components, as well as manufacturers of human cells, tissues, and cellular and tissue-based products. The account information subjected to unauthorized access included: each registered user's first and last name, the phone number and e-mail address associated with each account, and the username and password for each account.

While the CBER On-Line submission system contained approximately 14,209 current and former user accounts, these records corresponded to approximately 12,080 unique users, since many users had multiple accounts.

FDA takes very seriously any threat to its data security. In the CBER cybersecurity breach, FDA personnel were able to rapidly detect the breach and put in place actions to assess and mitigate potential harm resulting from the attack, as well as protect Agency data systems from further similar attacks. Moreover, in the wake of the breach, FDA also worked with the Department of Homeland Security to assess and ensure the adequacy of FDA's corrective actions taken in response to this incident.

The Agency was able to confirm that no system data was altered, and at this time, the Agency is not aware of any attempt to use any account information for criminal or other inappropriate purposes. As a precaution, FDA disabled the systems, immediately implemented corrective security measures, and administered password resets for approximately 5,000 active user accounts. FDA also ensured that the remaining accounts were deactivated prior to bringing the system back online.

FDA twice communicated directly with CBER On-Line system account holders in relation to the October 15, 2013, cybersecurity breach. On October 17, 2013, FDA deactivated 8,986 accounts that were deemed no longer active, based on having not been used since October 17, 2011. Prior to the breach, 122 accounts had already been disabled. The passwords were reset for the remaining 4,820 active accounts, and on October 18, 2013, FDA contacted the active account holders by e-mail, advising them to change their account password.

On November 8, 2013, FDA contacted e-mail holders of active accounts and those whose accounts had been deactivated. The communication indicated that the system had been compromised and recommended actions for account holders to take to further protect against any fraudulent use of their information.

Cyberattacks differ in magnitude, scope, and method of intrusion. FDA evaluates and responds to attacks on a case-by-case basis by extinguishing the immediate threat and developing a targeted remediation plan to protect against future intrusion.

a. **What is the Agency's enterprise-wide plan to ensure the security of electronic submissions, confidential patient information, and reporting systems?**

Importantly, the October 2013 cybersecurity breach of the CBER On-Line submission system did not permit access to any confidential patient information. To ensure the confidentiality, integrity, and availability of FDA data, the Agency evaluates the effectiveness of the security controls of its information systems in accordance with the Federal Information Security Management Act (FISMA) of 2002 and NIST special publications 800-37 and 800-53.

b. **How will stakeholders be assured of the Agency's ability to fulfill their legal obligation to protect the confidential commercial information that the Agency receives on a daily basis?**

Notably, the systems subject to incursion in the October 2013 breach did not contain confidential commercial information. FDA is committed to safeguarding the confidential commercial information it receives. FDA is continuously looking to strengthen its security posture in accordance with FISMA and appropriate NIST special publications 800-37 and 800-53.

21. **As part of the PDUFA V Goals Letter and related requirements under FDASIA, the goals and the statute provide implementation of a number of critical electronic submission and data standardization goals and requirements. As such, the FDA is required to public a strategic plan detailing how these goals and requirements will be implemented. Given that the last available PDUFA IT plan was published in September 2011 with information current as of May 2010, what is the status of the PDUFA IT plan?**

Will the plan include a strategy for the support, maintenance and security of critical, foundational systems, such as the Electronic Submissions Gateway, that are central to the FDA's ability to receive and process the electronic submissions that will be required of sponsors per Section 1135 of FDASIA?

The draft PDUFA V IT plan was published December 26, 2013 for public comment and is available at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm183308.htm*. The plan calls for an analysis of current demand and projected future increases in submission loads for the Electronic Submissions Gateway (ESG) operations. The analysis will consider the program structure of ESG, system capacity, adequacy of contingency planning and continuity of

operations, as required in section 1136 of FDASIA, and long-term viability of the current technology and security provisions.

22. I understand that the Agency utilized emergency funds to continue operations in response to sequestration. What is the current status of these emergency funds?

FDA has no designated "emergency funds." FDA has responded to the sequestration budget cuts by reducing staff training and by a major reduction in travel. Reduction in staff training impairs FDA's ability to remain current on the most recent scientific and regulatory advances. A major reduction in travel means FDA cannot as readily interact with key stakeholders and regulatory partners. Additionally, the development of reports, guidances, rules, and *Federal Register* notices to implement FDASIA provisions has been delayed. Meetings within the time frames specified in legislation have been adversely impacted.

25. FDA has stated that they will engage stakeholders in the process to facilitate treatments for those with serious and life-threatening illnesses particularly where there are little to no treatments available.

a. How are you engaging the pharmaceutical industry in this process? Specifically, what steps has the FDA taken to engage with the ME/CFS community and innovators with expertise in this area?

b. Under the new patient focused drug development meetings, what role do the drug innovators play?

In answer to Questions 25a and 25b, the patient-focused drug development meetings, conducted as part of a performance initiative FDA is undertaking under PDUFA V, are public meetings announced in the *Federal Register* and on *FDA.gov*. FDA not only expects participation from patients, caregivers, and health care practitioners, but we also anticipate involvement of the regulated industry. We held four patient-focused drug development meetings in FY 2013, and drug innovators attended each one. FDA has stated that hearing directly from those who experience the disease will highlight opportunities for enhancements in the treatment armamentarium for a given disease as well as outcome measures that matter to patients but may not currently be captured in clinical trials. In the long run, our patient-focused initiative has the strong potential to lead to clinical trial designs that will better target the impacts of disease that patients truly care about. This information will help encourage drug innovators to develop treatments for diseases currently without effective treatments.

One of the drug development meetings in FY 2013 focused on myalgic encephalomyelitis (ME) and chronic fatigue syndrome (CFS). Specifically, on April 25 and 26, 2013, FDA held a two-day public workshop with patients; patient representatives; and scientific, industry, and regulatory experts to discuss important issues regarding the development of safe and effective drugs for the treatment of patients with ME/CFS. The first day of the meeting was conducted as part of FDA's Patient-Focused Drug Development initiative and was an effort to more systematically gather patients' perspectives on their conditions and

available therapies to treat their conditions. Building on the perspectives expressed on the first day of the meeting, the second day was a scientific workshop to discuss how best to facilitate and expedite drug development for ME/CFS. This two-day public workshop allowed FDA to engage with the ME/CFS community and innovators with expertise in this area.

c. How exactly is FDA engaging with innovators on these unmet medical needs? Are you examining treatments currently in the pipeline?

FDA engages with innovators of drugs to treat unmet medical needs in a variety of ways. FDASIA provided FDA with a new expedited development tool known as the breakthrough therapy designation. This tool is designed to expedite the development of new drugs based on preliminary clinical evidence that indicates the drug may offer a substantial improvement over available therapies for patients with serious or life-threatening diseases. The sponsor of a product with breakthrough therapy designation receives, among other things, intensive guidance from the Agency on efficient drug development beginning as early as the Phase I period, organizational commitment involving senior managers, and eligibility for rolling review (early submission of portions of an application). CDER has been very active in the implementation of the breakthrough therapy program, meeting with companies and discussing ways to expedite the drug development process for drugs that show striking early results.

FDA reviews requests for breakthrough designations within 60 days of receipt of the request. As of October 17, 2014, approximately 202 requests have been received by CDER, and 60 applications have been granted the breakthrough designation[1] that have shown encouraging early clinical results in treating conditions such as cystic fibrosis. Many of the breakthrough therapy designations granted so far have been for rare disease indications. Additionally, CDER has approved 10 products for which a breakthrough therapy designation has been granted including, among others, Gazyva® for chronic lymphocytic leukemia, Solvaldi® for chronic hepatitis C infection, and Imbruvica ® for mantle cell lymphoma. As of September 30, 2014, CBER had received 37 breakthrough designation requests, and granted seven of those requests.[2]

FDA has various other expedited development and review tools, including accelerated approval, the fast-track program, and priority review. In June 2013, FDA published a draft guidance for industry entitled "Expedited Programs for Serious Conditions-Drugs and Biologics" to help industry better understand each of these tools, including when the tool can be used and the features of each. We issued the final guidance in May 2014. The guidance is available at
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidan

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[1] *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstothe FDCAct/FDASIA/ucm341027.htm*

[2] *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstothe FDCAct/FDASIA/ucm341027.htm*

ces/UCM358301.pdf. Among other important information, the draft guidance describes FDA's policies and the threshold criteria and features for each expedited program, defines and discusses important concepts (including "serious condition," "unmet medical need," and "available therapy"), and provides general considerations for products utilizing an expedited program, such as manufacturing and product quality, non-clinical considerations, and clinical inspection considerations.

The Honorable Marsha Blackburn

3. **How many Special Protocol Assessment (SPA) agreements has the review division and/or FDA interpreted to be no longer binding due to failure of a sponsor to follow a protocol agreed upon with the Agency?**

As of January 2014, FDA has interpreted five SPAs to be no longer binding, due to failure of a sponsor to follow a protocol agreed upon with the Agency.

4. **How many SPA agreements has the review division and/or Agency found to be no longer binding based on false statements, misstatements, or the omission of relevant facts?**

As of January 2014, FDA has found one agreement to be no longer binding, based on false statements, misstatements, or the omission of relevant facts.

5. **How frequently does the review division and/or Agency agree to modify a SPA?**

Since April 2012, the Agency has agreed to modify 66 SPAs regarding trials in 47 INDs. Within the 47 INDs there were 52 individual SPAs that had modifications; there were also 14 subsequent modifications of SPAs within the group of 52. Prior to April 2012, the way that modified SPAs were tracked and coded was different than it is currently; in order to accurately assess the number of agreed-upon SPA modifications prior to April 2012, an exhaustive manual review of individual correspondence would be necessary.

6. **How many SPA agreements has the review division and/or Agency rescinded based on review division and/or Agency determination that a substantial scientific issue essential to determining the safety or efficacy of the drug has been identified after the testing has begun?**

As of January 2014, FDA has rescinded four agreements based on review division and/or determination that a substantial scientific issue essential to determining the safety and efficacy of the drug has been identified after the testing has begun.

7. **One of the goals of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act was to spur innovation in treatments for children with rare diseases, and specifically for children with cancer. I would like to ask you whether you believe this legislation has been successful for children battling Pediatric Low-Grade Astrocytoma (PLGA) and other rare pediatric cancers. Pediatric Low-Grade**

Astrocytoma is a slow growing children's brain cancer that impacts over 20,000 children in the United States. Each year, over 1,000 new children are diagnosed with some type of astrocytoma brain tumor. The treatment options currently available to children with slow-growing PLGA brain tumors are invasive, highly toxic and ineffective.

Some pharmaceuticals that are effective in treating adult cancers are being examined to treat PLGA brain tumors. For example, a drug that is approved for treatment of primary kidney cancer and advanced primary liver cancer is being examined for treatment of PLGA. With funding from the PLGA Foundation and the Making Headway Foundation's Talbot Family Research Fund, a phase II clinical trial of this drug for the treatment of children and young adults with recunent or progressive Low-Grade Astrocytoma has opened. These are the kinds of research synergies and laboratory collaborations that hold promise for significant breakthroughs and give hope to children with PLGA and their families.

Are the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) helping to incentivize these types of research synergies for rare children's cancers like PLGA? Are there other barriers that exist to advancing new clinical trials for PLGA that Congress should be examining?

FDASIA made permanent the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). BPCA and PREA were passed by Congress to encourage the study of drugs and biological products in pediatric patients in order to provide adequate pediatric use information in drug and biological product labeling. These two programs have been very successful in achieving adequate pediatric-use information in drugs and biological product labeling for pediatric diseases, including pediatric cancers. Since the passage of these important laws, FDA has approved over 500 labeling changes to incorporate pediatric information. Under BPCA, labeling information obtained through studies conducted under Written Requests[3] in the treatment of PLGA in children include temozolomide, carboplatin, and irinotecan. It should be noted that products used to treat rare pediatric cancers may receive designation under the Orphan Drug Act, and as such, are exempt from requirements under PREA.[4] However, the Orphan Drug

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[3] Under BPCA, a Written Request is a specific document from FDA, generally signed by the applicable office director(s) or authorized delegate, requesting submission of a certain study or studies to determine whether the use of a drug (active moiety) could provide a meaningful health benefit in the pediatric population. The Written Request specifies the elements of the study or studies that FDA expects a sponsor or application holder to include to earn pediatric exclusivity. FDA can issue a Written Request at the request of an interested person or on its own initiative. Issuance of a Written Request to a sponsor or holder of an approved application does not require the recipient to conduct the pediatric studies described in the Written Request. It is the recipient's decision whether to conduct the studies and possibly obtain pediatric exclusivity.

[4] PREA requires applications (or supplements to applications) under section 505 of the FD&C Act or section 351 of the Public Health Service Act (PHSA), respectively, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to contain a pediatric assessment, unless the applicant has obtained a waiver or deferral (section 505B(a) of the FD&C Act). PREA also authorizes the FDA to require holders of applications for previously approved marketed drugs approved under section 505 of the FD&C Act and biological products licensed under section 351 of the PHSA, who are not seeking approval for one of the changes specified above, to submit a pediatric assessment under certain circumstances (section 505B(b) of the FD&C Act).

Act is an important and successful law that provides incentives for the development of products used to treat rare diseases, including rare pediatric cancers.

Additionally, under BPCA, the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (ODAC) was authorized to evaluate, and to the extent practicable prioritize, new and emerging therapeutic alternatives to treat pediatric cancer. Products under development for use in adult cancers are brought forward for discussion by the Pediatric Subcommittee of the ODAC after consideration by pediatric experts within FDA; advice and recommendation of outside pediatric oncology experts; and pediatric oncology advocacy groups. In 2013, Trametinib and TH-302 were brought forward for discussion at a Pediatric Subcommittee meeting of ODAC and it was the committee's recommendation that use in treatment of PLGA be investigated for each of these agents.

Children with recurrent PLGA are frequently enrolled in several Phase1 and/or 2 studies of new drug products in an attempt to identify active agents which might prove useful in the treatment of PLGA. PLGA and other primary brain tumors in children have been a focus of the Pediatric Subcommittee of the ODAC. The Agency is committed to leveraging both current scientific discovery and developments in potentially relevant new drug and biologic products and to working with investigators and sponsors to expedite new treatment options for children with PLGA.

The Honorable Michael Burgess

8. **FDASIA requires safety data be carefully weighed in a risk vs. benefit analysis, taking into account the needs and viewpoints of patients. In a case where a drug treats a rare and life threatening disease plus shows no adverse events and has no measurable or anticipated negative side effects, would you please explain in detail how the FDA would take into consideration this safety profile and the views of patients and families regarding risk and benefit?**

FDA considers several key decision factors in making a benefit-risk assessment for a particular drug, including an analysis of the condition the drug is intended to treat, current treatment options, the benefits and risks of the drug, as well as risk management considerations. FDA is working to implement a formal benefit-risk framework that incorporates these factors, as discussed in the Draft PDUFA V Implementation Plan, Structured Approach to Benefit-Risk Assessment in Drug Regulatory Decision-Making (February 2013) ("Draft Implementation Plan"), available at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf*. As discussed in the Draft Implementation Plan, FDA has approved drugs that are associated with significant safety concerns when those new therapies have a demonstrated clinical benefit.

One example of when FDA has conducted this type of benefit-risk assessment is with the drug Tysabri for multiple sclerosis. This drug was withdrawn from the market by the manufacturer in

2005, after it was linked with progressive multifocal leukoencephalopathy (PML), a rare, frequently fatal neurological condition. FDA reviewed a restricted distribution plan to manage the risk of PML, as well as additional efficacy data, and convened an advisory committee meeting in 2006 on remarketing Tysabri. At the meeting, patients, family members, and health care providers testified to the difference that Tysabri had made in the lives of MS patients, as well as the willingness of patients to continue treatment despite the risk of PML. This testimony and the unanimous Advisory Committee recommendation to return Tysabri to the market indicated that, despite other available therapy options for MS, there was still an unmet medical need in this progressively debilitating inflammatory neurological disease that was filled by Tysabri, a more effective drug than other available therapies. FDA ultimately determined that the serious risks associated with this drug were acceptable, because they were outweighed by the benefit of the drug to patients.

FDA generally approves several drugs for rare and life-threatening diseases in any given year. In many cases, these drugs are associated with serious safety concerns. A few recent examples from 2013 include Kynamro, Adempas, Opsumit, and Imbruvica.

Kynamro was approved to treat patients with a rare form of high cholesterol called homozygous familial hypercholesterolemia, a condition that often leads to heart attacks and death before age 30. Kynamro was approved despite its association with serious liver injury, the risk of which is addressed in a REMS.

Adempas and Opsumit were both approved to treat different forms of pulmonary hypertension, a chronic, progressive, debilitating disease that can lead to death or the need for a lung transplant. These drugs were both approved with boxed warnings and REMS to alert patients and health care professionals to avoid use of the drug in pregnant women because of potential harm to the fetus. Imbruvica is used to treat patients with a rare and aggressive type of blood cancer. FDA approved Imbruvica under the Agency's accelerated approval program, which allows FDA to approve a drug for a serious disease based on clinical data showing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients. Therefore, patients will have earlier access to this promising new drug while the company conducts confirmatory clinical trials. Imbruvica is associated with low levels of platelets in the blood (thrombocytopenia), diarrhea, a decrease in infection-fighting white blood cells (neutropenia), anemia, fatigue, and musculoskeletal pain, among other side effects.

The Honorable Phil Gingrey

11. **Just recently FDA released a proposed rule that would fundamentally change the way that doctors and pharmacists access and interpret drug labelling. Under the proposed rule, at any given time there can be multiple labels for a single medication. The FDA acknowledges that 1) the purpose of drug labeling is to inform prescriber decisions about the benefit and risk of medicines and 2) that health care practitioners are unlikely to review all of the product labeling, so a website is needed to view proposed but yet to be reviewed labeling changes.**

Aren't we creating a situation of great uncertainty for doctors and pharmacists? How will they know whether a proposed change is valid and if this information should be conveyed to patients? How does the FDA expect doctors to view these proposals, as valid changes before FDA has examined them or as mere proposals that have no validity until approved?

Furthermore, this seems to create a new burden to search a website every time the doctor wishes to prescribe a drug to see if any new label has been suggested. Given that doctors currently do not review these labels regularly, how will you ensure that doctors will review the site for the most recent information?

Because there is an ongoing rulemaking process at FDA concerning these issues, our response to this question reflects statements made publicly in the preamble to the proposed rule. All drug manufacturers (both brand and generic) have an ongoing obligation to ensure that their product labeling is accurate and up to date. When new information becomes available that causes information in labeling to be inaccurate, the manufacturer must take steps to change the content of its product labeling.

For most substantive changes to product labeling, a drug manufacturer is required to submit a prior approval supplement and receive FDA approval for the change. However, in the interest of public health, the regulations permit certain labeling changes based on newly acquired information about an approved drug to be implemented upon receipt by FDA of a "changes being effected" or "CBE-0" supplement, so that important safety-related labeling changes are made available to health care practitioners at the earliest possible time. In 2008, FDA clarified that a CBE-0 supplement may be used to add or strengthen a contraindication, warning, precaution, or adverse reaction only if there is sufficient evidence of a causal association with the approved product. These requirements are intended to help ensure that scientifically accurate information appears in product labeling for consideration by health care practitioners when making treatment decisions with their patients, based on the balance of potential benefits and risks of the drug product for that patient.

Under current regulations, only brand-drug manufacturers can independently update product labeling with certain newly acquired safety information and distribute revised labeling, before FDA reviews or approves the labeling change, by submitting a CBE-0 supplement. FDA generally has advised that a generic drug manufacturer may use the CBE-0 supplement process only to update its product labeling to conform with the FDA-approved labeling for the corresponding brand drug or to respond to FDA's specific request to submit a labeling change through the CBE-0 process. Accordingly, while FDA reviews a brand drug manufacturer's CBE-0 supplement, there currently is a difference between the brand drug labeling and generic drug labeling. Once FDA approves a change to the brand drug labeling, the generic drug manufacturer is required to revise its product labeling to conform to the approved labeling of the corresponding brand drug. FDA advises that this update should occur at the very earliest time possible; however, FDA has determined that there is often a delay, of varying lengths, between the date on which revised brand drug labeling is approved and the date on which the generic drug manufacturer submits such labeling updates. The proposed rule, if finalized, generally would

reduce the time in which all generic drug manufacturers make safety-related labeling changes by requiring generic drug manufacturers to submit conforming labeling changes within a 30-day time frame. Thus, the proposed rule would likely reduce the variation between brand and generic drug labeling.

The proposed rule, if finalized, also would allow generic drug manufacturers to independently update product labeling with newly acquired safety information and promptly distribute the revised labeling before FDA's review of the change, just as brand drug manufacturers are currently allowed to do. As the generic drug industry has matured and captured an increasing share of the market, tension has grown between the requirement that a generic drug have the same labeling as the corresponding brand drug, and the need for a generic drug manufacturer to be able to independently update its labeling as part of its independent responsibility to ensure that the labeling is accurate and up to date. In the current marketplace, in which approximately 80 percent of drugs dispensed are generic and brand-drug manufacturers may discontinue marketing after generic drug entry, FDA believes it is time to provide generic drug manufacturers with the means to update product labeling to reflect data obtained through post-market surveillance, even though this will result in temporary labeling differences among products while FDA reviews the proposed labeling change.

To minimize confusion and make safety-related changes to generic drug labeling readily available to prescribing health care professionals and the public while FDA is reviewing a CBE-0 supplement, if the proposal is finalized in its current form, the Agency would create a web page on which FDA would promptly post information about the safety-related labeling changes proposed by brand and generic drug manufacturers in CBE-0 supplements. The proposed FDA web page is expected to enhance transparency and facilitate public access to new safety-related information for all products–biological products licensed under the PHS Act as well as drug products approved under the FD&C Act–so that such information may be used to inform treatment decisions. The public would be able to subscribe to FDA's free e-mail subscription service to receive an e-mail message each time there is an update to this proposed web page. If finalized, this rule would help ensure that health care practitioners and the public have access to the latest safety information for the medications they use.

