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. 20515-6115

SEP 09 2014

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity 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." This is a partial response for the record to questions posed by you and several other Committee Members to Dr. Janet Woodcock, in a letter we received on December 17, 2013.

Please let us know if you have any further questions.

Sincerely,

Thomas A. Kraus
Associate Commissioner
for Legislation

Enclosure

cc: The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce

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

The Honorable Joseph R. Pitts

1. **Congress enacted Title VIII of FDASIA, entitled "Generating Antibiotic Incentives Now (GAIN)," to provide incentives for the development of antibacterial and antifungal drugs for human use intended to treat serious and life threatening infections. Under GAIN, a drug may be designated as a qualified infectious disease product (QIDP) if it meets the criteria outlined in the statute. A drug that receives QIDP designation is eligible under the statute for fast track designation and priority review. According to section 505E(d)(I), the Secretary shall, not later than 60 days after the submission of a QIDP designation request, determine whether the drug is a qualified infectious disease product. The Committee understands that the Agency has not met the 60-day deadline on a number of submissions for QIDP designation.**

December 31, 2013, was used as a cut-off date for counting actions related to submissions for QIDP designation. As of December 31, 2013, the Agency had received 45 QIDP designation requests. Of those 45 requests, 41 were due on or before December 31. Of those, 32 (78 percent) were acted on within 60 days. As discussed in more detail in response to Question 2 below, most delays have been due to complex legal, scientific, and policy questions that needed to be addressed in the context of particular requests for QIDP designation.

2. **Is there presently a backlog of pending QIDP submissions at the Agency? What percent of QIDP designations has the Agency acted on timely? As of September 30, 2013, how many sponsor submissions for QIDP designation were beyond the 60-day review period? And how many determinations, if any, has the Agency made since October 16, 2013? Is there presently a legal or policy issue under review within the Agency regarding QIDP designations?**

As of December 31, 2013, the Agency had received 45 QIDP designation requests. Of those 45 requests, 41 were due on or before December 31. Of those, 32 (78 percent) were acted on within 60 days. Most delays have been due to complex legal, scientific, and policy questions that needed to be addressed in the context of particular requests for QIDP designation. As of September 30, 2013, three requests were pending beyond their 60-day review period. Two other QIDP requests that were acted upon prior to September 30, 2013, were overdue at the time of action. Eight determinations were made between October 16 and December 31, 2013. As with any new legislation, there have been a number of legal and policy issues that had to be considered since the enactment of FDASIA. However, there are currently no issues that need to be resolved associated with any pending QIDP request.

3. **Congress is concerned that certain agency interpretations of the GAIN Act may inadvertently limit the development incentives Congress enacted. For example, we have heard that the agency may be designating QIDP status for a drug in a specific indication, rather than for a drug itself, and that the provisions of21 U.S.C. 355f(c) "Limitations" may be interpreted in a way that renders 5-year exclusivity extension unavailable if a**

sponsor initially seeks approval for a different indication. Requiring a particular sequencing of indications creates hurdles that could reduce the incentives to develop the drug, even once a drug has received QIDP status and therefore has been deemed to be intended to treat serious or life threatening conditions. Please explain how FDA has interpreted the statutory exclusivity to apply if a drug receives QIDP designation, but then receives a first NDA approval for a different indication than the one described in the QIDP application.

We believe that the Agency's implementation of the GAIN Act has been consistent with Congress' intended goal to encourage the development of antibacterial and antifungal drugs that treat pathogens that cause serious or life-threatening infections. Indeed, as of December 31, 2013, FDA has granted 35 QIDP designations. FDA believes the number of QIDP designations granted indicates that the Agency's interpretation of the GAIN provisions have not limited the development incentives intended by Congress.

As of December 2013, the Agency has not yet approved a new drug application (NDA) or made an exclusivity determination for a drug that has received QIDP designation. Since that time, the Agency has approved two drugs that were designated as QIDPs. However, because both of these drugs were new chemical entities and were approved for the indications for which they had received QIDP designation, we have not yet interpreted and applied the provisions of 355f(c) ("Limitations").