The Honorable Leonard Lance

3. **As you may be aware, I have authored legislation, the FDA Safety Over Sequestration (FDA SOS) Act, which would protect the FDA user fees from the threat of sequester, should Congress face a similar budget situation as we did earlier this year. This legislation is supported by many of my colleagues on this committee on both sides of the aisle and it is our hope that it be considered and passed soon in order to maintain predictability in the review process, as well as incentive to continue to engage in these agreements.**

   OMB unfortunately interpreted sequestration to apply equally to both FDA appropriations and industry user fees. As a result, more than $80 million in private user fee funding is being sequestrated in an agency account where they cannot be

spent or put to any practical purpose. The FDA Safety Over Sequestration (FDA SOS) Act would clarify that industry user fees cannot be sequestered. From the perspective of a senior FDA manager, what impact is the sequestration of user fees having on FDA operations, regulatory science, and product evaluation? Would you support passage of the FDA SOS bill?

As Commissioner Hamburg has said, an Agency as important as FDA needs predictability and cannot be run well if you don't know what budget you'll be given during the year, or if you do not know whether you can draw from certain resources or not. The Administration has not taken a position on this bill. The sequester restricted access to an estimated $79 million in users fees in FY 2013. Sponsors paid fees for specific commitments that were negotiated as part of the PDUFA, MDUFA, GDUFA, BsUFA, ADUFA, and AGDUFA agreements, but as of January, 2014, FDA did not have access to the full amount of the funds in FY 2013 due to the sequestration. Sequestration impacts FDA's ability to meet these commitments, such as the program enhancements specified in the PDUFA V and MDUFA III commitment letters. This work must be done by FDA, not other FDA constituencies. Many of these enhancements will have long-term benefits for the public health. The delay of these enhancements resulting from the sequester could postpone these benefits. If this bill moves forward and sequestration is mitigated in future years, FDA will have enhanced capacity to meet its commitments to industry and the public.

4. Briefly, how are Agency operations impacted by sequestration? As a result, how are you absorbing these cuts?

Previously we estimated the overall sequestration of FY 2013 user fees to be $85M. The estimate as of September 30, 2013, was $79M. Of that amount, $54M is attributable to PDUFA, GDUFA, BsUFA, and MDUFA. The reason for the change in sequestration amounts is that actual collections were different from the estimates at the beginning of FY 2013.

The FY 2013 sequestration and rescission reductions, as they stood in January 2014, have reduced FDA's ability to protect the public and ensure the safety of America's food and medical products. FDA was unable to hire to the appropriate staffing level for its workload. This reduced staffing level:

- delayed FDA's ability to conduct regulatory review and to issue regulations and guidance
- impaired FDA's ability to conduct inspections in a timely manner
- reduced FDA's capability to conduct relevant regulatory research.

Furthermore, due to the sequestration budget reductions, FDA reduced staff training and had a major reduction in travel. Reduced staff training impairs FDA's ability to remain current on the most recent scientific and regulatory advances, and a major reduction in travel means FDA cannot as readily interact with key stakeholders and regulatory partners. Additionally, the development of reports, guidances, rules, and *Federal Register* notices to implement FDASIA provisions has been delayed.

Any further reductions to FDA's resources in future fiscal years will exacerbate the challenges FDA faced as a result of the FY 2013 sequestration.

5. **How has sequestration affected product review times, if at all? Are certain products/review divisions/therapeutic areas more or less impacted than others?**

   How has sequestration, including of industry-paid user fees, impacted the Agency's ability to implement FDASIA in terms of the new responsibilities it is required to undertake with respect to promoting innovation, stakeholder engagement, and drug supply chain integrity?

As of January 2014, FDA did not have the additional resources needed to meet the new commitments made under PDUFA V that offered critical enhancements to communications with sponsors, new drug regulatory science, and more efficient and effective post-market safety oversight beginning in FY 2013.

FDA's capacity to effectively launch the new user fee programs, GDUFA and BsUFA, was reduced. These programs are designed to enable FDA to leverage user fee resources to provide many benefits to the public, including expediting the availability of high-quality, cost-effective generic drugs and biosimilars. The reduction in funding put at risk FDA's ability to meet the performance goals negotiated with industry, including performance goals for expediting the review of generic drugs and biosimilars.

Sequestration made it challenging for FDA to meet MDUFA performance goals, but FDA minimized the impact of sequestration where possible. FDA does not believe sequestration will impact MDUFA review times.

6. **It seems that the decision to sequester the PDUFA user fees violates the intent of the statute that the industry's user fees should only be used for the review of new medicines. Has the agency discussed any strategy to release the sequestered fees through the FY2014 fiscal process or otherwise?**

   Have you talked to either the House or Senate Appropriations Committees about finding a mechanism to release the fees? Has FDA requested that HHS or OMB release the fees? When and who took part in these discussions?
   Has FDA questioned OMB's analysis that PDUFA user fees are subject to sequester or any other use than for FDA's human drug review program? If so, when did FDA have these discussions and with whom?

As Commissioner Hamburg has said, an Agency as important as FDA needs predictability, and cannot be run well if you don't know what budget you'll be given during the year, or if you do not know whether you can draw from certain resources or not. To that end, FDA has discussed this issue within the Administration and with staff in Congress. We are pleased that the FY 2014 appropriation restores $124 million in budget authority to FDA, lost due to the FY 2013

sequestration and rescission cuts. Section 747 of the FY 2014 appropriation also includes funding for the FY 2013 sequestered user fees.

7. **FDA continues to be unable to access approximately $83 million in sequestered user fees for FY2013. The loss of these fees has meant that the implementation of key aspects of FDASIA have been delayed including the hiring of any new scientific and medical personnel to advance crucial regulatory science priorities. Undoubtedly, this is bad for patients, bad for science and bad for public health.**

   Given the gravity of the impact losing these fees has had on the agency's ability to fulfill its public health mission, shouldn't a mechanism to release them be among the Agency's top priorities for anomalies in any end of year fiscal package? Has the agency communicated with the Hill about such an anomaly? If so, to whom and when?

See response to Question 6.

8. **Budget and Appropriations leaders have indicated that giving "flexibility" to agencies in how sequester cuts are implemented is a top priority for the end of year fiscal package. What kind of authority would FDA need for there to be a real impact on how effectively the agency is able to mitigate the impact of the sequester, including user fee programs? Have you communicated this to Budget and Appropriations negotiators by providing them with language or engaging in any conversations at all?**

See response to Question 6.

<u>The Honorable Bill Cassidy</u>

2. **Does the FDA have a standard operating procedure as it relates to evaluating both domestic and foreign manufacturers for their ability to provide drugs unapproved by the FDA in the event of a drug shortage? If so, please provide that operating procedure.**

In deciding whether a manufacturer may be able to provide an unapproved drug product on a temporary basis to help address a shortage, the Agency evaluates the risks and benefits of possible products based on the facts of each case. In cases where U.S.-approved products have not been available in adequate quantities to address a shortage, the Agency has looked for other suppliers whose products can meet patient needs without posing undue risk to patients. FDA does not have standard operating procedures as it relates to evaluating both domestic and foreign manufacturers for their ability to provide drugs unapproved by FDA in the event of a drug shortage.

3. **In the Strategic Plan for Preventing and Mitigating Drug Shortages report released in October 2013, the FDA briefly mentions the Gray Market but notes that the agency has limited data on the gray market and no authority regarding production pricing.**

Has the FDA reached out to CMS to collaborate to learn more about the Gray Market and drug pricing in respect to studying the recent jump in drug shortages?

Regarding the gray market, FDA communicates with the Department of Justice by compiling and passing along reports of unusual pricing. FDA has not collaborated with CMS on this issue; however, we have worked with GAO on their drug shortage study, which included an analysis of gray market activity.

The Honorable Gus Bilirakis

1. **109 Members of Congress signed onto a letter urging the FDA to improve access to Accelerated Approval for Rare Disease as required by FDASIA. How is the FDA planning to improve the Final Expedited Approval Guidance due in July 2014 to be in compliance with FDASIA?**

The guidance, which was published on May 30, 2014, clarifies that FDA has a long history of applying the subpart E philosophy[5], through use of the Agency's expedited programs, including accelerated approval, to drugs for rare diseases. FDA recognizes that certain aspects of drug development that are feasible for common diseases may not be feasible for rare diseases and that development challenges are often greater with increasing rarity of the disorder. FDA will continue to apply flexibility in these situations to address particular challenges posed by each disease.

2. **It is our understanding that only 1 of the 13 accelerated approvals you cited during the last six years was for a disease without historic approvals. To be in compliance with FDASIA, the FDA must allow for novel approaches to use pathophysiologic and pharmacologic evidence to support the use of biomarker endpoint when the low prevalence of disease makes the existence of other types of data impractical to collect. What kind of novel approaches is the FDA planning to take to allow for the use of surrogate endpoints in clinical trials for rare diseases?**

For new molecular entity (NME)[6] and original biological products approved by CDER during the last seven calendar years (January 1, 2007 through December 20, 2013), there have been 14 Accelerated Approvals (including 13 unique products. One biologic–brentuximab, was granted Accelerated Approval for two different indications). One additional drug, ibrutinib, was approved under Accelerated Approval on November 13, 2013, but was not available in time to be included in the presentation to Congress on November 15, 2013. Thirteen of the Accelerated Approvals were for rare-disease indications (the one non-rare indication was for HIV). These 14 Accelerated Approvals are summarized in the following table:

Table 1. Accelerated Approvals, NME and Original Biologics, January 1, 2008 – December 31, 2013

[5] 21CFR Part 312 Subpart E, "Drugs Intended to Treat Life-threatening and Severely-debilitating Illnesses."
[6] NMEs are defined as drugs for which the active pharmaceutical ingredient has not previously been approved by FDA.

Drug (Trade name), AP date	Therapeutic Area	Abbrev. Indication	Rare Y/N
etravirine (Intelence) 18-Jan-08	Infectious disease	treatment-experienced HIV-1 patients who have evidence of viral replication and HIV-1 strains resistant to an NNRTI and other antiretroviral agents	No
eltrombopag (Promacta) 20-Nov-08	Hematology (non-onc)	thrombocytopenia in patients with chronic immune idiopathic thrombocytopenic purpura who have insufficient response to corticosteroids, immunoglobulins, or splenectomy	Yes
*pralatrexate (Folotyn) 24-Sep-09	Oncology	relapsed or refractory peripheral T-cell lymphoma	Yes
ofatumumab (Arzerra) 26-Oct-09	Oncology	chronic lymphocytic leukemia refractory to fludarabine and alemtuzumab	Yes
brentuximab (Adcetris) 19-Aug-11	Oncology	Hodgkin lymphoma after failure of autologous stem cell transplant or after failure of at least two prior multi-agent chemotherapeutic regimens	Yes
brentuximab (Adcetris) 19-Aug-11	Oncology	Relapsed systemic anaplastic large cell lymphoma	Yes
*crizotinib (Xalkori) 26-Aug-11	Oncology	non-small cell lung cancer (NSCLC) , anaplastic lymphoma kinase-positive (ALK+)	Yes
deferiprone (Ferriprone) 14-Oct-11	Hematology (non-onc)	Transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate	Yes
carfilzomib (Kyprolis) 20-Jul-12	Oncology	patients with multiple myeloma who received at least two prior therapies	Yes
omacetaxine (Synribo) 26-Oct-12	Oncology	chronic myeloid leukemia with resistance or intolerance to two or more tyrosine kinase inhibitors (TKIs)	Yes
ponatinib (Iclusig) 14-Dec-12	Oncology	chronic myeloid leukemia (CML) and Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) resistant or intolerant to prior TKI	Yes
*bedaquiline (Sirturo) 28-Dec-12	Infectious disease	pulmonary multi-drug resistant tuberculosis (TB)	Yes
Pomalidomide (Pomalyst) 08-Feb-13	Oncology	multiple myeloma in patients who have received at least two prior therapies	Yes

Ibrutinib (Imbruvica) 13-Nov-13	Oncology	mantle cell lymphoma in patients who have received at least one prior therapy	Yes

Three of the Accelerated Approvals were for diseases for which there was no prior FDA approved therapy specifically for the indication (marked with*: NSCLC that is ALK+, peripheral T-cell lymphoma, and pulmonary multi-drug resistant TB). We note, however, that the Accelerated Approval regulations require that drugs approved under this pathway generally provide meaningful advantage over available therapies. For example, many of the above disease indications are for refractory, resistant or previously treated diseases where patients had previously failed one or several other available therapies. Hence, these approvals were addressing unmet medical needs or providing patients with serious diseases important additional treatment options.

We additionally note that non-NME drugs and previously approved biologics may also be considered for Accelerated Approval. In addition to the above listed NME and original biologic product Accelerated Approvals, there were three additional non-NME or supplemental approvals under the Accelerated Approval pathway within this time frame, two of which were for rare disease indications. These additional Accelerated Approvals are summarized in the following table:

Table 2. Accelerated Approvals, Non-NME NDAs and Efficacy Supplements, January 1, 2008 – December 31, 2013

Drug (Trade name), AP date	Therapeutic Area	Abbrev. Indication	Rare Y/N
*Hydroxyprogesterone caproate (Makena) 18-Dec-08	Obstetrics	Reduce risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth	No
Vincristine sulfate liposomal injection (Marqibo) 09-Aug-12	Oncology	Philadelphia chromosome-negative acute lymphoblastic leukemia (ALL) in second or third relapse or whose disease has progressed following two or more anti-leukemic therapies.	Yes
Everolimus (Afinitor Disperz) 29-Aug-12	Oncology	Pediatric and adult patients with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected.	Yes

One of the approvals was for a disease with no prior FDA approved therapy, specifically for the indication (Makena, to reduce the risk of preterm birth). Similar to what is noted above for the NME and original biologics approvals, the other two Accelerated Approvals were assessed as providing meaningful advantage over available therapies, either by additional treatment for refractory ALL, or by providing an age-appropriate pediatric formulation with advantages for young pediatric TSC patients with SEGA.

Rare disease drug approvals have a long history of use of biomarkers as surrogate endpoints to support approvals, including traditional and Accelerated approvals. For example, in the past two years, there have been 22 NME and original biologics ("new product") rare disease approvals, 15 of which received traditional approvals, six received accelerated approvals, and one was approved under the animal rule. Excluding the one product approved under the animal rule (racibacumab (Abthrax) for inhalational anthrax), 18 of 21 (86 percent) rare disease approvals relied upon a surrogate endpoint for approval. A few examples include mipomersen (Kinamro) and lomitapide (Juxtapid) for homozygous familial hypercholesterolemia, based on changes to serum lipid parameters, and glucarpidase for the treatment of methotrexate toxicity in patients with impaired renal function, based on plasma methotrexate concentrations.

FDA continues to work with drug sponsors to apply flexibility, including the use of biomarkers, surrogate endpoints, non-traditional trial designs and other available tools, to expedite the development of new products for rare diseases. We note that a challenge associated with the use of surrogate endpoints in rare diseases is that there needs to be some empirical evidence to support the biological plausibility of the relationship between the disease, the endpoint, and the desired effect, and clinical data should be provided to support a conclusion that a relationship of an effect on the surrogate endpoint to an effect on the clinical outcome is reasonably likely.[7] In the rare disease field, there is often a lack of sufficient translational science development and understanding of the diseases' pathophysiology, natural history, and other data to support proposed surrogate endpoints. FDA has a number of initiatives in place to promote development of biomarkers, improve data collection in the natural disease studies and registries, and for the development of other translational science, such as the Critical Path Initiative (and other initiatives listed in the response to the Honorable Leonard Lance, Question 2).

3. How many treatments were approved with novel biomarkers used for the first time?

It is challenging to define biomarker novelty and to identify when such biomarkers were used for the first time. We are providing background information on biomarkers below and listings of a recent cohort of new drugs and accelerated approvals using biomarkers in Tables 1-3 in the enclosure to this response.

A biomarker is defined as:

> "A characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention."[8]

Biomarkers include laboratory tests (e.g., blood sugar or serum cholesterol), physical signs (e.g., blood pressure), and radiographic images, and are commonly used and relied upon throughout many phases of drug development from basic science, translational, and preclinical phases

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[7] Guidance for Industry. Expedited Programs for Serious Conditions –Drugs and Biologics. Draft Guidance.
[8] Biomarkers Definitions Working Group. Biomarkers and surrogate endpoints: Preferred definitions and conceptual framework. *Clin Pharmacol Ther.* 2001;69:89-95.

through to clinical testing. Biomarkers have many different uses. For example, they are used in pre-clinical animal toxicology testing to look for safety signals that indicate drug toxicity or target organ damage, in early-phase clinical testing for pharmacokinetic and pharmacodynamic testing, such as to assess drug exposure and metabolism, guide dosing, assist with early safety evaluation, and to inform the design and conduct of later-phase trials, and in mid-to-later phase clinical testing, such as to assess early effects of intervention on biochemical pathways (such as LDL-cholesterol lowering). In pre-clinical and early clinical phase testing, these biomarkers may not directly factor into an approval decision for a marketing application, but the information gained from the use of biomarkers is usually critical to the development of drugs. In later-phase clinical testing (e.g., Phase 3 efficacy or "pivotal" trials), in some circumstances, a biomarker may be used as a surrogate endpoint.

Surrogate endpoints are a subset of biomarkers that are used as a substitute for a clinical endpoint in a clinical trial. A surrogate endpoint is defined as "a marker that is thought to predict clinical benefit, but is not itself a measure of clinical benefit."[9] Depending on the strength of the evidence supporting the ability of a marker to predict clinical benefit, the marker may fall into one of three categories:[10]

1) The marker is *known* to predict clinical benefit, i.e., a validated surrogate endpoint that could be used as an endpoint in a clinical trial used to support a traditional approval. Some examples include HgA1C for diabetes medications and LDL-cholesterol ("bad" cholesterol) for statin medications used to treat hypercholesterolemia.

2) The marker is *reasonably likely to predict a drug's intended clinical benefit*, and could be used as a basis for accelerated approval. An example includes tumor stabilization or shrinkage for some cancers, which is thought to be reasonably likely to predict an effect on overall patient survival.

3) A marker for which there is *insufficient evidence* to support reliance on the marker as either kind of surrogate endpoint, and that, therefore, cannot be used to support traditional or accelerated approval of a marketing application. An example includes HDL-cholesterol ("good" cholesterol) raising in clinical testing of a class of drugs (CETP inhibitors) intended to treat hypercholesterolemia and prevent cardiovascular disease. A trial for one such drug was halted when excessive mortality was seen in the treatment group, despite the drug showing the intended pharmacologic effect of increasing HDL cholesterol levels in study subjects.[11] A trial with another drug in this same class also raised HDL cholesterol but had a neutral outcome (neither harmful nor beneficial for the indication).[12]

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[9] Guidance for Industry. Expedited Programs for Serious Conditions --Drugs and Biologics.at p. 17 (May 2014) *http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf.*

[10] ibid

[11] Barter PJ, Caulfield M, Eriksson M, et al. Effects of torcetrapib in patients at high risk for coronary events. *N Engl J Med.* 2007;357:2109-22.

[12] Schwartz GC, Olsson AG, Abt M, et al. Effects of dalcetrapib in patients with a recent acute coronary syndrome. *N Engl J Med.* 2012;367:2089-99.

Surrogate endpoints are most useful in settings where the disease course is long and an extended period of time is required to measure the intended clinical benefit of a drug. There may be many situations where the use of a clinical outcome assessment is more appropriate and where meaningful results can be more readily obtained.

For new drug development, many of the biomarkers, assays, tests, and measurements used during clinical development are product specific and need to be developed and tested during preclinical, early clinical, and later clinical phases of drug development. For example, markers of drug exposure (e.g., drug blood levels) or metabolism, or for biologic products, anti-drug antibodies, are commonly used in drug development and are likely to be product-specific (hence, novel). Thus, most new drug development programs will rely upon at least one (and often several) novel biomarker for product development and approval.

Novelty of a biomarker (or surrogate) can also include several different considerations:

- The biomarker may be entirely new and developed specifically for the drug development program.
- The biomarker (or surrogate) may have been available previously, but used for the first time for the disease or for the new drug (e.g., being adapted from a different disease or a different class of drugs).
- The biomarker (or surrogate) may have been available previously, but is now being used in a new way, such as a surrogate endpoint when previously used as a pharmacodynamic measure.

There are thousands of drugs that have been approved over the course of FDA's extensive drug approval history. It would be extremely difficult to compile a comprehensive list of all drug and biological product ("drug") approvals for which a novel biomarker was used. Surrogate endpoints are commonly used to support both traditional and accelerated approvals for rare and common diseases, for new products (new molecular entity (NME)[13] and original biologics) as well as for non-NME drugs and supplemental approvals (i.e., efficacy supplements).

We compiled the following list of primary endpoints used in clinical trials from a <u>limited subset only</u> of new product (NME and original biologic) approvals by FDA's CDER in a recent three-year period (January 1, 2010, through December 31, 2012 – please see Table 1 in enclosed attachment). These endpoints were classified as surrogates or clinical outcome assessments (COA) to illustrate the use of both these types of endpoints in product approvals. COAs are often defined as those endpoints that measure an effect upon how patients feel, function, or survive.[14] Summary results are as follows:

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[13] NMEs are defined as drugs for which the active pharmaceutical ingredient has not previously been approved by FDA.
[14] Temple RJ. A regulatory authority's opinion about surrogate endpoints. In: Nimmo WS, Tucker GT, editors. *Clinical Measurement in Drug Evaluation* New York, NY: J. Wiley; 1995. Pp. 3-22.

- There were 85 new drugs approved in this time period: 29 for rare diseases (Orphan drugs) and 56 for common diseases.
- Of these 85 approvals, 40 relied upon a surrogate endpoint as the primary endpoint for the pivotal clinical trials, and 45 relied upon a COA:
    - For rare diseases, 20 of 29 (69 percent) approvals relied upon a surrogate endpoint.
    - For common diseases, 21 of 56 (38 percent) approvals relied upon a surrogate endpoint.
    - Seven drugs received accelerated approval, all of which were based on a surrogate endpoint reasonably likely to predict clinical benefit, and all of which were for rare disease indications.

Given these factors, it is challenging to define biomarker novelty, and we do not feel that providing a listing on our part would be useful. Please refer to Tables 1-3, enclosed, for listings of a recent cohort of new drugs and accelerated approvals.

a. How many were for indications other than cancer and HIV?

For the 85 new drugs listed in Table 1:

- Twenty-three drugs were for cancer or cancer-related indications and four were for HIV or HIV-related indications.
- For the 58 non-cancer non-HIV indicated drugs:
    - 22 relied upon a surrogate endpoint as the primary endpoint for approval
    - 36 relied upon a COA as the primary endpoint for approval.
- Seven of the 85 drugs received accelerated approval, five of which were for cancer indications and two of which were for non-cancer non-HIV indications. There were no accelerated approvals for HIV drugs in this time period. The two non-cancer non-HIV drugs included:
    - Deferirpone (Ferriprox) for transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.
    - Bedaquiline (Sirturo) indicated as part of combination therapy in adults (≥18 years) with pulmonary multi-drug resistant tuberculosis (MDR-TB).

The five cancer drugs included:

- Brentuximab (Adcetris) for two indications: 1) systemic anaplastic large cell lymphoma after failure of at least one prior multi-agent chemotherapy regimen, and 2) Hodgkin lymphoma after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates.

- Crizotinib (Xalkori) for locally advanced metastatic non-small cell lung cancer that is anaplastic lymphoma kinase (ALK)-positive.

- Carfilzomib (Kyprolis) for patients with multiple myeloma who have received at least two prior therapies, including bortezomib and an immunomodulatory agent and have demonstrated disease progression on or within 60 days of completion of the last therapy.

- Omacetaxine (Synribo) for adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKI).

- Ponatinib (Iclusig) for adult patients with chronic phase, accelerated phase, or blast phase CML that is resistant prior to TKI therapy or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) that is resistant or intolerant to prior TKI therapy.

b. Have any accelerated approvals occurred with a novel marker and a never before treated disease?

For the most recent ~6.5-year Accelerated Approval[15] experience at CDER, inclusive of NME and original biological products (NBE), supplemental approvals and non-NME NDAs, approved by CDER between October 1, 2007, and April 30, 2014, there were 40 Accelerated Approvals during this time, including:

- Eighteen NME and original biologics Accelerated approvals (new drugs), and

- Twenty-two non-NME NDA or supplemental Accelerated approvals

The 18 novel product approvals are listed in the Appendix, Table 2. In summary, these include:

- Two Accelerated Approvals for HIV
- Twelve Accelerated Approvals for various Oncology indications
- Four non-HIV, non-Oncology Accelerated Approvals, which includes indications in the therapeutic areas of Hematology, Cardiovascular and Infectious Disease

[15] CDER Accelerated Approval list updated through June 30, 2014 available at *http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/UCM404466.pdf*

The 22 non-NME NDA and supplemental Accelerated Approvals are listed in the enclosed Table 3, including:

- One Accelerated Approval for HIV
- Sixteen Accelerated Approvals for various Oncology indications
- Five non-HIV, non-Oncology Accelerated Approvals, which includes indications in the therapeutic areas of Medical Countermeasures, Medical Genetics, and Obstetrics

Regarding novelty and disease indication, we note that the Accelerated Approval regulations require that drugs approved under this pathway generally provide meaningful advantage over available therapies. For example, many of the above disease indications are for refractory, resistant, or previously treated diseases where patients had previously failed one or several other available therapies, such as relapsed non-Hodgkin lymphoma (NHL) and tyrosine kinase-resistant chronic myelogenous leukemia (CML). While there are other drugs approved for these indications, refractory or relapsed NHL and CML are usually life-threatening, and hence, these approvals were addressing unmet medical needs or providing patients with serious diseases important additional treatment options.

c. How many new biomarkers did the FDA accept for a first time use in the last five years?

Please see responses to Questions 3a-b, above. Most drug development programs use biomarkers, and for new products, it would be expected that most (if not all) would use novel biomarkers. For descriptions of surrogate endpoints in a recent three-year period and accelerated approvals in a 6.5 year period, please see summaries above and Tables 1-3 in the enclosure.

4. What is being done to ensure that FDA reviewers have a scientific understanding of the diseases that they are reviewing?

To ensure that FDA reviewers are prepared to address the regulatory impact of today's rapidly evolving science and technology, FDA has established a robust, state-of-the-art regulatory and scientific training program as well as a culture supportive of individual professional development.

CDER's regulatory training program provides technical and regulatory staff in all CDER scientific disciplines appropriate opportunities to develop the knowledge and skills necessary to conduct high quality and rigorous evaluations of drugs and drug products, and provide oversight of post-marketed drugs. Topics include drug development and the review process, FDA regulations, discipline-specific review requirements, and communication, focusing on technical writing and presentations.

The advanced science education offered at CDER presents current, state-of-the-art, and cutting-

edge scientific information in the fields of drug discovery, use of newly synthesized compounds and analogs of natural substances leading to new drugs, drug development, diagnostics, pharmacotherapy, and medical interventions to treat and cure illnesses and diseases, and the regulatory review of drug compounds. Topics are identified through CDER's Committee for Advanced Scientific Education (CASE). CASE serves as the principal scientific educational advisory committee for CDER. Its mission is to promote excellence in advanced scientific education, and to assist CDER's scientific personnel in maintaining a high degree of currency and competency in the advanced regulatory and scientific knowledge needed to meet the complex challenges of evolving and innovative drug development in a global environment. This is accomplished through lecture series, workshops, and various programs including CDER Scientific Seminars and journal clubs. During these educational activities, reviewers are presented with new scientific knowledge with the intent that this knowledge be applied to positively impact the quality of drug evaluation, reviews, regulatory recommendations or decisions made in CDER.

CDER has also developed additional training programs to address specific needs. For example, CDER has held an annually recurring rare disease-specific training course since 2011 (the fourth annual course was held in March 2014). Hundreds of FDA staff members have participated in this course since its inception, including Medical Officers, Project Managers, and other review staff from CDER, CBER, CDRH, and OC. Course faculty includes FDA subject matter experts, as well as invited faculty from outside FDA, including industry representatives, academics, advocates and patients, and scientific experts from other governmental agencies (e.g., NIH). Course content has included topics such as flexible clinical trial design, endpoint development, incorporating the patient voice in drug development, and disease- and drug-specific topics, among others.

FDA recognizes that keeping up with current standards for practice is crucial for our physicians, pharmacists, nurses, and other scientific professionals, who are often required to attend accredited learning activities to maintain licensure. Furthermore, FDA requires scientists to be current with changes in practice to inform our scientific, review, and policy activities, and how we assess risk and benefit. In an effort to meet this requirement, CDER is approved to provide continuing medical education (CME), continuing nursing education (CNE), and continuing pharmacy education (CPE) by the Accreditation Council for Continuing Medical Education (ACCME), Accreditation Council for Pharmacy Education (ACPE), and the Maryland Nurses Association, which is an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation. As a result, a number of the courses and lectures given on the White Oak campus offer Continuing Education (CE) credits. FDA also maintains a staff Scientific Professional Development Calendar that features a comprehensive list of upcoming events, noting those with CE credit.

FDA collaborations are broadening possibilities for professional development by enabling our scientific staff to conduct clinical work, teaching, or research off site. Area federal hospitals and clinics, like NIH and Walter Reed National Medical Center, have created opportunities for FDA staff who wish to care for patients.

Training at a local level has helped to mitigate challenges presented by the fiscal environment in recent years, which has limited the ability of FDA employees to travel. To ensure employees have adequate knowledge to perform their jobs at an optimal level, FDA leadership believes it is critical that FDA reviewers be able to travel annually to scientific and medical meetings where the treatment of these diseases is discussed.

6. **Section 1121 of the FDASIA requires the Secretary of HHS, acting through FDA, to issue guidance on the advertising of "medical products" on the Internet by July 2014. When will the FDA issue a draft of its guidance?**

In January 2014 FDA issued draft guidance for industry, "Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics," available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf*. In June 2014, FDA issued two additional draft guidances on the promotion of medical products on the Internet, including social media: "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices" and "Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices." Both guidance documents are available on FDA's web site at *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm397791.htm*.

7. **How is the FDA interpreting the term "medical products?" Does it include prescription drugs? Over the counter drugs? Medical devices? Veterinary medicines? Other products?**

In developing guidance as directed by section 1121 of FDASIA regarding "promotion, using the Internet (including social media) of medical products that are regulated by [FDA]," FDA is concentrating on prescription drugs for humans and animals, prescription biologics, and medical devices.

8. **Has the FDA been meeting with parties that will be affected by the guidance required under section 1121-such as prospective advertisers, Internet advertising companies, and social media platforms?**

FDA carefully considers input from its stakeholders on issues that affect advertising and promotional labeling of prescription drug products, including comments to the dockets for all of our public meetings and draft or final guidances. In November 2009, FDA held a Part 15 public hearing to provide an opportunity for broad public participation and comment on promotion of FDA-regulated medical products using the Internet and social media tools, and the presentations and written comments to this docket that were submitted by "affected parties" (e.g., prospective advertisers, Internet advertising companies, social media platforms) are being used to help guide FDA in making policy decisions on issues related to the guidance required under section 1121.

FDA will also consider comments submitted by any party regarding our draft guidance documents addressing medical product promotion using the Internet, including social media.

9. **Does the FDA have adequate resources to issue guidance in this area? The FDA, for many years, has regulated print and television advertising of prescription drugs, for instance, but has not dealt with digital direct-to-consumer regulation until now. Does the FDA have adequate expertise to understand how various Internet company platforms operate technologically?**

FDA has prioritized its resources to place guidance development on Internet/social media promotion as one of its highest priorities. We have a group of employees who have developed expertise on the operation of various digital platforms through their focused work on related voluntary requests for comment on proposed promotional materials submitted by companies, enforcement actions, and guidance documents. FDA staff who concentrate on oversight of medical product promotion, such as CDER's Office of Prescription Drug Promotion, routinely work with other staff in the Agency who have technological expertise on digital platforms (e.g., the Office of Business Informatics and the Office of Information Management).

10. **Will the FDA consider the technological limitations and opportunities that the business models of the various Internet companies? Is the FDA approaching its guidance in a technologically neutral way?**

To avoid the potential for these guidances to become quickly outdated, we are focusing on concepts that have long-term applicability rather than on specific social media platforms, given the continually changing nature of these platforms (i.e., our guidances will be issue-specific and ***not*** platform-dependent).

TABLES 1-3

Table 1. Primary Endpoint Types 2010-2012

Type	#	Drug Name	Trade Name	Abbrev Indication	Primary Endpoint	Endpoint Type	AP date	Accel AP	Orphan Drug
BLA	125327	glucarpidase	Voraxaze	methotrexate toxicity	plasma MTX level	surrogate	17-Jan-12		Yes
NDA	022575	velaglucerase alfa	Vpriv	Type 1 Gaucher Disease	Hgb, plt ct, liver and spleen volume	surrogate	26-Feb-10		Yes
NDA	022562	carglumic acid	Carbaglu	NAGS, deficiency urea cycle disorder	ammonia level	surrogate	18-Mar-10		Yes
BLA	125293	pegloticase	Krystexxa	refractory gout	plasma uric acid level	surrogate	14-Sep-10		Yes
NDA	022405	vandetanib		Medullary thyroid cancer	PFS	surrogate	06-Apr-11		Yes
BLA	125388	brentuximab vedotin	Adcetris	1) systemic anaplastic large cell lymphoma; 2) Hodgkin's lymphoma	1) ORR, 2) ORR	surrogate	19-Aug-11	Yes	Yes
NDA	202570	crizotinib	Xalkori	locally advanced or metastatic anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC)	ORR	surrogate	26-Aug-11	Yes	Yes

Table 1. Primary Endpoint Types 2010-2012									
Type	#	Drug Name	Trade Name	Abbrev Indication	Primary Endpoint	Endpoint Type	AP date	Accel AP	Orphan Drug
NDA	021825	deferiprone	Ferriprox	Iron overload due to thalassemia	serum ferritin	surrogate	14-Oct-11	Yes	Yes
NDA	202192	ruxolitinib	Jakafi	myelofibrosis	reduction in spleen volume	surrogate	16-Nov-11		Yes
BLA	125359	asparaginase erwinia chrysanthemi	Erwinaze	acute lymphoblastic leukemia	serum asparaginase activity level	surrogate	18-Nov-11		Yes
NDA	203188	ivacaftor	Kalydeco	cystic fibrosis on G551D mutation	FEV1	surrogate	31-Jan-12		Yes
NDA	022458	taliglucerase alfa	Elelyso	Type 1 Gaucher Disease	spleen and liver volume, HGb, plt ct	surrogate	01-May-12		Yes
NDA	202714	carfilzomib	Kyprolis	patients with multiple myeloma who received prior therapy	ORR by IMWG criteria	surrogate	20-Jul-12	Yes	Yes
NDA	203341	bosutinib	Bosulif	Chronic myeloid leukemia	MCyR	surrogate	04-Sep-12		Yes
NDA	203585	omacetaxine mepesuccinate	Synribo	Chronic myeloid leukemia	MCyR or MaHR	surrogate	26-Oct-12	Yes	Yes

Table 1. Primary Endpoint Types 2010-2012									
Type	#	Drug Name	Trade Name	Abbrev Indication	Primary Endpoint	Endpoint Type	AP date	Accel AP	Orphan Drug
NDA	203756	cabozantinib	Cometriq	metastatic medullary thyroid cancer	PFS	surrogate	29-Nov-12		Yes
NDA	200677	pasireotide diaspartate	Signifor	Cushing's disease	urinary free cortisol	surrogate	14-Dec-12		Yes
NDA	203469	ponatinib	Iclusig	chronic myeloid leukemia (CML) and Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL)	MCyR	surrogate	14-Dec-12	Yes	Yes
NDA	203858	lomitapide	Juxtapid	homozygous familial hypercholesterolemia (HoFH)	LDL-C, Apo-B, TC, non-HDL-C, VLDL-C, TG, HDL-C	surrogate	21-Dec-12		Yes
NDA	204384	bedaquiline	Sirturo	MDR pulmonary tuberculosis	sputum culture conversion	surrogate	28-Dec-12	Yes	Yes
NDA	022250	dalfampridine	Ampyra	multiple sclerosis	timed 25-foot walk test	COA	22-Jan-10		Yes
BLA	125338	clostridial collagenase histolyticum	Xiaflex	Dupuytren's contracture	Contracture reduction	COA	02-Feb-10		Yes
BLA	125291	alglucosidase alfa	Lumizyme	non-infantile onset Pompe disease (8 years and older)	6MWT	COA	24-May-10		Yes
BLA	125377	ipilimumab	Yervoy	unresectable or metastatic melanoma	OS	COA	25-Mar-11		Yes

Table 1. Primary Endpoint Types 2010-2012

Type	#	Drug Name	Trade Name	Abbrev Indication	Primary Endpoint	Endpoint Type	AP date	Accel AP	Orphan Drug
BLA	125288	belatacept	Nulojix	organ rejection prophylaxis in kidney for EBV seropositive patients	biopsy proven active rejection, raft loss, death or LTFU	COA	15-Jun-11		Yes
NDA	202429	vemurafenib	Zelboraf	unresectable or metastatic melanoma with BRAF mutation	OS	COA	17-Aug-11		Yes
NDA	022150	icatibant acetate	Firazyr	hereditary angioedema	VAS composite symptom/pain score	COA	25-Aug-11		Yes
NDA	202067	clobazam	Onfi	Lennox-Gastaut, seizure disorder	frequency of drop seizures	COA	21-Oct-11		Yes
NDA	203441	teduglutide (rDNA origin)	Gattex	short bowel syndrome	reduction in TPN	COA	21-Dec-12		Yes
NDA	022341	liraglutide	Victoza	Type 2 Diabetes Mellitus	HGA1C	surrogate	25-Jan-10		
BLA	125320	denosumab	Prolia	treatment of post-menopausal osteoporosis	new morphometric vertebral fractures on Xray	surrogate	01-Jun-10		

Table 1. Primary Endpoint Types 2010-2012									
Type	#	Drug Name	Trade Name	Abbrev Indication	Primary Endpoint	Endpoint Type	AP date	Accel AP	Orphan Drug
NDA	022505	tesamorelin for injection	Egrifta	Lipodystrophy in HIV patients	% change visceral adipose tissue by CT scan	surrogate	10-Nov-10		
NDA	200796	azilsartan medoxomil	Edarbi	hypertension	BP	surrogate	25-Feb-11		
NDA	022522	roflumilast	Daliresp	chronic obstructive pulmonary disease (COPD)	FEV1	surrogate	28-Feb-11		
NDA	202258	boceprevir	Victrelis	chronic hepatitis C (CHC) in subjects with genotype 1 hepatitis C virus (HCV)	SVR	surrogate	13-May-11		
NDA	202022	rilpivirine	Edurant	treatment-naïve HIV-1 infection	viral load	surrogate	20-May-11		
NDA	201917	telaprevir	Incivek	chronic hepatitis C (CHC) in subjects with genotype 1 hepatitis C virus (HCV)	SVT	surrogate	23-May-11		
NDA	022383	indacaterol maleate	Arcapta Neohaler	chronic obstructive pulmonary disease (COPD)	FEV1	surrogate	01-Jul-11		

Table 1. Primary Endpoint Types 2010-2012									
Type	#	Drug Name	Trade Name	Abbrev Indication	Primary Endpoint	Endpoint Type	AP date	Accel AP	Orphan Drug
NDA	202324	axitinib	Inlyta	advanced renal cell carcinoma (RCC)	PFS	surrogate	27-Jan-12		
NDA	203388	vismodegib	Erivedge	locally advanced or unresectable basal cell carcinoma	ORR	surrogate	30-Jan-12		
NDA	202514	tafluprost	Zioptan	open-angle glaucoma	IOP	surrogate	10-Feb-12		
NDA	202799	peginesatide	Omontys	anemia in chronic kidney disease	Hgb, plt ct, liver and spleen volume	surrogate	27-Mar-12		
BLA	125409	pertuzumab	Perjeta	HER2-positive (HER2+) metastatic breast cancer	PFS	surrogate	08-Jun-12		
NDA	022529	lorcaserin hydrochloride	Belviq	obesity	weight loss	surrogate	27-Jun-12		
NDA	202450	aclidinium bromide	Tudorza Pressair	chronic obstructive pulmonary disease (COPD)	FEV1	surrogate	23-Jul-12		
NDA	203100	elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate	Stribild	treatment-naïve HIV-1 infection	viral load	surrogate	27-Aug-12		

Table 1. Primary Endpoint Types 2010-2012									
Type	#	Drug Name	Trade Name	Abbrev Indication	Primary Endpoint	Endpoint Type	AP date	Accel AP	Orphan Drug
BLA	125294	tbo-filgrastim		chemotherapy-induced neutropenia	duration of severe neutropenia	surrogate	29-Aug-12		
BLA	125422	ocriplasmin	Jetrea	symptomatic vitreomacular adhesion	vitreomacular adhesion resoluton	surrogate	17-Oct-12		
NDA	201280	linagliptin	Tradjenta	Type 2 Diabetes Mellitus	HgA1C	surrogate	02-May-11		
BLA	125418	ziv-aflibercept	Zaltrap	metastatic colorectal cancer	OS	COA	03-Aug-12		
BLA	125276	tocilizumab	Actemra	rheumatoid arthritis	ACR20, 50, 75	COA	08-Jan-10		
NDA	021201	polidocanol	Asclera	varicose veins	visual improvement in veins	COA	30-Mar-10		
NDA	022252	estradiol valerate and estradiol valerate/dionogest	Natazia	contraception	Pearl index	COA	06-May-10		
NDA	201023	cabazitaxel	Jevtana	hormone refractory metatstatic prostate cancer	OS	COA	17-Jun-10		
NDA	022134	alcaftadine	Lastacaft	allergic conjunctivitis	ocular itching	COA	28-Jul-10		

Table 1. Primary Endpoint Types 2010-2012									
Type	#	Drug Name	Trade Name	Abbrev Indication	Primary Endpoint	Endpoint Type	AP date	Accel AP	Orphan Drug
BLA	125360	incobotulinumtoxin A	Xeomin	1) cervical dystonia; 2) blepharospasm	1) torticollis rate scale (TWSTRS), 2) Jankovic rating scale	COA	30-Jul-10		
NDA	022474	ulipristal acetate	Ella	Emergency contraception	pregnancy	COA	13-Aug-10		
NDA	022527	fingolimod	Gilenya	multiple sclerosis	annualized relpase rate by expanded disability status scale	COA	21-Sep-10		
NDA	022512	dabigatran etixilate mesylate	Pradaxa	reduction of stroke and systemic embolism in atrial fibrillation	composite endpoint stroke and systemic embolism	COA	19-Oct-10		
NDA	200603	lurasidone hydrochloride	Latuda	schizophrenia	2 symptom scales	COA	28-Oct-10		
NDA	200327	ceftaroline fosamil	Teflaro	1) acute bacterial skin and skin structure infections (ABSSSI); 2) Community-acquired pneumonia	1) cessation of lesion spread and absence of fever, clinical cure rates Test of Cure 2) composite clinical signs + symptom scale	COA	29-Oct-10		
NDA	201532	eribulin mesylate	Halaven	Metastatic breast cancer	OS	COA	15-Nov-10		

Table 1. Primary Endpoint Types 2010-2012									
Type	#	Drug Name	Trade Name	Abbrev Indication	Primary Endpoint	Endpoint Type	AP date	Accel AP	Orphan Drug
NDA	022408	spinosad	Natroba	head lice	live lice	COA	18-Jan-11		
NDA	022567	vilazodone	Viibryd	major depressive disorder	depressive symptoms	COA	21-Jan-11		
BLA	125370	belimumab	Benlysta	systemic lupus erythematosus (SLE)	SLE composite scale and time to flare	COA	09-Mar-11		
NDA	022399	gabapentin enacarbil	Horizant	restless legs syndrome	IRLS SG criteria	COA	06-Apr-11		
NDA	202379	abiraterone acetate	Zytiga	metastatic castration-resistant prostate cancer following chemotherapy	OS	COA	28-Apr-11		
NDA	201699	fidaxomicin	Dificid	C. dificile-associated diarrhea	clinical response (diarrhea or other symptoms)	COA	27-May-11		
NDA	022345	ezogabine	Potiga	partial-onset seizures	% reduction seizure frequency	COA	10-Jun-11		
NDA	022406	rivaroxaban	Xarelto	prophylaxis of deep vein thrombosis which may lead to PE	VTE	COA	01-Jul-11		