4. **Does FDA interpret 21 U.S.C. 360n-1 and 356(a)(l) (as amended by the GAIN Act) to require the Agency to mandatorily apply fast track and priority review procedures, or only if an application for a product with QIDP status requests these review timelines and procedures? Does FDA regard this issue as impacting the availability of exclusivity in any way?**

FDA determines whether an application qualifies for priority review (versus standard review) for every application, not just when requested by the applicant. Therefore, the Agency will grant priority review to an application for a QIDP, regardless of whether the sponsor requests priority review status. However, while the GAIN Act guarantees that a product receiving a QIDP designation automatically qualifies for fast track designation, 21 U.S.C. 356(a)(1) states that fast track is granted "at the request of the sponsor of a drug." This request can be made with the QIDP designation request, or at any time during drug development, and can be quite simple (e.g., "Company X requests designations of QIDP and fast-track status for…"). No additional justification by the sponsor is needed to support the fast track designation of a drug that is granted a QIDP designation. The Agency does not believe this issue will impact the availability of exclusivity.

5. **To further oversight and reassessment of QIDP incentives within 5 years after the enactment of GAIN, the Secretary of Health and Human Services must submit certain program information to the House Energy and Commerce and Senate HELP Committees, including, for example, a list of qualified infectious disease products and information on the types of exclusivity granted for each product, along with other product information. Does FDA intend to limit the disclosed information in accordance with existing protections of the Freedom of Information Act and other applicable laws? For example,**

will information about unapproved applications be disclosed or protected from disclosure?

FDA intends to limit the disclosed information in accordance with existing protections of the Freedom of Information Act and other applicable laws and regulations. Specific information about unapproved applications will not be disclosed.

6. **The Committee would like to thank the FDA for its outstanding work to address the public health crisis of unintentional overdoes of acetaminophen. Recognizing the high incidence of liver damage due to acetaminophen overdosing, the Agency has responded with a variety of measures to improve safety, including developing education programs and improving the labeling of acetaminophen-containing products. However, one aspect of the Agency's response still concerns me and that is the removal of prescription combination products containing acetaminophen in quantities greater than 325 mg by January 14, 2014.**

   So that we can continue to protect the health of U.S. citizens from the unintentional overdoses of acetaminophen, please provide a response to the following questions:

   a. **What are the plans of the FDA to enforce the January 14, 2014, deadline and ensure that no prescription products containing no more than 325 mg of acetaminophen remain on the market after that date?**

   FDA received voluntary requests for withdrawal from all but six of the affected holders of Abbreviated New Drug Applications (ANDAs) for prescription combination drug products containing more than 325 mg acetaminophen per dosage unit. This comprised 108 individual ANDAs. Those products were listed in a *Federal Register* Notice that immediately withdrew approval of those applications upon its publication on May 1, 2014.

   On May 1, 2014, FDA also announced its intention to withdraw approval of the ANDAs for the six remaining sponsors that did not voluntarily withdraw approval via a Notice and Opportunity for a Hearing (NOOH). All of those sponsors had already stopped marketing their products. None of the ANDA holders listed in the NOOH requested a hearing, and FDA intends to issue a notice withdrawing approval of their ANDAs shortly. Upon publication of that notice in the *Federal Register*, there will no longer be any approved prescription combination drug products containing more than 325 mg acetaminophen per dosage unit.

   b. **Does the FDA intend to do a full and total recall on January 14, 2014, including one that has pharmacies removing these products from inventory for sale? If not, what steps is the FDA taking today to ensure that manufacturers have stopped production, distributors have slowed distribution, wholesalers have scaled back inventory, and pharmacies are allowing current stock of the high dose products to run out and are prepared to transition to the new products on January 14, 2014?**

Please see our answer to Question 6a above, regarding withdrawal of approval or prescription combination drug products containing more than 325 mg acetaminophen per dosage unit. In addition, FDA issued multiple statements and reminders to health care providers to stop prescribing prescription drug combination products that contain more than 325 mg of acetaminophen per dosage unit. In addition, we recommended that pharmacists stop dispensing those products, and that when a pharmacist receives a prescription for a product containing more than 325 mg of acetaminophen per dosage unit, they contact the prescriber to discuss a product with a lower dose of acetaminophen.

c. **If a full and total recall on January 14, 2014, is not the intention of the FDA, are you going to share with the industry and the public the rationale for that decision, in light of the safety concerns that prompted the original request in January 2011?**

As noted in our responses to Question 6a above, FDA has initiated, and is close to completing, the necessary regulatory steps to withdraw approval of all ANDAs for prescription combination drug products containing more than 325 mg acetaminophen per dosage unit.