Table 1. Primary Endpoint Types 2010-2012									
Type	#	Drug Name	Trade Name	Abbrev Indication	Primary Endpoint	Endpoint Type	AP date	Accel AP	Orphan Drug
NDA	022433	ticagrelor	Brilinta	acute coronary syndrome	composite CV death, MI, stroke	COA	20-Jul-11		
BLA	125387	aflibercept	Eylea	age-related macular degeneration	maintenance of vision	COA	18-Nov-11		
NDA	202833	ingenol mebutate	Picato	actinic keratosis	clearance rate (no visivle AK lesions)	COA	23-Jan-12		
NDA	021746	lucinactant	Surfaxin	prevention of RDS in premature infants	co-primary RDS (xray and O2 sat) and RDS-remated mortality	COA	06-Mar-12		
NDA	202276	avanafil	Stendra	erectile dysfunction	3 functional scales	COA	27-Apr-12		
NDA	202611	mirabegron	Myrbetriq	overactive bladder	co-primary incontinenece episodes and mean micturitions	COA	28-Jun-12		
NDA	202535	sodium picosulfate, magnesium oxide, citric acid	Prepopik	colon cleansing prior to colonoscopy in adults	successful cleansing (ClinRO)	COA	16-Jul-12		
NDA	202811	linaclotide	Linzess	1) chronic idiopathic constipation; 2) irritable bowel syndrome with	1) sponstaneous bowel movement 2) ROME II criteria (PRO)	COA	30-Aug-12		

Table 1. Primary Endpoint Types 2010-2012									
Type	#	Drug Name	Trade Name	Abbrev Indication	Primary Endpoint	Endpoint Type	AP date	Accel AP	Orphan Drug
				constipation					
NDA	203415	enzalutamide	Xtandi	metastatic castration-resistant prostate cancer	OS	COA	31-Aug-12		
NDA	202992	teriflunomide	Aubagio	multiple sclerosis	annualized relapse rate, disability score	COA	12-Sep-12		
NDA	203085	regorafenib	Stivarga	metastatic colorectal cancer	OS	COA	27-Sep-12		
NDA	202834	perampanel	Fycompa	partial-onset seizures	seizure frequency	COA	22-Oct-12		
NDA	203214	tofacitinib citrate	Xeljanz	rheumatoid arthritis	ACR 20	COA	06-Nov-12		
NDA	202155	apixaban	Eliquis	prevention of stroke or systemic embolism associated with atrial fibrillation	events of stroke or systemic embolism	COA	28-Dec-12		

Table 1. Primary Endpoint Types 2010-2012									
Type	#	Drug Name	Trade Name	Abbrev Indication	Primary Endpoint	Endpoint Type	AP date	Accel AP	Orphan Drug
NDA	202292	crofelemer	Fulyzaq	HIV-associated diarrhea	clinical response, ≤2 watery blowel movements/week	COA	31-Dec-12		

Table 2. CDER NME/NBE Accelerated Approvals Oct 1, 2007 through April 30, 2014

Type	Application ID	Drug (Trade name)	Therapeutic Area	Abbrev. Indication	AP date	Rare Y/N
NDA	22145	raltegravir (Isentress)	Infectious disease	treatment-experienced HIV-1 infection	10/12/2007	No
NDA	22068	nilotinib (Tasigna)	Oncology	Philadephia chromosome positive CML	10/29/2007	Yes
NDA	022187	etravirine (Intelence)	Infectious disease	treatment-experienced HIV-1 pagtients who have evidence of viral replication and HIV-1 strains resistant to an NNRTI and other antiretroviral agents	18-Jan-08	No
NDA	022291	eltrombopag (Promacta)	Hematology (non-onc)	thrombocytopenia in patients with chronic immune idiopathic thrombocytopenic purpura who have insufficient response to corticosteroids, immunoglobulins, or splenectomy	20-Nov-08	Yes
NDA	022468	pralatrexate (Folotyn)	Oncology	relapsed or refractory peripheral T-cell lymphoma	24-Sep-09	Yes
BLA	125326	ofatumumab (Arzerra)	Oncology	chronic lymphocytic leukemia refractory to fludarabine and alemtuzumab	26-Oct-09	Yes
BLA	125388	brentuximab (Adcetris)	Oncology	Hodgkin lymphoma after failure of autologous stem cell transplant or after failure of at least two prior multi-agent chemotherapeutic regimens	19-Aug-11	Yes
BLA	125388	brentuximab (Adcetris)	Oncology	Relapsed systemic anaplastic large cell lymphoma	19-Aug-11	Yes
NDA	202570	crizotinib (Xalkori)	Oncology	non-small cell lung cancer, anaplastic lymphoma kinase-positive (ALK+)	26-Aug-11	Yes
NDA	021825	deferiprone (Ferriprone)	Hematology (non-onc)	Transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate	14-Oct-11	Yes
NDA	202714	carfilzomib (Kyprolis)	Oncology	patients with multiple myeloma who received at least two prior therapies	20-Jul-12	Yes
NDA	203585	omacetaxine (Synribo)	Oncology	chronic myeloid leukemia with resistance or intolerance to two or more TKIs	26-Oct-12	Yes
NDA	203469	ponatinib	Oncology	chronic myeloid leukemia (CML) and Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) resistant or intolerant to prior TKI	14-Dec-12	Yes

NDA	204384	bedaquiline	Infectious disease	pulmonary multi-drug resistant tuberculosis	28-Dec-12	Yes
NDA	204026	pomalidomide	Oncology	multiple myeloma in patients who have received at least two prior therapies	08-Feb-13	Yes
NDA	205552	ibrutinib	Oncology	mantle cell lymphoma in patients who have received at least one prior therapy	13-Nov-13	Yes
NDA	203202	droxidopa	Cardiovascular	neurogenic orthostatic hypotension	2/18/2014	Yes
NDA	205755	ceritinib	Oncology	alk+ NSCLC	4/29/2014	Yes

Table3. CDER AA Non-NME/NBE October 1, 2007 through April 30, 2014

Type	#/suppl	Drug (Trade name)	Therapeutic Area	Abbrev. Indication	AP date	Rare
NDA	205552	Ibrutinib (Imburvica)	Oncology	CLL	2/12/2014	Yes
NDA	204114/S-001	Trametinib (Mekinist)	Oncology	Melanoma BRAF V600 E or K	1/8/2014	Yes
NDA	202806/S-002	Dabrafenib (Tafinlar)	Oncology	Melanoma BRAF V600 E or K	1/9/2014	Yes
BLA	125151/S-184	Idursulfase (Elaprase)	IEM	Hunter Syndrome	6/24/2013	Yes
NDA	202497	Vincristine sulfate liposomal injection (Marqibo)	Oncology	Philadelphia chromosome-negative acute lymphoblastic leukemia (ALL) in second or third relapse or whose disease has progressed following two or more anti-leukemic therapies.	8/9/2012	Yes
NDA	203985	Everolimus (Afinitor Disperz)	Oncology	Pediatric and adult patients with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected.	8/29/2012	Yes
NDA	21945	*Hydroxyprogesterone caproate (Makena)	Obstetrics	Reduce risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth	2/3/2011	No
NDA	022393/S-004	ROMIDEPSIN FOR INFUSION	Oncology	peripheral T-cell lymphoma	6/16/2011	Yes
NDA	022334 / 6	AFINITOR	Oncology	subependymal giant cell astocytoma associated with tuberous sclerosis	10/29/2010	Yes
NDA	021986 / 8	SPRYCEL	Oncology	Ph+ CML in chronic phase	10/28/2010	Yes
NDA	022068 / 5	TASIGNA (NILOTINIB, AMN107)	Oncology	Ph+ CML in chronic phase	6/17/2010	Yes
NDA	022059 / 7	TYKERB TABLETS	Oncology	HER2+ breast cancer	1/29/2010	No

NDA	022187 / 1	TMC 125 ETRAVIRINE	Infectious Disease	HIV-1	11/24/2009	No
NDA	021588 / 25	GLEEVEC (IMATINIB MESYLATE) 100/400MG	Oncology	CD117+ GIST	12/19/2008	Yes
NDA	021462 / 15	ALIMTA (PEMETREXED DISODIUM) 500MG VIALS	Oncology	NSCLC	9/26/2008	No
NDA	050718 / 33	DOXIL	Oncology	AIDS-related Kaposi's Sarcoma	6/10/2008	No
NDA	020634 / 47	LEVAQUIN	Infectious Disease	Inhalational anthrax	5/5/2008	Yes
NDA	020635 / 51	LEVAQUIN	Infectious Disease	Inhalational anthrax	5/5/2008	Yes
NDA	021721 / 15	LEVAQUIN(LEVOFLAXIN ORAL SOLUTION)25MG/M	Infectious Disease	Inhalational anthrax	5/5/2008	Yes
BLA	125085/S-169	bevacizumab	Oncology	Glioblastoma	5/5/2009	Yes
BLA	125085/S-091	bevacizumab	Oncology	HER2- breast cancer	2/22/2008	No
NDA	22273	fludarabine phosphate	Oncology	B-cell CLL whose disease has not responded to or has progressed during or after treatment with at least one standard alkylating-agent containing regimen	18-Dec-08	Yes

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1	I	100		PDUFA	X.A	FDA will begin execution of the plan to implement the benefit-risk framework across review divisions in the pre and post-market human drug review process by the end of the fourth quarter of FY 2013, and the Agency will update the plan as needed and post all updates on the FDA website	Plan	9/30/2013	9/30/2013	9/30/2013	CDER	Completed	9/30/2013	Y	Completed 09/30/2013 Implementation of this plan is in process http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
2	I	100		PDUFA	IX.B.2	By the end of FY 2013, FDA will hold a public meeting engaging stakeholders in discussing current and emerging scientific approaches and methods for the conduct of meta-analyses, and to facilitate stakeholder feedback and input regarding the use of meta-analyses in the FDA's regulatory review process	Public Meeting	9/30/2013	11/25/2013	11/25/2013	CDER	Completed	11/25/2013	Y	On November 25, 2013, FDA conducted a public meeting on Meta-Analyses of Randomized Controlled Clinical Trials for the Evaluation of Risk to Support Regulatory Decisions The input from the meeting will be used to develop a draft guidance that describes best practices for the conduct of meta-analyses and FDA's intended approach for the use of meta-analyses in regulatory decision-making. FDA is also publishing a white paper to facilitate discussion at the public meeting, which is available online at: http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm360080.htm	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
3	I	100		PDUFA	IX.E.4	By mid-FY 2014, FDA, through the Rare Disease Program, will conduct a public meeting to discuss complex issues in clinical trials for studying drugs for rare diseases, including such questions as endpoint selection, use of surrogate endpoints/Accelerated approval, and clinical significance of primary endpoints; reasonable safety exposures; assessment of dose selection; and development of patient-reported outcome instruments	Public Meeting	4/30/2014	1/6/2014	1/6/2014	CDER	Completed	-	Y	The Public Workshop on Complex Issues in Rare Disease Drug Development was a 3-day meeting that was held January 6-8, 2014. The main goals were that FDA would foster discussion, hear diverse perspectives from experts, and for pediatric rare diseases (per statute), use the interactions to develop a strategic plan to encourage and accelerate development of pediatric rare disease therapies	http://www.fda.gov/Drugs/NewsEvents/ucm367820.htm
4	I	100		PDUFA	XI.A.2	By the end of FY 2013, FDA will hold one or more public meetings to include the pharmaceutical industry, other government healthcare providers, patient groups, and partners from other sectors of the healthcare delivery system to explore strategies to standardize REMS, where appropriate, with the goal of reducing the burden of implementing REMS on practitioners, patients, and others in various healthcare settings	Public Meeting	9/30/2013	7/26/2013	7/26/2013	CDER	Completed	7/25/2013	Y	Completed 7/25/2014 To obtain input from stakeholders about REMS standardization and evaluation, FDA held a public meeting to give stakeholders including health care providers prescribers, patients, pharmacists, distributors, drug manufacturers, vendors, researchers, standards development organizations, and the public an opportunity to provide input on ways to standardize and assess REMS. A link to the information can be found by following this link http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm351029.htm	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm351029.htm

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5	I	100		PDUFA	X C.	FDA will initiate a public process to nominate a set of disease areas that could benefit from a more systematic and expansive approach to obtaining the patient perspective on disease severity or unmet medical need. FDA will convene 4 meetings per year (CDER will host 17 meetings and CBER will host 3 meetings throughout PDUFA V).	Public Meeting	–	9/24/2013	9/24/2013	CDER	Completed	9/24/2013	Y	This is an annual requirement. FY 2013 was completed 09/24/2013 An FR notice announcing the diseases for FY 14-15 published 4/11/2013 (http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm) For FY 2013 the public process was begun with a FR Notice in September 2012 and public meeting was held on October 25, 2012, which proposed a set of disease areas and requested public comment on them through a docket The first 4 meetings were held on Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis, HIV, Lung Cancer, and Narcolepsy. Direct Meeting links below The regularly updated Schedule for future meetings (along with recordings from past meetings) can now be found at this link: http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm347317.htm	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm347317.htm
6	I	100		PDUFA	XI B 4	By the end of FY 2017, FDA will conduct (or fund by contract) an assessment to evaluate the strengths, limitations, and the appropriate use of Sentinel for informing regulatory actions (e.g., labeling changes, PMRs and PMCs) to manage safety issues.	Self-assessment	9/30/2017	9/30/2017	9/30/2017	CDER	Scheduled to begin later	–	N		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
7	I	100		PDUFA	IX E 5	By the end of FY 2015, FDA will develop and implement staff training related to development, review, and approval of drugs for rare diseases	Other	9/30/2015	9/30/2015	9/30/2015	CDER	Substantially complete, on track to meet due date	–	N		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
8	I	100		PDUFA	XII G	FDA shall periodically publish final guidance specifying the completed data standards, formats, and terminologies that sponsors must use to submit data in applications.	Final Guidance	–	7/30/2014	7/30/2014	CDER	In process, on track to meet due date	–	Y		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
9	I	100		PDUFA	XII F	To address FDA-identified nonclinical data standards needs, FDA will request public input on the use of relevant already-existing data standards and the involvement of existing standards development organizations to develop new standards or refine existing standards. FDA will obtain this input via publication of a Federal Register notice that specifies a 60-day comment period.	FR Notice	–	3/30/2014	3/30/2014	CDER	In process, on track to meet due date	–	Y		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm

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10	I	100		PDUFA	XII.E.1	FDA shall develop a project plan for distinct therapeutic indications, prioritizing clinical terminology standards development within and across review divisions. FDA shall publish a proposed project plan for stakeholder review and comment by **June 30, 2013. FDA shall** update and publish its project plan annually	Plan	6/30/2013	6/30/2013	10/23/2013	CDER	Completed	10/23/2013	Y	http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm287408.htm Open for public comment http://www.regulations.gov/#!documentDetail;D=FDA-2013-N-1277-0001 FR Notice posted. Public Meeting held on Nov 5, 2012. http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-0760-0001 Meeting summary: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm332003.htm	http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm287408.htm
11	I	100		PDUFA	XII.B	FDA will **issue** final guidance **no** later than 12 months from the close of the public comment period for the Draft eCTD Guidance on the standards and format of electronic submission of NDA, BLA and IND applications	Final Guidance	3/4/2014	9/30/2014	9/30/2014	CDER	In process, on track to meet due date	–	Y		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
12	I	100		PDUFA	XII.A	To enhance the quality and efficiency of FDA's review of NDAs, BLAs, and INDs, FDA shall consult with stakeholders, including pharmaceutical manufacturers and other research sponsors, to issue draft guidance on the standards and format of electronic submission of applications by December 31, 2012	Draft Guidance	12/31/2012	12/31/2012	12/31/2012	CDER	Completed	1/3/2013	Y	Completed 01/03/2013 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf
13	I	100		PDUFA	XI.B.3	By the end of FY 2015, FDA will conduct (or fund by contract) an interim assessment to evaluate the strengths, limitations and the appropriate use of Sentinel for informing regulatory **actions (e.g., labeling** changes, **PMRs** and PMCs) to manage safety issues.	Self-assessment	9/30/2015	9/30/2015	9/30/2015	CDER	Scheduled to begin later	–	Y		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
14	I	100		PDUFA	XI.B.1	By the end of FY 2013, FDA will hold **or** support public meetings engaging stakeholders to discuss current and emerging Sentinel projects and facilitate stakeholder feedback and input regarding Sentinel projects that would be appropriate to meet the goals stated in the guidance	Public Meeting	9/30/2013	1/31/2013	1/31/2013	CDER	Completed	1/31/2013	Y	Completed Jan 31, 2013 http://www.brookings.edu/events/2013/01/31-sentinel-public-workshop	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
15	I	100		PDUFA	XI.A.3	FDA will issue guidance by the end of FY 2014 on methodologies for **assessing a Risk** Evaluation and **Mitigation** Strategy. This guidance should specifically address methodologies for determining **whether a** specific Risk Evaluation and **Mitigation** Strategy with elements to assure safe **use (ETASU)** is: (i) commensurate with the specific serious risk listed in the labeling of the drug and (ii) considering the observed risk, not unduly burdensome on patient access to the drug	Draft Guidance	9/30/2014	9/30/2014		CDER	In process, on track to meet due date	–	Y		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm

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16	I	100		PDUFA	XI.A.3	By the end of FY 2013, FDA will initiate one or more public workshops on methodologies for assessing whether REMS are mitigating the risks they purport to mitigate and for assessing the effectiveness and impact of REMS, including methods for assessing the effect on patient access, individual practitioners, and the overall burden on the healthcare delivery system.	Public Meeting	9/30/2013	7/26/2013	7/26/2013	CDER	Completed	7/26/2013	Y	Completed 07/26/2013. FDA held a 2-day public meeting to obtain input on issues and challenges associated with the standardization and assessment of risk evaluation and mitigation strategies (REMS) for drug and biological products. The docket for written comments will remain open indefinitely. A link to the information can be found by following this link http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm351029.htm	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm351029.htm
17	I	100		PDUFA	XI.A.2	To move towards increased integration of REMS into the healthcare delivery system, FDA will issue a report of its findings by the first quarter of FY 2014 that will identify at least one priority project in each of the following areas including a work plan for project completion: pharmacy systems, prescriber education, providing benefit/risk information to patients, and practice settings.	Public Report	12/31/2013	6/30/2014	3/31/2014	CDER	Scheduled to begin later	–	Y	Impacted by sequestration	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
8	I	100		PDUFA	XI.A.1	By the end of FY 2013, FDA will develop and issue guidance on how to apply the statutory criteria to determine whether a Risk Evaluation and Mitigation Strategy is necessary to ensure that the benefits of a drug outweigh the risks.	Draft Guidance	9/30/2013	6/14/2014		CDER	In process, on track to meet due date	–	Y		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
19	I	100		PDUFA	X.B.	As appropriate, FDA will revise the CDER Clinical Review Template, Office and Division Director Summary Memo Templates, and corresponding Manuals of Policies and Procedures (MaPP) [and equivalent documents in CBER] to incorporate a structured benefit/risk assessment into the human drug review process on a timeframe outlined in the five-year plan referenced in Goal X.A.	SOP / New Template				CDER	In process, on track to meet due date	–	N	Revision will be made, as appropriate.	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
20	I	100		PDUFA	X.A	By the end of the first quarter of 2013, FDA will publish, for public comment, its draft plan to further develop and implement a structured benefit/risk assessment in the new drug approval process.	Plan	3/29/2013	3/29/2013	3/29/2013	CDER	Completed	3/5/2013	Y	Completed03/05/2013: http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
21	I	100		PDUFA	IX.E.6.	By the end of FY 2016, FDA, through the Rare Disease Program, will develop an evaluation tool to evaluate the success of the activities of the Rare Disease Program, including the reviewer training.	Other	9/30/2016	9/30/2016	9/30/2016	CDER	Scheduled to begin later	–	N		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
22	I	100		PDUFA	IX.E.1	By the end of FY 2013, FDA will complete a staffing and implementation plan for the CDER Rare Disease Program within the Office of New Drugs and a CBER Rare Disease liaison within the Office of Center Director	Plan	9/30/2013	9/30/2014	9/30/2014	CDER	In process, on track to meet due date	–	N	Final Staffing and implement plan Staffing for CDER was Compleld 12/12/2013 and Program is running.	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
23	I	100		PDUFA	IX.D.2	By the end of FY 2014, FDA will hold a public meeting to discuss FDA's qualification standards for drug development tools, new measurement theory, and implications for multi-national trials	Public Meeting	9/30/2014	9/30/2014	9/30/2014	CDER	Scheduled to begin later	–	Y		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
24	I	100		PDUFA	IX.C.3	By the end of FY 2013, FDA will hold a public meeting to discuss the current status of biomarkers and pharmacogenomics and potential strategies to facilitate scientific exchanges in regulatory and non-regulatory contexts.	Public Meeting	9/30/2013	9/30/2014	9/30/2014	CDER	Scheduled to begin later	–	Y		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm

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25	I	100		PDUFA	IX.B 4.	FDA will complete the final guidance describing FDA's intended approach to the use of meta-analyses in the FDA's regulatory review process (or revised draft guidance, if appropriate) within 1 5 years of the close of the public comment period for the draft guidance.	Final Guidance	–	6/30/2017	6/30/2017	CDER	Scheduled to begin later	–	N		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
26	I	100		PDUFA	IX B 3	Considering feedback and input received through a public meeting, FDA will publish draft guidance for comment describing FDA's intended approach to the use of meta-analyses in the FDA's regulatory review process by the end of FY 2015	Draft Guidance	9/30/2015	9/30/2015	6/30/2015	CDER	In process, on track to meet due date	–	Y		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
27	I	100		PDUFA	IX B 1	FDA will develop a dedicated review team with appropriate expertise to evaluate different scientific methods and to explore the practical application of scientific approaches and best practices, including methodological limitations, for the conduct of meta-analyses in the context of FDA's regulatory review process	Other	–	12/30/2015	12/30/2015	CDER	In process, on track to meet due date	–	N		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
28	I	100		PDUFA	IX A 8	FDA will publish final guidance (for review staff and industry describing best practices for communication between FDA and IND sponsors during drug development) within 18 months of the close of the comment period for the draft guidance	Final Guidance	12/31/2016	9/30/2016	9/30/2016	CDER	Scheduled to begin later	–	N		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
29	I	100		PDUFA	IX A 8	By the end of the second quarter of FY 2015, FDA will publish draft guidance for review staff and industry describing best practices for communication between FDA and IND sponsors during drug development.	Draft Guidance	3/31/2015	3/31/2015	3/31/2015	CDER	Scheduled to begin later	–	Y		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
30	I	100		PDUFA	IX A 7	By the end of FY 2014, the OND drug development and communication staff will provide training to all CDER staff involved in review of INDs	Other	9/30/2014	9/30/2014	9/30/2014	CDER	In process, on track to meet due date	–	N		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
31	I	100		PDUFA	IX.A 2.	By the end of FY 2013, FDA will develop a dedicated drug development communication and training staff within the Office of New Drugs in CDER and augment the manufacturers assistance staff in CBER, focused on enhancing communication between FDA and sponsors during drug development	SOP / New Template	9/30/2013	9/30/2014	9/30/2014	CDER	Scheduled to begin later	–	N		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
32	I	100		PDUFA	II B 2	FDA will hold a public meeting by no later than March 30, 2017, during which public stakeholders may present their views on the success of the new review program, including improving the efficiency and effectiveness of the first cycle review process and decreasing the number of review cycles ultimately necessary for new drugs and biologics that are approved	Public Meeting	3/30/2017	3/30/2017	3/30/2017	CDER	Scheduled to begin later	–	Y		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
33	I	100		PDUFA	II.B 2	A final assessment of the new review program will be published by December 31, 2016, for public comment	Third Party Assessment	12/31/2016	12/31/2016	12/31/2016	CDER	Scheduled to begin later	–	Y		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm

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34	I	100		PDUFA	II B.1.	By June 30, 2015, FDA will hold a public meeting during which public stakeholders may present their views on the success of the new review program to date including: improving the efficiency and effectiveness of the first cycle review process; decreasing the number of review cycles ultimately necessary for new drugs and biologics that are approved; and helping to ensure that patients have timely access to safe, effective, and high quality new drugs and biologics.	Public Meeting	6/30/2015	6/30/2015	6/30/2015	CDER	Scheduled to begin later	–	Y		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
35	I	100		PDUFA	II.B.1	An interim assessment of the new program for enhanced review transparency and communication for new molecular entity NDAs and original BLAs ("new review program") will be published by March 31, 2015, for public comment	Third Party Assessment	3/31/2015	3/30/2015	3/30/2015	CDER	Scheduled to begin later	–	Y		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
36	I	100		PDUFA	II B	The new review program for new molecular entity NDAs and original BLAs shall be evaluated by an independent contractor with expertise in assessing the quality and efficiency of biopharmaceutical development and regulatory review programs. The statement of work for this effort will be published for public comment prior to beginning the assessment. The assessments will occur continuously throughout the course of the new review program	FR Notice	–	–	7/9/2012	CDER	Completed	7/9/2012	Y		http://www.gpo.gov/fdsys/pkg/FR-2012-07-06/pdf/2012-16529.pdf
37	I	100		PDUFA	II.A	FDA will establish a new review model that will apply to all New Molecular Entity New Drug Applications (NME NDAs) and original Biologics License Applications (BLAs),including applications that are resubmitted following a Refuse-to-File action, received from October 1, 2012, through September 30, 2017.	SOP / New Template	–	10/1/2012	10/1/2012	CDER	Completed	10/1/2012	N		http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
38	I	103	(2)(a)	NO		FDA shall determine the inflation and workload adjustments for PDUFA and publish them in the Federal Register	FR Notice	8/2/2012	8/3/2012	8/2/2012	OFM	Completed	8/1/2012	Y	8/1/2012 Completed http://www.gpo.gov/fdsys/pkg/FR-2012-08-01/pdf/2012-18711.pdf	David Miller David.Miller@fda.hhs.gov
39	I	103	(2)(a)	NO		FDA shall contract with an independent accounting or consulting firm to periodically review the adequacy of the workload adjustment for PDUFA and publish the results of those reviews for public comment. The first review, due at the end of FY 2013, is to examine the performance of the adjustment since fiscal year 2009.	Public Report	9/30/2013	9/30/2013	9/30/2013	OPL	Completed	5/6/2013	Y	Completed 05/06/2013 http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM350567.pdf	Giles Miles giles.mills@fda.hhs.gov
40	I	103	(2)(a)	NO		FDA shall establish fees for PFUFA and publish the fees and rationale for any adjustments in an FR notice.	FR Notice	8/2/2012	8/3/2012	8/3/2012	OFM	Completed	8/1/2012	Y	8/1/2012 Completed http://www.gpo.gov/fdsys/pkg/FR-2012-08-01/pdf/2012-18711.pdf	David Miller David.Miller@fda.hhs.gov
41	I	103	(2)(a)	NO		FDA shall contract with an independent accounting or consulting firm to periodically review the adequacy of the PDUFA workload adjustment and publish the results of those reviews for public comment. The second review, due at the end of FY 2015, is to examine the continued performance of the adjustment.	Public Report	9/30/2015	9/30/2015	9/30/2015	OPL	Scheduled to begin later	–	Y		Giles Miles giles.mills@fda.hhs.gov
42	I	104		NO		FDA shall submit to Congress an annual Performance Report for PDUFA	Report to Congress	1/28/2014	1/28/2014	12/31/2013	OPL	Completed	1/31/2014	Y	Completed 1/31/2014 : http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/PDUFA/ucm384028.htm	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/default.htm

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43	II	200		MDUFA	I.D (b)	FDA will update its website to reflect the following: 1. A list of prioritized device guidance documents (an "A-list") that the Agency intends to publish within 12 months of the date this list is published each fiscal year, and 2. A list of device guidance documents (a "B-list") that the Agency intends to publish, as the Agency's guidance-development resources permit each fiscal year.	FR Notice	–	1/1/2013	1/1/2013	CDRH	Completed	–	Y		
44	II	200		MDUFA	I.D (a)	FDA will update its website in a timely manner to reflect the following: 1. The Agency's review of previously published device guidance documents, including the deletion of guidance documents that no longer represent the Agency's interpretation of, or policy on, a regulatory issue, and notation of guidance documents that are under review by the Agency.	FR Notice	–	11/23/2012	11/23/2012	CDRH	In process, on track to meet due date	–	N		CDRH-FDASIA@fda.hhs.gov
45	II	200		MDUFA	I.C	FDA will update the interactive review guidance to enhance the interactive review process between FDA and applicants to facilitate timely completion of premarket reviews based on accurate and complete information	Final Guidance	–	9/1/2013	9/1/2013	CDRH	Undergoing FDA Clearance	–	Y		CDRH-FDASIA@fda.hhs.gov
46	II	200		MDUFA	I.B	FDA will publish final guidance outlining electronic copy of submissions (e-Copy)	Final Guidance	–	1/1/2013	1/1/2013	CDRH	Completed	12/31/2012	Y	Completed 12/31/2012 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf	CDRH-FDASIA@fda.hhs.gov
47	II	200		MDUFA	I.B	FDA will publish draft guidance outlining electronic copy of submissions (e-Copy)	Draft Guidance	–	10/1/2012	10/17/2012	CDRH	Completed	10/17/2012	Y	Completed 10/17/2012	CDRH-FDASIA@fda.hhs.gov
48	II	200		MDUFA	I.A	FDA will issue final guidance on a structured process for managing Pre-Submissions (draft guidance issued on 7/13/12)	Final Guidance	–	2/4/2014	2/4/2014	CDRH	Undergoing FDA Clearance	–	Y		CDRH-FDASIA@fda.hhs.gov
49	II	200		MDUFA	II.E	FDA will issue guidance regarding the review and management expectations for Clinical Laboratory Improvement Amendment waivers throughout the entire submission process.	Draft Guidance	–	3/31/2014	3/31/2014	CDRH	In process, on track to meet due date	–	Y		CDRH-FDASIA@fda.hhs.gov
50	II	200		MDUFA	V	After the completion of the 3rd party assessment and issuance of the GRMP guidance, FDA's implementation of the GRMP guidance will include initial and ongoing training of FDA staff, and periodic audits of compliance with the guidance.	SOP / New Template	–	2/1/2017	2/1/2017	CDRH	Scheduled to begin later	–	N		CDRH-FDASIA@fda.hhs.gov
51	II	200		MDUFA	V	After the completion of the 3rd party assessment, FDA will solicit public comments on the Good Review Management Practices (GRMP) draft guidance document and then finalize the guidance document	Final Guidance	–	2/1/2017	2/1/2017	CDRH	Scheduled to begin later	–	Y		CDRH-FDASIA@fda.hhs.gov
52	II	200		MDUFA	V	After the completion of Phase 1 of the 3rd party assessment, FDA will incorporate the results of the independent assessment of the review process for device submissions into a Good Review Management Practices (GRMP) draft guidance document	Draft Guidance	–	9/30/2015	9/30/2015	CDRH	Scheduled to begin later	–	Y		CDRH-FDASIA@fda.hhs.gov
53	II	200		MDUFA	V	FDA will analyze the recommendations for improvement opportunities identified in the assessment, develop and implement a corrective action plan, and assure its effectiveness	Plan	–	9/30/2016	9/30/2016	CDRH	Scheduled to begin later	–	N		CDRH-FDASIA@fda.hhs.gov
54	II	200		MDUFA	V	For Phase 2 of the assessment, the contractor will evaluate the implementation of recommendations and publish a written assessment no later than February 1 2016	Third Party Assessment	2/1/2016	2/1/2016		CDRH	Scheduled to begin later	–	Y		CDRH-FDASIA@fda.hhs.gov

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55	II	200		MDUFA	V	FDA will publish an implementation plan within 6 months of receipt of the final recommendations from the independent assessment.	Plan	–	12/11/2014	12/11/2014	CDRH	Scheduled to begin later	–	Y		CDRH-FDASIA@fda.hhs.gov
56	II	200		MDUFA	V	FDA will publish an implementation plan based on the independent assessment's set of high-priority recommendations within 6 months of receipt	Plan	–	6/11/2014	6/11/2014	CDRH	In process, on track to meet due date	–	Y		CDRH-FDASIA@fda.hhs.gov
57	II	200		MDUFA	V.	The final comprehensive findings and recommendations from the independent assessment will be published within 1 year of contract award.	Third Party Assessment	–	6/11/2014	6/11/2014	CDRH	In process, on track to meet due date	–	Y		CDRH-FDASIA@fda.hhs.gov
58	II	200		MDUFA	V	Findings on high-priority recommendations from the independent assessment will be published within six months of awarding the contract:	Third Party Assessment	12/15/2013	9/30/2013		CDRH	Completed	12/11/2013	Y	http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM378202.pdf	CDRH-FDASIA@fda.hhs.gov
59	II	200		MDUFA	V	FDA and the device industry will participate in a comprehensive two-phase assessment of the process for the review of device applications. For Phase 1, no later than the end of the second quarter of FY 2013, FDA will contract with a private, independent consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to address the assessment scope.	Other	3/31/2013	5/30/2013		CDRH	Completed	6/12/2013	Y		CDRH-FDASIA@fda.hhs.gov
60	II	200		MDUFA	IV B (b)	FDA will hold a minimum of two medical device Vendor Days each year	Other	9/30/2013	9/30/2013	8/22/2013	CDRH	Completed	8/22/2013	Y		CDRH-FDASIA@fda.hhs.gov
61	II	200		MDUFA	IV B	FDA will implement its Reviewer Certification Program for CDRH reviewers and publish the curriculum of this program and other course offerings. FDA will consider comments from stakeholders when making updates to courses and determining course offerings	List	–	9/30/2013		CDRH	Completed	9/30/2013	N	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109210.htm	CDRH-FDASIA@fda.hhs.gov
62	II	200		MDUFA	IV.A	During MDUFA III, FDA will also work with industry to benchmark best practices for retaining employees (both financial and non-financial)	Plan		12/31/2014	12/31/2014	CDRH	In process, on track to meet due date	–	N		CDRH-FDASIA@fda.hhs.gov
63	II	200		MDUFA	II D	FDA will issue guidance providing objective criteria for making decisions to accept or refuse to accept 510(k) premarket notifications for review.	Final Guidance	–	1/1/2013	1/1/2013	CDRH	Completed	12/31/2012	Y		CDRH-FDASIA@fda.hhs.gov
64	II	200		MDUFA	II. A	FDA will issue guidance providing objective criteria for making decisions to accept or refuse to accept premarket approval applications for review.	Final Guidance	–	1/1/2013	1/1/2013	CDRH	Completed	12/31/2012	Y		CDRH-FDASIA@fda.hhs.gov
65	II	200		MDUFA	I.G	By the end of FY 2015, FDA intends to issue a final rule exempting additional low risk medical devices from premarket notification	Final Guidance	9/30/2015	9/30/2015	9/30/2015	CDRH	Scheduled to begin later	–	Y		CDRH-FDASIA@fda.hhs.gov
66	II	200		MDUFA	I.G	By the end of FY 2013, FDA intends to develop a draft list of low risk medical devices that will be considered for exemption from premarket notification	Draft Guidance	9/30/2013	2/1/2014		CDRH	Undergoing FDA Clearance	–	Y		CDRH-FDASIA@fda.hhs.gov

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67	II	200		MDUFA	I F	Over the period of MDUFA III, FDA will meet with patient groups to better understand and characterize the patient perspective on disease severity or unmet medical need. In addition, FDA will increase its utilization of FDA's Patient Representatives as Special Government Employee consultants to CDRH to provide patients' views early in the medical product development process and ensure those perspectives are considered in regulatory discussions. Applicable procedures governing conflicts of interest and confidentiality of proprietary information will be utilized for these consultations	Public Meeting	–	9/30/2013	9/30/2013	CDRH	completed	9/18/2013	N		CDRH-FDASIA@fda.hhs.gov
68	II	200		MDUFA	I D	FDA will establish a process allowing stakeholders an opportunity to:1. Provide meaningful comments and/or propose draft language for proposed guidance topics in the "A" and "B" lists.2. Provide suggestions for new or different guidance documents; and3. Comment on the relative priority of topics for guidance	FR Notice	–	11/23/2012	11/23/2012	CDRH	Completed	–	N		CDRH-FDASIA@fda.hhs.gov
69	II	200		MDUFA		FDA will update the interactive review guidance to enhance the interactive review process between FDA and applicants to facilitate timely completion of premarket reviews based on accurate and complete information.	Draft Guidance	–	3/5/2013	3/5/2013	CDRH	Completed	3/5/2013	Y	Completed January 2013 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAII/ucm321367.htm	
70	II	203	(c)(4)	NO		FDA shall establish fees for MDUFA and publish the fees and rationale for any adjustments in an FR notice	FR Notice	8/2/2012	8/3/2012	8/3/2012	OFM	Completed	7/31/2012	Y	Completed 7/31/2012 http://www.gpo.gov/fdsys/pkg/FR-2012-07-31/html/2012-18647.htm	David Miller David.Miller@fda.hhs.gov
71	II	204	(b)	NO		FDA shall submit to Congress an annual Performance Report for MDUFA	Report to Congress		1/28/2014	12/31/2013	OPL	Completed	1/31/2014	Y	Completed 1/31/2014 http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/MDUFMA/ucm383988.htm	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/default.htm
72	II	204	(b)	NO		FDA shall make the annual Performance Report available on the FDA website	Public Report	1/28/2014	1/28/2014	1/28/2014	OPL	Completed	1/31/2014	N	Completed 1/31/2014 http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/MDUFMA/ucm383988.htm	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/default.htm
73	II	204	(b)	NO		FDA shall make MDUFA quarterly performance data publicly available on the FDA website	Public Report	3/1/2013	3/1/2013	3/1/2013	CDRH	Completed	2/12/2013	Y	Completed 2/12/2013 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM339668.pdf	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/default.htm
74	II	205		MDUFA	IV.A	FDA may hire employees for activities related to the process for the review of device applications outside of the competitive service provisions of the federal civil service for 3 years after the date of enactment. The FDA shall institute appropriate internal controls for appointments under this section	Plan	--	10/1/2012		CDRH	Completed	--	N		

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75	III	300		GDUFA	2.C	To maximize the number of applications that can be reviewed within the metric goals and to assist in securing the pharmaceutical supply chain, FDA will employ a risk-adjusted biennial CGMP surveillance inspection model for inspection of generic API and FDF manufacturers, with the goal of achieving parity of inspection frequency between foreign and domestic establishments in FY 2017 and will prioritize inspections of establishments associated with ANDAs that are otherwise approvable or eligible for tentative approval except for an outstanding inspection, as well as establishments that have not been inspected previously.	Other	–	–		ORA	Completed	–	N		www.fda.gov/gdufa AskGDUFA@fda.hha.gov
76	III	300		GDUFA	4.D	FDA will conduct risk-adjusted biennial CGMP surveillance inspections of generic API and generic finished dosage form (FDF) manufacturers, with the goal of achieving parity of inspection frequency between foreign and domestic firms in FY 2017	Other	9/30/2017			CDER	Scheduled to begin later	--	N		www.fda.gov/gdufa AskGDUFA@fda.hha.gov
77	III	300		GDUFA	4.A	FDA will hire and train at least 25 percent of incremental staff in FY 2013, 50 percent in FY 2014 and will strive to complete GDUFA-funded human resources hiring goals in FY 2015 as necessary to achieve the program's performance metrics and goals.	Other	–	9/30/2013	9/4/2013	CDER	Completed	9/4/2013	N		www.fda.gov/gdufa AskGDUFA@fda.hha.gov
78	III	300		GDUFA	3.B	FDA will solicit input from industry and other stakeholders to develop an annual list of regulatory science initiatives	List	–			CDER	Completed		N	Annual process Regulatory Research Results for FY 2013 have been posted as well as Project Continuation in the FY14 priorities. Information regarding these efforts can be found. http://www.fda.gov/Drugs/NewsEvents/ucm367997.htm	www.fda.gov/gdufa AskGDUFA@fda.hha.gov
79	III	300		GDUFA	3.A	FDA will convene a working group and consider suggestions from industry and other stakeholders to develop an annual list of regulatory science initiatives for review by CDER Director	Public Meeting	–	6/21/2013	6/21/2013	CDER	Completed	6/21/2013	N	Annual process June 21, 2013, public meeting held and comments submitted to a public docket. Regulatory Research Results for FY 2013 have been posted as well as Project Continuation in the FY14 priorities. Information regarding these efforts can be found: http://www.fda.gov/Drugs/NewsEvents/ucm367997.htm	www.fda.gov/gdufa AskGDUFA@fda.hha.gov
80	III	300		GDUFA	2.D	FDA will develop a current chemistry manufacturing and controls (CMC) records database to aid in the efficiency of review and inspection.	Database/IT System	–	–		CDER	In process, on track to meet due date	–	N		www.fda.gov/gdufa AskGDUFA@fda.hha.gov

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81	III	300		GDUFA	2.D	FDA will develop new and/or enhance existing facility databases (API and FDF manufacturing and clinical/ bioequivalence site) to be populated by industry. These databases will, at a minimum, contain information for generics-related firms, including addresses and Data Universal Numbering System (DUNS) numbers, and will link facilities to DMFs and ANDAs and will contain other information as necessary	Database/IT System	–	9/30/2013	2/28/2013	CDER	Completed	2/28/2013	Y	Completed 02/28/2013	www.fda.gov/gdufa AskGDUFA@fda.hhs.gov
82	III	300		GDUFA	2.C	During the five years of the program, FDA will undertake a study of foreign government regulator inspections (CGMP and bioequivalence), report findings publicly, and develop a program to utilize foreign inspection classifications when and where appropriate	Other	–	9/30/2017		CDER	Scheduled to begin later	–	Y		www.fda.gov/gdufa AskGDUFA@fda.hhs.gov
83	III	300		GDUFA	2.C	FDA will make inspection classification results and date of the last facility inspection available to the public and industry on FDA's website on timely basis	Public Report	–	10/1/2012		CDER	Completed	10/2/2012	Y	http://www.accessdata.fda.gov/scripts/insps/search/	www.fda.gov/gdufa AskGDUFA@fda.hhs.gov
84	III	302		NO		FDA will publish in the Federal Register the one-time backlog fee for abbreviated new drug applications (ANDAs) that are pending on October 1, 2012, and that have not received a tentative approval prior to that date (GDUFA Fee)	FR Notice	10/31/2012	10/31/2012	10/31/2012	OFM	Completed	10/25/2012	Y	Action Completed October 25, 2012 http://www.gpo.gov/fdsys/pkg/FR-2012-10-25/pdf/2012-26257.pdf	http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm322629.htm
85	III	302		NO		FDA shall establish fees for GDUFA (drug master file fees and filing fees) and publish the fees in an FR notice.	FR Notice	10/31/2012	10/31/2012	10/31/2012	OFM	Completed	10/25/2012	Y	Action Completed October 25, 2013 http://www.gpo.gov/fdsys/pkg/FR-2012-10-25/pdf/2012-26256.pdf	http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm322629.htm
86	III	302		NO		FDA will establish generic drug user fee rates (GDUFA) for domestic and foreign active pharmaceutical ingredient (API) and finished dosage format (FDF) facilities and publish the fees in an FR notice	FR Notice	1/14/2013	1/15/2013	1/15/2013	OFM	Completed	1/17/2013	Y	Completed January 17, 2013 http://www.gpo.gov/fdsys/pkg/FR-2013-01-17/pdf/2013-00851.pdf	http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm322629.htm
87	III	302		NO		FDA will publish in the Federal Register a notice requiring each person that owns certain specified facilities or organizations to submit to FDA information on the identity of each such facility, site, or organization. The facilities and organizations specified are those that produce one or more finished dosage forms of a human generic drug or an active pharmaceutical ingredient (API) contained in a human generic drug, or a site or organization in which a bioanalytical study is conducted, a clinical research organization, a contract analytical testing site, or a contract repackager site	FR Notice	10/1/2012	10/1/2012	10/1/2012	CDER	Completed	10/1/2012	Y	Completed http://www.gpo.gov/fdsys/pkg/FR-2012-10-02/pdf/2012-24326.pdf	www.fda.gov/gdufa AskGDUFA@fda.hhs.gov
88	III	302		NO		The Secretary shall assess and collect fees in accordance with this section: one-time backlog fee, drug master file fee, abbreviated new drug application and prior approval supplement filing fee, generic drug facility fee and active pharmaceutical ingredient facility fee	Other	10/1/2012	10/1/2012	10/1/2012	OFM	Completed	10/1/2012	N	Action completed http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm322629.htm	http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm322629.htm
89	III	302		NO		FDA shall publish in the Federal Register the amount of the GDUFA inflation adjustment	FR Notice	10/31/2013	11/1/2013	11/1/2013	OFM	Scheduled to begin later	–	N		http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm322629.htm

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90	III	302		NO		FDA shall make available on its Web site a list of DMF numbers for DMFs that have undergone an initial completeness assessment and are available for reference.	Website	–	–		CDER	Completed	12/19/2012	Y	http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM332875.pdf	www.fda.gov/gdufa AskGDUFA@fda.hhs.gov
91	III	303		NO		FDA shall submit to Congress an annual Performance Report for all generic drug applications, amendments and prior approval supplements, that includes the number of applications that met the GDUFA goals, the average total time to decision, including the number of calendar days spent during FDA review and calendar days spent by sponsor; total number of applications that were pending for more than 10 months on July 9, 2012, and the number of pending applications on which FDA took final regulatory action in the previous fiscal year	Report to Congress	1/28/2014	1/28/2014	12/31/2013	OPL	Completed	1/31/2014	Y	Completed 1/31/2014 http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm384247.htm	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/default.htm
92	III	303		NO		FDA shall submit to Congress an annual Fiscal Report for GDUFA	Report to Congress	1/28/2014	1/28/2014	1/28/2014	OFM	Completed	4/30/2014	Y	Completed 4/30/2014 http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/FinancialReports/GDUFA/ucm395903.htm	http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm322629.htm
93	III	303		NO		FDA shall submit recommendations to Congress for generic drug user fee reauthorization.	Report to Congress	1/13/2017	10/15/2016	10/1/2016	CDER	Scheduled to begin later	–	Y	–	www.fda.gov/gdufa AskGDUFA@fda.hhs.gov
94	III	303		NO		FDA shall present recommendations to Congress on GDUFA reauthorization, publish in Federal Register and provide a 30 day comment period for the public; hold a public meeting on recommendations, and after consideration of public views, revise such recommendations.	Public Meeting	1/13/2017	10/31/2016	10/15/2016	CDER	Scheduled to begin later	–	N		www.fda.gov/gdufa AskGDUFA@fda.hhs.gov
95	III	303		NO		Prior to beginning negotiations with the generic industry concerning extension of generic drug user fees beyond Fiscal Year 2017, FDA shall consult with stakeholders	FR Notice	–	4/1/2015	3/15/2015	CDER	Scheduled to begin later	–	Y		www.fda.gov/gdufa AskGDUFA@fda.hhs.gov
96	III	303		NO		FDA shall make the annual GDUFA performance report available on FDA website.	Public Report	–	2/28/2014	2/28/2014	OPL	Completed	1/31/2014	N	Completed 1/31/2014 http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm384247.htm	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/PDUFA/default.htm
97	III	303		NO		FDA shall make the annual GDUFA fiscal report available on FDA website.	Public Report	–	2/28/2014	2/28/2014	OFM	Completed	4/30/2014	Y	Completed 4/30/2014 http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/FinancialReports/GDUFA/ucm395903.htm	http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm322629.htm
98	III	303		NO		FDA shall make minutes of GDUFA negotiation meetings available on the FDA website.	Public Report	2/13/2017	2/13/2017	2/13/2017	CDER	Scheduled to begin later	–	N		www.fda.gov/gdufa AskGDUFA@fda.hhs.gov
99	IV	402		NO		FDA shall establish Initial Biosimilar Biological Product Development Fee, Annual Biosimilar Biological Product Development Fee, Reactivation Fee, Biosimilar Biological Product Application Fee, Establishment Fee, and Product Fee and publish fees in an FR notice.	FR Notice	8/1/2012	8/1/2012	8/1/2012	OFM	Completed	8/1/2012	Y	Completed August 1, 2012 http://www.gpo.gov/fdsys/pkg/FR-2012-08-01/pdf/2012-18712.pdf	http://www.gpo.gov/fdsys/pkg/FR-2012-08-01/pdf/2012-18712.pdf
100	IV	402		NO		FDA shall collect fees from industry to support the Agency's biosimilar biological product review activities under a new biosimilar user fee program from FY2013 through FY2017. Fee amounts are based on adjusted PDUFA fee amounts for each fiscal year.	Other	10/1/2012	10/1/2012	10/1/2012	OFM	Completed	–	N		http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/ucm320768.htm

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101	IV	403	(d)	NO		FDA shall contract with independent accounting or consulting firm to study the workload volume and full costs associated with the process for review of biosimilar biological product applications, and publish, for public comment, interim results of the study.	Third Party Assessment	6/1/2015	6/1/2015		CDER	Scheduled to begin later	–	Y		druginfo@fda.hhs.gov
102	IV	403	(d)	NO		FDA shall contract with independent accounting or consulting firm to study the workload volume and full costs associated with the process for review of biosimilar biological product applications, and publish, for public comment, final results of the study	Third Party Assessment	9/29/2016	9/29/2016		CDER	Scheduled to begin later	–	Y		druginfo@fda.hhs.gov
103	IV	403	(e. 1)	NO		FDA shall consult with stakeholders and publish an FR notice requesting public input on recommendations for biosimilar user fee program reauthorization; shall hold a public meeting, solicit comments, and publish comments on the FDA website	Public Meeting	1/13/2017	10/15/2016		CDER	Scheduled to begin later	--	N		druginfo@fda.hhs.gov
104	IV	403	(e,3)	NO		FDA shall submit recommendations to Congress for biosimilar user fee program reauthorization.	Report to Congress	1/13/2017	1/13/2017		CDER	Scheduled to begin later	–	Y		druginfo@fda.hhs.gov
105	IV	403		NO		FDA shall submit to Congress an annual Fiscal Report for BSUFA.	Report to Congress	1/28/2014	1/28/2014	1/28/2014	OFM	Scheduled to begin later	–	Y	Completed 1/31/2014	http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm322629.htm
106	IV	403		NO		FDA shall submit to Congress an annual Performance Report for BSUFA	Report to Congress	1/28/2014	1/28/2014	12/31/2013	OPL	Completed	1/31/2014	Y	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/MDUFMA/ucm383988.htm Completed 4/30/2014	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/default.htm
107	IV	403		NO		FDA shall make annual BSUFA fiscal report available on the FDA website	Public Report	–	1/28/2014	1/28/2014	OFM	Completed	4/30/2014	Y	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/FinancialReports/BsUFA/ucm395872.htm Completed 1/31/2014	http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/ucm320768.htm
108	IV	403		NO		FDA shall make the annual BSUFA performance report available on the FDA website	Public Report	–	2/28/2014	2/28/2014	OPL	Completed	1/31/2014	N	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/MDUFMA/ucm383988.htm	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/default.htm
109	IV	408		NO		FDA shall submit to Congress an annual report that includes the number of biosimilar applications filed; the percentage of filed biosimilar applications that were approved and an explanation of how FDA is managing the biosimilar review program to ensure that PDUFA funds are not being used to support the review of biosimilar applications	Report to Congress	1/28/2015	1/28/2015	1/28/2015	OPL	Scheduled to begin later	–	Y		http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/default.htm
110	V	502	(b)	NO		FDA must describe the rationale for not requesting studies in neonates in written requests	Other	7/9/2012	7/9/2012	7/9/2012	CDER	Completed	7/9/2012	N		pdit@fda.hhs.gov

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111	V	503		NO		FDA shall issue internal standard operating procedures for any significant modifications to initial pediatric study plans, agreed initial pediatric study plans, and written requests. Such operating procedures shall be posted to FDA's website.	SOP / New Template	7/9/2013	7/9/2013	7/9/2013	CDER	Completed	6/25/2013	Y	Below is a link to a presentation recently presented to Industry outlining how to apply the new pediatric laws to current drug development including the recent modifications to initial pediatric study plans: http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM359009.pdf Additionally, an outline of procedures and timelines for review of PSPs and Written Requests by the Pediatric Review Committee can be found by this link: http://inside.fda.gov:9003/downloads/CDER/OfficeofNewDrugs/ImmediateOffice/PediatricandMaternalHealthStaff/UCM359955.pdf	pdit@fda.hhs.gov
112	V	504		NO		Not later than 3 years after the date of enactment of FDASIA, FDA shall post to FDA's website medical, statistical, and clinical pharmacology reviews of pediatric studies under 505A(b) or (c) submitted between 01/04/2002 and 09/27/2007 for which 6 months of exclusivity was granted & that resulted in a labeling change	Other	7/9/2015	7/9/2015	7/9/2015	CDER	Scheduled to begin later	–	N		pdit@fda.hhs.gov
113	V	505	(a)(1(B)	NO		New procedure for deferrals, deferral extensions, and reporting. For a deferral that expired prior to the date of enactment or that expired prior to 270 days after the date of enactment and for which a deferral extension request was submitted no later than 180 days after enactment (January 5, 2013), response by FDA due 1 year after enactment; FDA shall make certain information from annual review of deferred studies information publicly available on the FDA website.	SOP / New Template	7/9/2013	--	1/5/2013	CDER	Completed	1/5/2013	N	Completed. Process for reviewing and granting Deferral Extensions implemented	http://inside.fda.gov:9003/CDER/OfficeofNewDrugs/ImmediateOffice/PediatricandMaternalHealthStaff/ucm027829.htm
114	V	505	(b)	NO		Amends FD&C Act Section 505B(f)(6)(D) to require tracking and aggregation on an annual basis of the total number of deferrals/deferral extensions requested and granted pursuant to 505B of the FDCA and the reasons for deferral/deferral extensions, the timeline for completion of assessments and the number of assessments complete.	Public Report				CDER	In process, on track to meet due date	–	N		pdit@fda.hhs.gov
115	V	505	(c)	NO		Beginning 270 days after enactment, FDA shall issue non-compliance letter informing of failure to submit assessments pursuant to or meet certain requirements of 505B of FDCA; letter shall require response within 45 calendar days of issuance. Requires posting of non-compliance letters and responses; Requires tracking of the number of postmarket non-compliance letters issued pursuant to 505B of the FDCA and recipients	Other	–	7/9/2013	7/9/2013	CDER	Completed	4/5/2013	N	Completed 4/5/2014 The process for issuing non-compliance letters and responses has been implemented. Samples of these letters have been posted: http://inside.fda.gov:9003/CDER/OfficeofNewDrugs/ImmediateOffice/PediatricandMaternalHealthStaff/ucm027829.htm	pdit@fda.hhs.gov

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116	V	506	(a)	NO		Not later than 1 year after enactment, FDA shall issue guidance to implement requirements relating to the submission of plans to study drugs in children	Draft Guidance	7/9/2013	7/9/2013	7/9/2013	CDER	Completed	7/15/2013	Y	FDA is announcing the availability of a draft guidance for industry entitled "Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans." The purpose of this draft guidance is to assist sponsors in the submission of an initial PSP and any amendments to the PSP. The FR Notice published on 7/15/2013 and can be found by following this link http://www.gpo.gov/fdsys/pkg/FR-2013-07-15/pdf/2013-16825.pdf	pdil@fda.hhs.gov
117	V	506	(a)	NO		Not later than 1 year after enactment, FDA shall promulgate proposed regulations to implement requirements relating to the submission of plans to study drugs in children	Proposed Rule	7/9/2013	12/31/2014	10/30/2014	CDER	In process, on track to meet due date	–	Y		pdil@fda.hhs.gov
118	V	506	(c)	NO		At least 180 days before submission of the report to Congress, FDA shall consult with stakeholders to obtain recommendations including suggestions for modifications that would improve pediatric drug research and labeling	FR Notice	–	1/9/2016		OPT	Scheduled to begin later	–	Y		Debbie Avant debbie.avant@fda.hhs.gov
119	V	506		NO		Not later than 4 years after enactment, FDA shall submit a report to Congress discussing the implementation of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act which generally provide for the improved study of drugs in children. The report shall include assessments of the timeliness and effectiveness of pediatric study planning, efforts to increase studies in newborns, and information on drugs for pediatric cancers. The reports must also be made publicly available on FDA's Internet website	Report to Congress	7/8/2016	7/8/2016	7/1/2016	OPT	In process, on track to meet due date	–	Y		Debbie Avant debbie.avant@fda.hhs.gov
120	V	510	(a)	NO		Not later than 18 months after enactment, FDA shall hold at least one public meeting to discuss ways to encourage/accelerate development of new therapies for pediatric rare diseases.	Public Meeting	1/9/2014	1/8/2014		OOPD	Completed	1/8/2014	Y	Meeting was held January 6-8, 2014 as a 3 day public workshop on Complex Issues in Rare Disease Drug Development. Links to additional information are http://www.fda.gov/Drugs/NewsEvents/ucm367820.htm http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm367656.htm	http://www.fda.gov/Drugs/NewsEvents/ucm367820.htm
121	V	510	(b)	NO		Not later than 180 days after the public meeting, FDA shall issue a report that includes a strategic plan for encouraging/accelerating development of new therapies for pediatric rare diseases	Public Report	–	7/7/2014	7/7/2014	OOPD	In process, on track to meet due date	–	Y		Gayatri Rao (MAY CHANGE)

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122	V	511		NO		The Office of Pediatric Therapeutics shall include an individual with expertise in pediatric epidemiology, and an individual with expertise in in a pediatric subpopulation that is less likely to be studied as part of a written request issued under 505A of the FDCA or an assessment under 505B of the FDCA (for 5 years after enactment the latter individual shall be an individual with expertise in neonatology)	Other	–	–		OPT	In process, on track to meet due date	–	N		Debbie Avant debbie.avant@fda.hhs.gov
123	V	511		NO		The Office of Pediatric Therapeutics shall include an individual with expertise in pediatric epidemiology, and an individual with expertise in in a pediatric subpopulation that is less likely to be studied as part of a written request issued under 505A of the FDCA or an assessment under 505B of the FDCA (for 5 years after enactment the latter individual shall be an individual with expertise in neonatology).	Other	–	–		OPT	In process, on track to meet due date	–	N		Debbie Avant debbie.avant@fda.hhs.gov
124	VI	601		NO		FDA intends to revise and re-issue the draft guidance, entitled, "FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations.." This guidance, when final, will, among other things, provide FDA's interpretation of and policy on section 601 of FDASIA, which states that FDA may not disapprove an IDE because, among other reasons, the investigation may not support a device clearance or approval or a different investigation may be necessary to support clearance or approval	Draft Guidance	–	6/14/2013	6/14/2013	CDRH	Completed	6/14/2013	Y	"Completed 6/14/20132013 ttp://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279107.pdf"	CDRH-FDASIA@fda.hhs.gov
125	VI	603	(b)	NO		FDA intends to issue a final appeals guidance, which will include, among other things, information regarding the requirements under section 603 of FDASIA for a request for a supervisory review of a significant decision.	Final Guidance	–	5/17/2013	5/17/2013	CDRH	Completed	5/17/2013	Y	Completed 05/17/2013 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm284651.htm	CDRH-FDASIA@fda.hhs.gov
126	VI	603		NO		FDA intends to issue a Q&A draft appeals guidance to provide proposed interpretation of key provisions of section 603 of FDASIA, including, among othes, what constitutes a "significant decision." When finalized, FDA intends to include the questions and answers in the draft guidance as an appendix to the appeals guidance.	Draft Guidance	–	5/30/2013	5/30/2013	CDRH	Completed	5/17/2013	Y	Completed 05/17/2013 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm352248.htm	CDRH-FDASIA@fda.hhs.gov
127	VI	604		NO		FDA shall withdraw the draft guidance entitled "Guidance for Industry and FDA Staff-510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device (July 27, 2011).	Other	–	7/17/2012	7/17/2012	CDRH	Completed	7/17/2012	N	Completed 7/17/2012	CDRH-FDASIA@fda.hhs.gov
128	VI	604		NO		FDA shall consider the input of interested stakeholders prior to submiting a report to Congress regarding when a 510(k) premarket notification should be submitted for modifications or changes to a legally marketed device.	FR Notice	–	5/8/2013	5/8/2013	CDRH	Completed	5/8/2013	N	Completed 5/8/13 http://www.gpo.gov/fdsys/pkg/FR-2013-05-08/html/2013-10888.htm?source=govdelivery	
129	VI	604		NO		FDA shall consider the input of interested stakeholders prior to submiting a report to Congress regarding when a 510(k) premarket notification should be submitted for modifications or changes to a legally marketed device	Public Meeting	–	6/13/2013	6/13/2013	CDRH	Completed	6/13/2013	N		CDRH-FDASIA@fda.hhs.gov

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130	VI	604		NO		FDA shall submit a report to Congress regarding when a 510(k) premarket notification should be submitted for modifications or changes to a legally marketed device.	Report to Congress	1/9/2014	1/9/2014	1/8/2014	CDRH	Completed	2/25/2014	Y	Completed 2/25/2014 http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm269873.htm	CDRH-FDASIA@fda.hhs.gov
131	VI	605		NO		FDA intends to improve the Medical Device Recalls database and provide links to the recall database from FDA's 510(k) and PMA databases in order to increase access to safety information on marketed medical devices, as part of the implementation of section 605 of FDASIA, which, among other things, requires FDA to establish a program to routinely and systemically assess information relating to device recalls and to use such information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices.	Other	–	12/13/2013	12/13/2013	CDRH	Completed	12/13/2013	N		CDRH-FDASIA@fda.hhs.gov
132	VI	607		NO		FDA intends to issue a a regulation to, among other things, implement the new de novo pathway in section 607 of FDASIA, which does not require a sponsor to first submit a 510(k) before requesting de novo classification.	Proposed Rule	–	5/30/2014	5/30/2014	CDRH	Undergoing FDA Clearance	–	N		CDRH-FDASIA@fda.hhs.gov
133	VI	607		NO		FDA intends to issue a a regulation to, among other things, implement the new de novo pathway in section 607 of FDASIA, which does not require a sponsor to first submit a 510(k) before requesting de novo classification.	Final Rule	–	11/30/2015	11/30/2015	CDRH	Scheduled to begin later	–	N		
134	VI	607		NO		In lieu of submitting a report under section 510(k) and submitting a [de novo] request for classification under clause (i) for a device, if a person determines there is no legally marketed device upon which to base a determination of substantial equivalence ... a person may submit a [de novo] request under this clause for the FDA to classify the device	Other	–	–		CDRH	Completed	–	Y	FDA is using its authority under this new provision to review 'direct' de novo petitions from sponsors (i.e., de novo petitions for devices for which the sponsor did not first submit a 510(k) and receive an NSE decision from FDA)	CDRH-FDASIA@fda.hhs.gov
135	VI	608	(a)(1)	NO		FDA intends to issue a regulation to implement section 608 of FDASIA, which, among other things, amended the procedures for requiring premarket approval for preamendments class III devices under section 515(b) of the FD&C Act and for reclassifying devices under section 513(e) of the FD&C Act to an administrative order process.	Proposed Rule	–	2/28/2014	2/28/2014	CDRH	Undergoing FDA Clearance	–	N		CDRH-FDASIA@fda.hhs.gov
136	VI	608	(a)(1)	NO		FDA intends to issue a regulation to implement section 608 of FDASIA, which, among other things, amended the procedures for requiring premarket approval for preamendments class III devices under section 515(b) of the FD&C Act and for reclassifying devices under section 513(e) of the FD&C Act to an administrative order process	Final Rule	–	8/28/2015	8/28/2015	CDRH	Scheduled to begin later	–	N		
137	VI	608	(b)(1)	NO		Section 608 of FDASIA changed the process for reclassifying devices and requiring premarket approval for preamendment devices from rulemaking to an administrative order process, which includes publication of a proposed order in the Federal Register, consideration of comments, and panel meeting before issuing a final order	Other	–	–		CDRH	Completed	–	Y	FDA is using its authority under this new provision to reclassify devices and call for PMAs by administrative order	CDRH-FDASIA@fda.hhs.gov

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138	VI	608	(c)	NO		FDA shall annually post on its website the number and type of class I and II devices reclassified as class II or III; the number and type of class II and class III devices reclassified as class I or class II, and, the number and types of devices reclassified in the previous calendar year under section 515 of the FD&C Act.	List	–	12/31/2013	12/31/2013	CDRH	Completed	12/17/2013	N		CDRH-FDASIA@fda.hhs.gov
139	VI	611		NO		FDA shall establish and publish in the Federal Register criteria to reaccredit or deny reaccreditation of third-party reviewers (called "Accredited Persons"). Any reaccreditation must specify the particular activities and the devices, for which such persons are accredited to review.	FR Notice	11/6/2012	2/15/2013	2/15/2013	CDRH	Completed	2/15/2013	Y	Action Completed Feb 15, 2013 Link to FR Notice announcing availability of draft guidance. http://www.gpo.gov/fdsys/pkg/FR-2013-02-15/html/2013-03538.htm Link to draft guidance: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm339695.htm	CDRH-FDASIA@fda.hhs.gov
140	VI	613		NO		FDA intends to issue guidance that includes an interpretation of section 613 of FDASIA, which, among other things, expands the types of devices approved under a humanitarian device exemption that can be sold for profit. Such devices now include devices intended for treatment or diagnosis of a disease/condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is "impossible, highly impracticable, or unsafe." This guidance, when final, will supersede the guidance entitled "Humanitarian Device Exemption (HDE) Regulation: Questions and Answers," issued July 8, 2010.	Draft Guidance	–	3/31/2014	3/31/2014	CDRH	Completed	3/18/2014	Y	Completed 03/18/2014 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm389154.htm	CDRH-FDASIA@fda.hhs.gov
141	VI	613		NO		FDA intends to issue guidance that includes an interpretation of section 613 of FDASIA, which, among other things, expands the types of devices approved under a humanitarian device exemption that can be sold for profit. Such devices now include devices intended for treatment or diagnosis of a disease/condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is "impossible, highly impracticable, or unsafe." This guidance, when final, will supersede the guidance entitled "Humanitarian Device Exemption (HDE) Regulation: Questions and Answers," issued July 8, 2010.	Final Guidance	–	9/30/2015	9/30/2015	CDRH	Scheduled to begin later	–	N	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm389154.htm	
142	VI	614		NO		FDA must issue final Unique Device Identifier (UDI) regulations not later than 6 months after the close of the comment period for the proposed rule. FDA shall implement these final UDI regulations for devices that are implantable, life-saving, and life-sustaining, not later than 2 years after regulations are finalized.	Final Rule	6/19/2013	6/19/2013	9/24/2013	CDRH	Completed	9/24/2013	Y	Completed 9/24/2013 https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system	CDRH-FDASIA@fda.hhs.gov

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143	VI	614		NO		FDA must issue proposed Unique Device Identifier (UDI) regulations by December 31, 2012.	Proposed Rule	12/31/2012	7/10/2012	7/13/2011	CDRH	Completed	7/10/2012	Y	Action Completed 7/10/2012 UDI Proposed Rule 7/10/12. https://www.federalregister.gov/articles/2012/07/10/2012-16621/unique-device-identification-system UDI Amendment to Proposed Rule 11/19/12 https://www.federalregister.gov/articles/2012/11/19/2012-28015/unique-device-identification-system	CDRH-FDASIA@fda.hhs.gov
144	VI	615		NO		FDA shall amend the procedures to expand the postmarket risk identification and analysis system (Sentinel) to include and apply to devices, and engage stakeholders in development of such system	Public Meeting	--	9/13/2012	9/13/2012	CDRH	Completed	9/13/2012	N	Completed 9/13/2012	CDRH-FDASIA@fda.hhs.gov
145	VI	617		NO		Not later than 2 years after the date of enactment, FDA shall issue final guidance on replication of custom devices used to treat rare conditions such that no other device is domestically available to treat, where conducting a clinical investigation on such device would be impractical, and production of such devices is limited to no more than 5 units per year of the device type.	Draft Guidance	--	1/31/2014	1/31/2014	CDRH	Completed	1/14/2014	Y	Published January 14, 2014. Link to Notice of Availability for draft guidance http://www.gpo.gov/fdsys/pkg/FR-2014-01-14/html/2014-00528.htm	CDRH-FDASIA@fda.hhs.gov
146	VI	617		NO		Not later than 2 years after the date of enactment, FDA shall issue final guidance on replication of custom devices used to treat rare conditions such that no other device is domestically available to treat, where conducting a clinical investigation on such device would be impractical, and production of such devices is limited to no more than 5 units per year of the device type.	Final Guidance	7/9/2014	7/9/2014	7/9/2014	CDRH	Undergoing FDA Clearance	--	Y		CDRH-FDASIA@fda.hhs.gov
147	VI	618	(a)	NO		FDA, in consultation with the National Coordinator for Health Information Technology (ONC) and the Federal Communications Commission (FCC), shall post on the FDA, ONC, and FCC websites, a report containing 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	Public Report	1/9/2014	3/31/2014	2/14/2014	CDRH	Completed	4/3/2014	Y	Completed 4/3/2014 http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm390588.htm	CDRH-FDASIA@fda.hhs.gov
148	VI	620	(b)	NO		Not later than December 31, 2012, FDA shall issue a proposed rule that requires submitters to FDA of premarket approval applications (PMAs), supplements to PMAs, humanitarian device exemption applications (HDEs), and product development protocols (PDPs) for devices to include, if readily available, information about pediatric subpopulations that suffer from a disease or condition that the device is intended to treat, diagnose, or cure.	Proposed Rule	12/31/2012	2/19/2013	2/19/2013	CDRH	Completed	2/19/2013	Y	Action Completed Feb 19, 2013 Link to FR notice for Proposed Rule http://www.gpo.gov/fdsys/pkg/FR-2013-02-19/html/2013-03647.htm	CDRH-FDASIA@fda.hhs.gov

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149	VI	620	(b)	NO		Not later than December 31, 2013. FDA shall issue a final rule that requires submitters to FDA of premarket approval applications (PMAs), supplements to PMAs, humanitarian device exemption applications (HDEs), and product development protocols (PDPs) for devices to include, if readily available, information about pediatric subpopulations that suffer from a disease or condition that the device is intended to treat, diagnose, or cure.	Final Rule	12/31/2013	12/31/2013	12/31/2013	CDRH	Completed	1/10/2014	Y	Published January 10, 2014 https://www.federalregister.gov/articles/2014/01/10/2014-00267/requirement-for-submission-of-information-on-pediatric-subpopulations-that-suffer-from-a-disease-or	CDRH-FDASIA@fda.hhs.gov
150	VI	620	(b)	NO		Not later than December 31, 2012. FDA shall issue a proposed rule that requires submitters to FDA of premarket approval applications (PMAs), supplements to PMAs, humanitarian device exemption applications (HDEs), and product development protocols (PDPs) for devices to include, if readily available, information about pediatric subpopulations that suffer from a disease or condition that the device is intended to treat, diagnose, or cure. FDA intends to issue a companion guidance to this rule.	Final Guidance	–	3/31/2014	3/31/2014	CDRH	Completed	5/1/2014	Y	Completed May 1, 2014 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm339162.htm	CDRH-FDASIA@fda.hhs.gov
151	VI	620	(b)	NO		Not later than December 31, 2012. FDA shall issue a proposed rule that requires submitters to FDA of premarket approval applications (PMAs), supplements to PMAs, humanitarian device exemption applications (HDEs), and product development protocols (PDPs) for devices to include, if readily available, information about pediatric subpopulations that suffer from a disease or condition that the device is intended to treat, diagnose, or cure. FDA intends to issue a companion guidance to this rule.	Draft Guidance	–	2/19/2013	2/19/2013	CDRH	Completed	2/19/2013	Y	Action Completed Feb 19, 2013Link to FR notice: http://www.gpo.gov/fdsys/pkg/FR-2013-02-19/html/2013-03652.htm Link to draft guidance http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm339162.htm	
152	VII	701		NO		FDA shall specify the unique facility identifier (UFI) system to be used for domestic and foreign drug establishment registrations.	Draft Guidance	–	9/5/2013	9/5/2013	CDER	Completed	9/5/2013	Y	Completed 09/05/2013 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM367199.pdf	CDERCompliancePublic@fda.hhs.gov
153	VII	701		NO		FDA shall specify the unique facility identifier (UFI) system to be used for domestic and foreign drug establishment registrations.	Final Guidance	–	4/9/2015	1/29/2015	CDER	In process, on track to meet due date		Y		CDERCompliancePublic@fda.hhs.gov
154	VII	701		NO		FDA will issue a rule that will reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments, and will reflect the requirements for registration of domestic and foreign drug establishments in Sections 701 and 702.	Final Rule	–	4/30/2015	2/27/2015	CDER	In process, on track to meet due date	–	N		CDERCompliancePublic@fda.hhs.gov
155	VII	702		NO		FDA will issue a rule that will reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments, and will reflect the requirements for registration of domestic and foreign drug establishments in Sections 701 and 702.	Final Rule	–	4/30/2015	2/27/2015	CDER	In process, on track to meet due date	–	N		CDERCompliancePublic@fda.hhs.gov

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156	VII	702		NO		FDA will issue a rule that will reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments, and will reflect the requirements for registration of domestic and foreign drug establishments in Sections 701 and 702	Draft Guidance		9/5/2013	9/5/2013	CDER	Completed	9/5/2013	Y	Completed 09/05/2013 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM367199.pdf	CDERCompliancePublic@fda.hhs.gov
157	VII	702		NO		FDA will issue a rule that will reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments, and will reflect the requirements for registration of domestic and foreign drug establishments in Sections 701 and 702.	Final Guidance		4/9/2015	1/29/2015	CDER	In process, on track to meet due date		Y		CDERCompliancePublic@fda.hhs.gov
158	VII	703		NO		Drug listings shall identify the establishments used in production of excipients of the listed drug, including contact information and UFI.	Other	–	–	–	CDER	Scheduled to begin later	–	N		CDERCompliancePublic@fda.hhs.gov
159	VII	704		NO		FDA shall maintain an electronic database after specifying a UFI system, and ensure the accuracy and coordination of relevant FDA databases in order to identify and inform risk-based inspections under section 510 of the FD&C Act	Database/IT System	–	6/30/2016	6/30/2016	CDER	In process, on track to meet due date	–	N		CDERCompliancePublic@fda.hhs.gov
160	VII	705	6	NO		Starting in 2014, the FDA will publish by February 1 of each year a website report on the number of establishments registered with FDA and inspected by FDA, and the percentage of the FDA budget used to conduct these inspections	Public Report	1/31/2014	1/31/2014	12/31/2013	CDER	Completed	1/31/2014	Y	Completed 1/31/2014 http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM384063.pdf	CDERCompliancePublic@fda.hhs.gov
161	VII	706	(4)(b)	NO		FDA will issue interim policy and procedures for requesting records in the event of a public health incident related to human or animal drugs, including human biological products, under section 706	SOP / New Template	–	7/15/2014	7/15/2014	ORA	In process on track to meet due date	–	N		FDASIAImplementationORA@fda.hhs.gov
162	VII	707	(b)	NO		Not later than 1 year after the date of enactment, FDA shall issue guidance that defines the circumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection	Draft Guidance	7/9/2013	7/15/2013	7/15/2013	ORA	Completed	–	Y	Completed 7/15/2013 https://www.federalregister.gov/articles/2013/07/15/2013-16841/draft-guidance-for-industry-on-circumstances-that-constitute-delaying-denying-limiting-or-refusing-a	FDASIAImplementationORA@fda.hhs.gov
163	VII	707	(b)	NO		shall issue guidance that defines the circumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection	Final Guidance		12/22/2014	8/1/2014	ORA	Inprocess and ontrack to meet due date	–	Y		FDASIAImplementationORA@fda.hhs.gov
164	VII	708	(b), (d)	NO		Not later than 2 years after the date of enactment, FDA shall issue regulations providing for notice and an opportunity to appear and introduce testimony prior to administrative destruction of a refused admission drug valued under $2,500	Proposed Rule	–	4/18/2014	12/24/2013	ORA	Completed	5/6/2014	Y	Completed 5/6/2014 https://federalregister.gov/a/2014-10304	FDASIAImplementationORA@fda.hhs.gov
165	VII	708	(b), (d)	NO		Not later than 2 years after the date of enactment, FDA shall issue regulations providing for notice and an opportunity to appear and introduce testimony prior to administrative destruction of a refused admission drug valued at $2,500 or less.	Final Rule	7/9/2014	9/14/2015	5/7/2015	ORA	In process, on track to meet due date	–	Y		FDASIAImplementationORA@fda.hhs.gov

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166	VII	709	(b)(1)	NO		Not later than 2 years after the date of enactment and after consulting with stakeholders including manufacturers of drugs, FDA shall promulgate regulations to implement administrative detention authority with respect to drugs	Final Rule	7/9/2014	7/9/2014	3/21/2014	ORA	In process, on track to meet due date	–	Y		FDASIAImplementation ORA@fda.hhs.gov
167	VII	709	(b)(2)	NO		Before issuing regulations to implement administrative detention authority with respect to drugs, FDA shall consult with stakeholders, including drug manufacturers	FR Notice	–	4/9/2013	4/9/2013	ORA	Completed	4/28/2013	Y	Completed 4/28/2013 https://www.federalregister.gov/articles/text/raw_text/2013/08/120.txt	FDASIAImplementation ORA@fda.hhs.gov
168	VII	709	(b)(2)	NO		Not later than 2 years after date of enactment and after consulting with stakeholders including drug manufacturers, FDA shall issue regulations to implement administrative detention authority with respect to drugs	Proposed Rule	–	7/15/2013	7/15/2013	ORA	Completed	–	Y	Completed 7/15/2013 https://www.federalregister.gov/articles/2013/07/15/2013-16843/administrative-detention-of-drugs-intended-for-human-or-animal-use	FDASIAImplementation ORA@fda.hhs.gov
169	VII	711		NO		FDA may revise regulations to implement Section 711 and other Sections of Title VII.	Proposed Rule	–	1/4/2016	8/27/2015	CDER	In process, on track to meet due date	–	Y		CDERCompliancePublic@fda.hhs.gov
170	VII	711		NO		FDA may revise regulations to implement Section 711 and other Sections of Title VII.	Final Rule	–	4/7/2017	12/3/2016	CDER	In process, on track to meet due date	–	Y		CDERCompliancePublic@fda.hhs.gov
171	VII	713		NO		Not later than 18 months after the date of enactment, FDA shall adopt final regulations which may require importers to submit certain electronic information as a condition of import.	Final Rule	1/9/2014	1/10/2017	9/2/2016	CDER	In process, on track to meet due date	–	Y		CDERCompliancePublic@fda.hhs.gov
172	VII	713		NO		Not later than 18 months after the date of enactment, FDA shall adopt final regulations which may require importers to submit certain electronic information as a condition of import.	Proposed Rule	–	9/25/2015	5/20/2015	CDER	In process, on track to meet due date	–	Y		CDERCompliancePublic@fda.hhs.gov
173	VII	714	(b)	NO		Not later than 36 months after date of enactment, FDA, in consultation with the Secretary of Homeland Security, acting through Customs and Border Protection, shall issue regulation to establish good importer practices for drugs.	Proposed Rule	–	4/29/2015	12/26/2014	OP	Inprocess and ontrack to meet due date	–	Y		Brian Pendleton brian.pendleton@fda.hhs.gov
174	VII	714	(b)	NO		Not later than 36 months after date of enactment, FDA, in consultation with the Secretary of Homeland Security, acting through Customs and Border Protection, shall issue regulation to establish good importer practices for drugs.	Final Rule	7/9/2015	1/31/2017	9/8/2016	OP	In process, on track to meet due date	–	Y		Brian Pendleton brian.pendleton@fda.hhs.gov
175	VII	714	(c), (d)	NO		Not later than 36 months after the date of enactment, FDA, in consultation with the Secretary of Homeland Security acting through Customs and Border Protection, shall issue regulations to require registration of commercial importers of drugs.	Final Rule	7/9/2015	1/31/2017	9/8/2016	OP	Inprocess and ontrack to meet due date	–	Y		Brian Pendleton brian.pendleton@fda.hhs.gov

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176	VII	714	(c), (d)	NO		Not later than 36 months after the date of enactment, FDA, in consultation with the Secretary of Homeland Security acting through Customs and Border Protection, shall issue regulations to require registration of commercial importers of drugs.	Proposed Rule	–	4/29/2015	12/26/2014	OP	Inprocess and ontrack to meet due date	–	Y		Brian Pendleton brian.pendleton@fda.hhs.gov
177	VIII	801	(a)	NO		Not later than 2 years after the date of enactment, FDA shall adopt final regulations, following specified procedures, to implement this section, including establishing a list of qualifying pathogens	Final Rule	7/9/2014	7/7/2014	12/15/2013	CDER	In process, on track to meet due date	–	Y		druginfo@fda.hhs.gov
178	VIII	801	(a)	NO		Not later than 2 years after the date of enactment, FDA shall adopt final regulations, following specified procedures, to implement this section, including establishing a list of qualifying pathogens	Proposed Rule	–	8/19/2013	6/5/2013	CDER	Completed	6/5/2013	Y	FR Notice released 6/5/2013 Public comment period ends on 8/12/2013 FDA has published a proposed rule that establishes a proposed list of "qualifying pathogens" that have the potential to pose a serious threat to public health, and describes the methodology for creating and maintaining the list. Establishing this list is related to FDA's efforts to encourage the development of new antibacterial and antifungal drugs for the treatment of serious or life-threatening infections http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1037-0013 6/5/2013 Proposed Rule for 801 contains the proposed list http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1037-0013 Open for public comment until 8/12/2013	druginfo@fda.hhs.gov
179	VIII	801	(a)	NO		At least every 5 years FDA shall review, modify, and publish the list of qualifying pathogens and issue a regulation revising the list as needed. FDA shall consult with CDC and others when establishing the list also make the methodology for developing the list publicly available.	List	7/7/2017	7/7/2014	1/15/2014	CDER	Substantially complete, on track to meet due date	–	Y	Consulted with CDC and NIH via public meeting (Part 15 Hearing): http://www.fda.gov/Drugs/NewsEvents/ucm319619.htm	druginfo@fda.hhs.gov

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180	VIII	804	(a)(1)	NO		FDA shall review and, if needed, revise no fewer than 3 guidance documents per year regarding the conduct of clinical trials for antibacterial and antifungal drugs	Other	7/9/2013	7/9/2013	10/12/2012	CDER	Completed	10/12/2012	Y	Chronic Bronchitis in Patients with Chronic Obstructive Pulmonary Disease: Final published 09/28/12 (conversion of draft guidance to final) http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm321330.htm 2. Acute Bacterial Otitis Media: Final published 10/01/12 (conversion of draft guidance to final) http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm323763.htm 3. Acute Bacterial Sinusitis: Final published 10/05/12 (conversion of draft guidance to final) http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm322630.htm	druginfo@fda.hhs.gov
181	VIII	805		NO		FDA shall submit a report to Congress on the designation, review, and approval of qualified infectious disease products and recommendations regarding qualifying pathogens and any additional programs or incentives that may be needed to promote the development of antibacterial drugs	Report to Congress	7/7/2017	7/7/2017	3/1/2017	HHS/CDER	Scheduled to begin later	–	Y		druginfo@fda.hhs.gov
182	VIII	806	(a)	NO		Not later than June 30, 2013, FDA shall publish draft guidance that addresses how data may be used for the efficient and streamlined development of antibacterial drugs to treat serious or life-threatening bacterial infections, including approaches for developing limited-spectrum antibacterials.	Draft Guidance	6/28/2013	6/28/2013	6/28/2013	CDER	Completed	7/1/2013	Y	FDA Webinar presented on new Draft Guidance for Industry on 9/27/2013 Completed 7/1/2013 Draft Guidance published: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM359184.pdf	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM359184.pdf
183	VIII	806	(b)	NO		Not later than December 31, 2014, FDA shall publish final guidance, after notice and opportunity for public comment, that addresses how data may be used for the efficient and streamlined development of antibacterial drugs to treat serious or life-threatening bacterial infections.	Final Guidance	12/31/2014	12/18/2014	10/30/2014	CDER	In process, on track to meet due date	–	Y		druginfo@fda.hhs.gov
184	IX	901	(b)	NO		Awareness Efforts: FDA shall (1) develop and disseminate to certain groups listed in the statute a description of provisions on accelerated approval and fast track products; and (2) establish a program to encourage the development of surrogate and clinical endpoints and other scientific methods and tools to assist in determining whether evidence is reasonably likely to predict clinical benefit	Other	–	6/30/2015	6/30/2015	CDER	Scheduled to begin later	–	N		druginfo@fda.hhs.gov

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185	IX	901	(c)	NO		Not later than 1 year after the date of enactment, FDA shall issue draft guidance on the clarified standard for accelerated approval and fast track processes, including issues for drugs for a rare disease or condition.	Draft Guidance	7/9/2013	7/9/2013	6/17/2013	CDER	Completed	6/25/2013	Y	Completed 6/25/2013 Draft Guidance for industry: Expedited Programs for Serious Conditions–Drugs and Biologics http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf	druginfo@fda.hhs.gov
186	IX	901	(c)	NO		Not later than 1 year after the issuance of draft guidance, FDA shall issue final guidance on the clarified standard for accelerated approval and fast track processes, including issues for a rare disease or condition.	Final Guidance	7/9/2014	7/9/2014	5/15/2014	CDER	In process, on track to meet due date	–	Y		druginfo@fda.hhs.gov
187	IX	902	(b)	NO		Not later than 18 months after the date of enactment FDA shall issue draft guidance implementing the requirements on breakthrough therapies to treat a serious or life-threatening condition where early evidence shows the drug may offer substantial improvement over existing treatments	Draft Guidance	1/9/2014	1/9/2014	6/26/2013	CDER	Completed	6/26/2013	Y	Completed 6/26/13 Draft Guidance for industry. Expedited Programs for Serious Conditions–Drugs and Biologics http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf Federal Register Notice https://www.federalregister.gov/articles/2013/06/26/2013-15250/draft-guidance-for-industry-on-expedited-programs-for-serious-conditions-drugs-and-biologics	druginfo@fda.hhs.gov
188	IX	902	(b)	NO		Not later than 1 year after the close of the comment period for the draft guidance, FDA shall issue draft final guidance on implementing the requirements with respect to breakthrough therapies to treat a serious or life-threatening condition where early evidence shows the drug may offer substantial improvement over existing treatments	Final Guidance	7/9/2014	7/9/2014	6/9/2014	CDER	In process, on track to meet due date	–	Y		druginfo@fda.hhs.gov
189	IX	903	(a)(b)	NO		(1) FDA shall ensure that opportunities exist for consultations with stakeholders, when appropriate and consistent with PDUFA on the topics described in section 903(b) related to rare diseases (2) FDA shall develop and maintain a list of external experts for consultation on issues related to the review of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted	List	--	-		CDER	Completed	2/28/2013	N	In the Center for Drug Evaluation and Research (CDER), the Division of Advisory Committee and Consultant Management (DACCM) maintains an extensive list of special government employees (SGEs) for advisory committees (ACs) and other consultative needs. Currently, DACCM has a listing of approximately 1,200 SGEs categorized by therapeutic area expertise, many of whom are on the roster for a specific AC. Depending on the drug and disease under discussion, ACs may be supplemented with temporary members to provide additional expertise on the topic. Many diseases have multi-system effects, so it is useful for FDA to have access to a diverse list of experts from a variety of fields available for consultation	druginfo@fda.hhs.gov

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190	IX	904	(b)	NO		GAO study regarding the extent to which pharmacies are utilizing best practices and the extent to which barriers to accessible information on prescription drug container labels for blind and visually impaired individuals continue, requires the study to begin 18 months after completion of the development of best practices and to be submitted to Congress no later than September 30, 2016.	GAO Report	9/30/2016	9/30/2016	9/30/2016	GAO/OPP	Scheduled to begin later	–	N		Claudia Grillo Claudia.grillo@fda.hhs.gov
191	IX	904		NO		The Architectural and Transportation Barriers Compliance Board to convene a stakeholder working group to develop best practices on access to information on prescription drug container labels for individuals who are blind or visually impaired, within 1 year of enactment. National Council on Disability shall conduct educational campaign about best practices	Public Report	7/9/2013	7/9/2013		CDER/Architectural and Transportation Barriers Compliance Board	Completed	7/10/2013	N	Completed 7/10/2013 http://www.access-board.gov/guidelines-and-standards/health-care/about-prescription-drug-container-labels/working-group-recommendations	CDER EXECSEC for CDER
192	IX	907	(a)	NO		Not later than 1 year after enactment, FDA will issue a report that describes the participation of demographic subgroups (sex, age, race, and ethnicity) in clinical studies submitted to FDA in marketing applications. The report will also describe the inclusion of safety and effectiveness data for demographic subgroups in marketing applications submitted to FDA. The report will be posted on FDA's website and provided to Congress	Public Report	7/9/2013	7/9/2013	7/9/2013	OWH	Completed	8/20/2013	Y	Completed 8/20/2013 http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM365544.pdf	Pamela.Scott@fda.hhs.gov
193	IX	907	(b)	NO		Not later than 1 year after providing the report to Congress, FDA shall publish an action plan on the FDA website with recommendations on improving the completeness and quality of data analyses on demographic subgroups, including such data in labeling, and making such data available to patients and providers.	Plan	8/20/2014	8/20/2014	8/20/2014	OMH	In process on track to meet due date	–	Y		Jonca Butt@fda.hhs.gov
194	IX	908		NO		FDA shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay a fee, determined based on the differences between the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous year, and the average cost incurred by FDA in the review of a human drug application not subject to priority review in the previous year	FR Notice	–	–		OPL	Scheduled to begin later	–	N		Clark Nardinelli clark.nardinelli@fda.hhs.gov
195	IX	908		NO		GAO shall study the effectiveness of awarding rare pediatric disease products priority review vouchers in the development of human drug products that treat or prevent such diseases.	GAO Report	–	–		GAO/OPP	Scheduled to begin later	–	N		Claudia Grillo Claudia.grillo@fda.hhs.gov
196	IX	908		NO		When after the last day of the 1-year period that begins on the date that FDA awards the third rare pediatric disease priority voucher, a sponsor of an application uses such a voucher, FDA shall submit a document to Congress notifying them of the use of such voucher and identifying the drug for which it was used.	Report to Congress	–	–		OOPD	Scheduled to begin later	–	N		druginfo@fda.hhs.gov
197	IX	908		NO		FDA shall publish in the Federal Register notice of issuance of voucher and approval of products using a priority review voucher.	FR Notice	–	–		OOPD	Scheduled to begin later	–	N		druginfo@fda.hhs.gov

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198	X	1001	(i)	NO		Not later than 18 months after the date of enactment, FDA shall adopt final regulations implementing provisions regarding drug shortages, including defining certain terms	Proposed Rule	–	7/9/2013	10/23/2013	CDER	Completed	10/31/2013	Y	FDA has the proposed rule, Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Productsissued. If finalized, the rule will expand the requirement for drug and biologic manufacturers to notify FDA early about issues that could lead to a potential shortage. The FR notice Published on 10/31/2013 https://federalregister.gov/a/2013-25956	http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm
199	X	1001	(i)	NO		Not later than 18 months after the date of enactment, FDA shall adopt final regulations implementing provisions regarding drug shortages, including defining certain terms	Final Rule	1/9/2014	1/9/2014		CDER	In process, delayed and may not meet due date	–	Y	FDA issued a proposed rule on 10/31/2013 and has requested public comments	https://www.federalregister.gov/articles/2013/11/04/2013-25956/permanent-discontinuance-or-interruption-in-manufacturing-of-certain-drug-or-biological-products
200	X	1001	c	NO		To the maximum extent practicable, FDA shall distribute information on the discontinuation or interruption of the manufacture of drugs (about which FDA is notified) to appropriate organizations including physicians, health care providers, patient organizations.	Website	7/9/2012	7/9/2012	7/9/2012	CDER	Completed	7/9/2012	N		http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm
201	X	1001	e	NO		FDA shall determine whether a notification of shortage pertains to a controlled substance subject to a production quota under section 306 of the CSA and, if necessary, notify the Attorney General of a discontinuance of a controlled substance and request DOJ to increase the quota	Other	7/9/2012	7/9/2012	7/9/2012	CDER	Completed	–	N		http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm
202	X	1002		NO		FDA shall submit an annual report to Congress providing information on drug shortages, including information on the agency's efforts to prevent or mitigate shortages	Report to Congress	12/31/2013	12/31/2013	12/1/2013	CDER	Completed	2/6/2014	Y	Completed 2/5/2014 Drug Shortages Report to Congress http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm384691.htm	http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm
203	X	1003	(a)	NO		enforcement action or issuance of a warning letter that the Secretary determines could reasonably be anticipated to lead to a meaningful disruption in the supply in the U.S. of a drug under 506C(a), there is a communication with the appropriate office of the FDA with expertise regarding drug shortages regarding whether the action or letter could cause, or exacerbate, a shortage of the drug. If so, the Secretary shall evaluate the risks associated with the impact of such shortage upon patients and those risks associated with the violation involved before taking such action or issuing such letter, unless there is imminent risk of serious adverse health consequences or death to humans"	SOP / New Template	–	–		CDER	Scheduled to begin later	–	N		CDERCompliancePublic@fda.hhs.gov

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204	X	1003	(d)	NO		FDA shall identify or establish a mechanism by which health care providers and other third-party organizations may report to FDA evidence of a drug shortage	Other	–	12/18/2013	12/18/2013	CDER	Completed	1/11/2013	Y	Completed 01/11/2013 http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm142398.htm	http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm
205	X	1003		NO		FDA shall establish a task force to develop and implement a strategic plan for enhancing the Secretary's response to preventing and mitigating drug shortages	Strategic Plan	7/9/2013	7/9/2013	10/31/2013	CDER	Completed	10/31/2013	Y	The Agency has issued a long-term strategic plan that focuses on preventing many of the underlying causes of most drug shortages. The plan outlines the Agency's strategy for improving its response to early notifications of a potential shortage, as well as long-term tactics to address the underlying causes of shortages. Plan published and can be accessed through this link: http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf	http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm
206	X	1003		NO		Not later than one year after the date of enactment, FDA shall publish the drug shortage strategic plan and submit the report to Congress	Public Report	7/9/2013	7/9/2013	7/9/2013	CDER	Completed	10/31/2013	N	First, the Agency has issued a long-term strategic plan that focuses on preventing many of the underlying causes of most drug shortages. The plan outlines the Agency's strategy for improving its response to early notifications of a potential shortage, as well as long-term tactics to address the underlying causes of shortages	http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf
207	X	1005		NO		Attorney General shall promptly review requests for an adjustment in applicable quotas made by the manufacturer of a schedule II drug on FDA's drug shortage list. If the AG determines the level requested is not necessary to address a shortage, the AG shall provide a written response detailing the basis for such determination. The Secretary shall make such a written response available to the public on the FDA website.	Public Report	–	–		CDER/DOJ	Other	–	N		druginfo@fda.hhs.gov
208	X	1006		NO		Attorney General shall submit a report to Congress identifying the number of requests it receives to adjust quotas for drugs in shortage, and the number of requests granted and denied, and the reason for each denial. The report must also describe the coordination between DEA and FDA on efforts to prevent or alleviate drug shortages.	Report to Congress	1/9/2013	–		CDER/DOJ	Other	–	N		druginfo@fda.hhs.gov
209	X	1007		NO		Allows hospitals to repackage certain drugs in shortage into smaller doses for transfer within the same healthcare system, without having to register with FDA. This section sunsets if FDA issues guidance on this issue	Final Guidance	–	–		CDER	Scheduled to begin later	–	N		CDERCompliancePublic@fda.hhs.gov
210	X	1008		NO		GAO shall conduct a study to examine the cause of, and give recommendations on how to prevent or alleviate, drug shortages in the United States. GAO shall report the results of the study to Congress	GAO Report	1/9/2014	2/7/2014	2/7/2014	GAO/OPP	Completed	2/10/2014	N	GAO has completed and published the report: http://www.gao.gov/products/GAO-14-194	druginfo@fda.hhs.gov

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211	XI-B	1112	(a)	NO		Not later than 18 months after the date of enactment, FDA shall determine whether any changes to FDA drug regulations are necessary for medical gases. FDA will obtain input from medical gas manufacturers and other interested members of the public about whether changes are needed The agency will submit a report to Congress regarding any changes to the regulations	Report to Congress	1/9/2014	1/9/2014	1/9/2014	CDER	In Process, delayed and did not meet the due date	–	Y	On 11/1/2013, announced public meeting to be held on 12/6/2013, on whether any changes to Federal drug regulations are necessary for medical gases https://federalregister.gov/a/2013-26056 Created a certification program for designated medical gases (1111) Comments on Certification (FDASIA Section 1111) http://www.regulations.gov/#!documentDetail D=FDA-2012-N-1090-0001 3/22/2013 Opened the docket for the Med Gas Reg Medical Gases--Medical Gases--Comments to Changes in Regulations (FDASIA Section 1112) http://www.regulations.gov/#!documentDetail D=FDA_FRDOC_0001-3802	CDERCompliancePublic@fda.hhs gov
212	XI-B	1112	(b)	NO		If FDA determines to that any changes to the Federal drug regulations are necessary for medical gases pursuant to Sec 1112 (a) (1), FDA shall issue revised regulations	Proposed Rule	7/8/2016	7/8/2016	10/30/2015	CDER	Scheduled to begin later	–	N		CDERCompliancePublic@fda hhs gov
213	XI-C	1121		NO		Not later than 2 years after the date of enactment, FDA shall issue guidance describing FDA policy regarding Internet promotion, including social media, of medical products regulated by FDA.	Draft Guidance	7/9/2014	7/9/2014	3/15/2014	CDER/OMP/OPDP	In process, on track to meet due date	–	Y	druginfo@fda hhs gov	druginfo@fda.hhs gov druginfo@fda.hhs.gov
214	XI-C	1122	(a)	NO		To fight the significant rise in prescription drug abuse, FDA, in coordination with other federal agencies as appropriate, shall review federal initiatives and identify gaps and opportunities regarding the safe use of prescription drugs with potential for abuse and the treatment of prescription drug dependence	Other	7/9/2013	–	2/1/2013	CDER/OASH	Completed	2/20/2013	N	Completed 02/20/2013	DrugInfo@fda.hhs gov
215	XI-C	1122	(b)	NO		Not later than one year after the date of enactment, the Secretary of Health and Human Services will post on the HHS Internet website a report on the findings of the review of federal initiatives, gaps, and opportunities regarding the safe use of prescription drugs with potential for abuse and the treatment of prescription drug dependence.	Public Report	7/9/2013	7/9/2013	10/23/2013	CDER/OASH/CDC	Completed	10/23/2013	N	Report was sent to Congress 10/23/2013 CDC is working with OASH to post the report on the web CDER and DDI have a copy of the Report	DrugInfo@fda.hhs gov
216	XI-C	1122	(c)	NO		Not later than 6 months after the date of enactment, FDA shall promulgate guidance on the development of abuse-deterrent drug products	Draft Guidance	1/9/2013	1/9/2013	11/20/2012	CDER	Completed	1/9/2013	Y	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf	druginfo@fda.hhs gov
217	XI-C	1123		NO		FDA shall (1) work with other regulatory authorities to...foster and encourage uniform, scientifically driven clinical trial standards with respect to medical products around the world, (2) enhance commitment to provide consistent parallel advice to manufacturers seeking simultaneous global development of new medical products	Other	–	--		OPP	Scheduled to begin later	–	N		

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218	XI-C	1123		NO		FDA shall accept data from clinical investigations conducted outside the U.S. for drug and device applications if the applicant demonstrates that such data are adequate under applicable standards for approval in United States; FDA shall provide written notice to the sponsor if FDA finds the foreign data to be inadequate and provide a rationale for this finding	SOP / New Template	–	–		OPP	Scheduled to begin later	–	N		
219	XI-C	1124		NO		Not later than 1 year after the date of enactment, FDA shall develop a strategy and implementation plan for advancing regulatory science for medical products in order to promote the public health and advance innovation in regulatory decision-making. The plan developed must be consistent with the goals established in the user fee negotiations for drugs and biologics (PDUFA), devices (MDUFA), generic drugs (GDUFA), and biosimilars BSUFA)	Strategic Plan	7/9/2013	7/9/2013	7/9/2013	OPL	Completed	7/9/2013	Y	Completed 7/9/2013 http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM359956.pdf	Danan Tarver danan.tarver@fda.hhs.gov
220	XI-C	1124		NO		For fiscal years 2014 through 2016 FDA shall include information on the progress made in advancing regulatory science in the annual performance reports on the implementation of the user fee programs for drugs and biologics (PDUFA), devices (MDUFA), generic drugs (GDUFA), and biosimilars BSUFA)	Report to Congress	1/31/2015	1/31/2015	1/31/2015	OPL	Scheduled to begin later	–	Y		Danan Tarver danan.tarver@fda.hhs.gov
221	XI-C	1125		NO		Not later than 1 year after the date of enactment, FDA shall submit a report to Congress on the milestones and a completion date for developing and implementing a comprehensive information technology strategic plan, a comprehensive inventory of FDA's information technology systems, how FDA uses the strategic plan to guide the agency's modernization projects; and the extent to which FDA is implementing information technology recommendations of the Government Accountability Office.	Report to Congress	7/9/2013	7/9/2013	6/10/2013	OO (OIM)	Completed	11/4/2013	Y	Completed 11/4/2013	Carolyn Yancey Carolyn.Yancey@fda.hhs.gov
222	XI-C	1125		NO		GAO is required to report on the comprehensive IT plan and the implementation of such plan by the FDA, reporting progress made by the FDA.	GAO Report	12/31/2015	12/31/2015	12/31/2015	GAO/OPP	Scheduled to begin later	–	N		Claudia Grillo Claudia.grillo@fda.hhs.gov
223	XI-C	1126		NO		Requires various ongoing efforts related to regulatory science regarding nanotechnology in FDA-regulated products	Other	–	8/1/2013	8/1/2013	OCS	Completed	8/1/2013	N		Jed Costanza jed.costanza@fda.hhs.gov
224	XI-C	1127		NO		GAO report on online pharmacy websites that violate state or federal law	GAO Report	7/9/2013	7/9/2013	7/9/2013	GAO/OPP	Completed	7/13/2013	N	Final Report issued 7/13/13 Internet Pharmacies: Federal Agencies and States Face Challenges Combating Rogue Sites http://www.gao.gov/products/GAO-13-560	http://www.gao.gov/products/GAO-13-560
225	XI-C	1128		NO		Not later than one year after the date of enactment, FDA shall submit a report to Congress on the agency's small business assistance activities, including information on all of FDA's small business assistance offices, partnership efforts between FDA and the Small Business Administration, outreach efforts to small businesses, and other specified topics.	Report to Congress	7/9/2013	7/9/2013	6/17/2013	OP	Completed	7/9/2013	Y	Completed July 9, 2013 http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM360058.pdf	

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226	XI-C	1131		NO		"Not later than one year after enactment, FDA will submit a report to Congress on a strategic management plan for CDER, CBER, and CDRH which will include goals and priorities for improving efficiency, actions that will develop the workforce at all the centers, and the mechanisms that will be used to measure progress in achieving the goals of the plan.	Strategic Plan	7/9/2013	7/9/2013	6/14/2013	OPL	Completed	7/9/2012	Y	Completed July 9, 2013 http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM360047.pdf	Patricia Stewart patricia.stewart@fda.hhs.gov
227	XI-C	1132	(b)(c)	NO		Not later than 1 year after the date of enactment, FDA shall issue guidance describing the types of modifications to approved Risk Evaluation and Mitigation Strategies that shall be considered to be minor modifications of such strategies for the purposes of section 505-1(h)(2)(A).	Draft Guidance	7/9/2013	7/9/2013	7/9/2013	CDER	Undergoing FDA Clearance	–	Y		druginfo@fda.hhs.gov
228	XI-C	1136		NO		Beginning at least two years after FDA finalizes a guidance that specifies the electronic format for any submission related to an IND, BLA, or NDA, all such submissions must be made in the format specified in such guidance *	Draft Guidance	–	1/31/2014	1/31/2014	CDER	Completed	2/6/2014	N	Completed 2/6/2014 FDASIA Electronic Submissions Guidance http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM384686.pdf	
229	XI-C	1136		NO		Beginning at least two years after FDA finalizes a guidance that specifies the electronic format for any submission related to an IND, BLA, or NDA, all such submissions must be made in the format specified in such guidance *	Final Guidance	–	9/30/2014	9/30/2014	CDER	In process, on track to meet due date		N		
230	XI-C	1136		NO		"Beginning after the issuance of final guidance presubmissions and submissions for devices . . . and any supplements to such presubmissions or submissions, shall include an electronic copy of such presubmissions or submissions "	Final Guidance	–	12/31/2012	12/31/2012	CDRH	Completed	12/31/2012	N	Action Completed Dec 31, 2012 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf	
231	XI-C	1137		NO		FDA shall develop and implement strategies to solicit patients' views during the medical product development and regulatory processes, including fostering participation of a patient representative who may serve as a special government employee in appropriate agency meetings with medical product sponsors and investigators exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry	Plan	–	–		OSHI	Scheduled to begin later	–	N		
232	XI-C	1138		NO		Not later than one year after the date of enactment, FDA must issue a communication plan to inform and educate health care providers and patients, with a particular focus on underrepresented subpopulations, on the benefits and risks of medical products. FDA must seek public comment on the communication plan and post it on the agency's Internet website.	Plan	7/9/2013	7/9/2013	7/9/2013	OMH OPA	Completed	7/9/2013	Y	Completed 07/09/2013 http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM359890.pdf Will open docket for comment on the plan	Jonca.Bull@fda.hhs.gov

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233	XI-C	1139		NO		Not later than 60 days after the date of enactment (if practicable) FDA must hold a public meeting to ask for advice and recommendations to help make scheduling recommendations to the Drug Enforcement Administration regarding drugs that contain hydrocodone, either combined with other pain medicines (analgesics) or used as a cough medicine (antitussive).	Public Meeting	9/7/2012	10/29/2012		CDER	Completed	1/24/2013	Y	This meeting was rescheduled to January 2013 due to the postponement of the October 29-30, 2012, because of the unanticipated weather conditions caused by Hurricane Sandy	CDER EXECSEC
234	XI-C	1140		NO		GAO study on benefits and efficiencies of electronic patient labeling of prescription drugs	GAO Report	7/9/2013	7/9/2013	7/9/2013	GAO/OPP	Completed	8/1/2013	N	Final Report Issued 8/1/13 GAO released the final report on Electronic Drug Labeling: No Consensus on the Advantages and Disadvantages of Its Exclusive Use http://www.gao.gov/products/GAO-13-592	http://www.gao.gov/products/GAO-13-592
235	XI-C	1141		NO		The Secretary may facilitate, and, as appropriate, may consult with the Attorney General to facilitate, to develop recommendations for interoperability standards to exchange prescription drug monitoring information across state lines by states receiving grants under the Harold Rogers Prescription Drug Monitoring Program (PDMP) and the Controlled Substance Monitoring Program. The section also imposes requirements for information to consider when developing recommendations	Plan	7/9/2013	7/9/2013	10/23/2013	CDER/CDC	Completed	10/23/2013	N	CDC sent report to Congress on 10/23/2013 ONC is working on publishing the 1141 report on the web DDI and CDER have copies of the report.	druginfo@fda.hhs.gov
236	XI-C	1141		NO		Not later than one year after the date of enactment, FDA must submit a report to Congress on enhancing the interoperability of State prescription drug monitoring programs with other technologies used for detecting and reducing fraud, diversion, and abuse of prescription drugs.	Report to Congress	7/9/2013	7/9/2013	10/23/2013	CDER/SAMSHA/ONCDP	Completed	10/23/2013	N	Report has not been posted on any public web page, as of 10/23/2013. But CDER has a copy of the final report that has already been sent to the Hill	druginfo@fda.hhs.gov
237	XI-C	1142	(e)(1)	NO	NA	Not later than February 1 of each year, FDA shall submit a report to Congress describing specific information on FDA advisory committees including such things as the number of people nominated to the committees, the number who are nominated and willing to serve, the number of vacancies on committees, and the number of people contacted to serve on a committee who did not because of the potential for their participation to constitute a disqualifying financial interest under federal law	Report to Congress	2/1/2014	2/1/2014	2/1/2014	ACOMS	Completed	2/3/2014	Y	Completed 02/03/2014 http://www.fda.gov/downloads/AdvisoryCommittees/AboutAdvisoryCommittees/UCM396811.pdf	Michael Ortwerth michael.ortwerth@fda.hhs.gov
238	XI-C	1142	(e)(2)	NO	NA	Not later than 30 days after submitting any report under 712(e)(1) of the FDCA to Congress, FDA shall make the report available to the public.	Public Report	3/1/2014	3/1/2014	3/1/2014	ACOMS	Completed	5/12/2014	N		Michael Ortwerth michael.ortwerth@fda.hhs.gov
239	XI-C	1142	(g)	NO	NA	FDA shall issue guidance describing how it reviews financial interests that do not meet the statutory definition of a disqualifying interest under section 208 of Title 18, United States Code for the purposes of participating in a particular matter	Draft Guidance	--	12/31/2014	12/31/2014	ACOMS	In process, on track to meet due date	–	Y		Michael Ortwerth michael.ortwerth@fda.hhs.gov

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240	XI-C	1142		NO	NA	[* No statutory language *] Update 3 existing Guidance documents for Advisory Committees to conform to changes in the FD&C Act enacted as part of FDASIA	Draft and Final Guidances	–	5/31/2014		ACOMS	In process, on track to meet due date	–	N	1 Update Guidance on "Public Availability of Advisory Committee Members' Financial Interest Information and Waivers" to conform to changes in the FD&C Act enacted as part of FDASIA (target date 3/30/2014) 2. Update Guidance on "The Open Public Hearing at FDA Advisory Committee Meetings" to conform to changes in the FD&C Act enacted as part of FDASIA (completed 5/15/2013) 3 Update Guidance on "Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees" to conform to changes in the FD&C Act enacted as part of FDASIA (target date 5/31/2014)	Michael Ortwerth michael.ortwerth@fda.hhs.gov
241	XI-D	1152		NO		Amends the Controlled Substances Act to add synthetic cannabinoids and other synthetic substances to Schedule I of the CSA	Other	–	–		DOJ/CDER	Scheduled to begin later	–	N		

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