Consistent with the Agency's authority, we often implement safety withdrawals by requesting that sponsors voluntarily withdraw the product from the market. Subsequent regulatory steps are then undertaken to formally withdraw the applications for the products that were not voluntarily withdrawn and to make a determination that they have been withdrawn for reasons of safety. In the case of prescription combination drug products containing acetaminophen, given the large number of applications and various regulatory considerations (such as the fact that the subject drugs are "scheduled" and subject to Drug Enforcement Administration (DEA) quotas), we used a public notice with ample lead time to initiate this action.

Generally, we only request withdrawal of a product from the patient or pharmacy level where there is a risk of imminent harm to the patient. The intent of this effort was to reduce the amount of acetaminophen to 325 mg per dosage unit so as to lessen the overall exposure of patients to acetaminophen and thereby diminish the potential for exceeding the toxic threshold of the drug that could cause liver injury. The Agency has not identified an imminent hazard associated with the use of the product by individual patients that would warrant immediate removal of these products at the patient level.

Finally, we believe that by telling health care providers to stop prescribing combination drug products that contain more than 325 mg of acetaminophen per dosage unit and pharmacists to stop dispensing those products, the products will leave the market in an efficient manner, and that this exit also will be sufficiently gradual so as not to disrupt clinical practice or create shortages of these important drugs.

d. **Does the FDA have an early indication of whether all pharmaceutical manufacturers intend to meet the FDA's request that all prescription products with more than 325 mg of acetaminophen be withdrawn from the market by January 14, 2014?**

Yes. As noted in our response to Question 6a above, as of January 14, 2014, all but six of the affected ANDA holders voluntarily withdrew their products from the market. The remaining six sponsors had already discontinued marketing their products, but did not adequately respond to the January 2011 *Federal Register* notice. Therefore, those sponsors were notified via a NOOH that approval of their applications was going to be withdrawn. Because none of them requested a hearing, FDA proceeded with the necessary regulatory steps to withdraw approval of their applications.

7. **How does the FDA work with DEA after they have reviewed an application and made a scheduling recommendation? Is the DEAs scheduling review process incorporated into the PDUFA timeline? What could be done to improve the DEA scheduling process from the FDA's perspective?**

Generally, after DEA receives a scheduling recommendation from the Department of Health and Human Services (HHS) and prior to DEA's publication of the Notice of Proposed Rule Making (NPRM), FDA staff are available to provide clarifying information to any questions about the recommendation that DEA may need answered. The DEA scheduling review process is not incorporated into the PDUFA timeline, because scheduling of a drug falls under the Controlled Substances Act, which DEA administers, and not the Federal Food, Drug, and Cosmetic Act (FD&C Act), under which drugs are approved by FDA. While FDA understands how important it is to make sure the scheduling process is efficient and timely, we do not have enough knowledge of the DEA internal review processes to make any comments on ways to improve them. FDA has focused our efforts on improving our internal processes, with a goal of preparing a scientifically rigorous recommendation for HHS to transmit to DEA as quickly as possible.

8. **One of the anecdotes we hear from industry and investors, and the data seem to support, is that for certain therapeutic areas, such as oncology, the FDA has an exceptional track record of rigorous but efficient and timely review process, but for others it is long and drawn out. FDASIA requires some very basic review-level data and provides an opportunity for further analysis to enhance our understanding by looking at review times and other metrics by review division. Recognizing differences in science and disease understanding, what are you doing to replicate some of the best practices in your strongest review divisions across the agency?**

CDER developed a standardized review model that applies to the review of all new drugs and biologics applications. The model is called "21st Century Review" and has been applied to all applications across all review divisions, starting in FY 2009. CDER staff has received extensive training on this new review model, which was designed to ensure consistent application of best practices across all review divisions. Implementation of the new review model has been very successful and served to lay the groundwork for implementation of the "Program" for review of new molecular entity NDAs and new BLAs that is a new performance goal under PDUFA V. Of note, CDER's Office of Hematology and Oncology Products (OHOP) has established a commendable track record in expediting the review of promising new drugs for patients with cancer. The same principles and best practices utilized in OHOP are also applied in other divisions and offices to expedite the review and approval of promising new drugs that treat serious and life-threatening diseases in patients with unmet medical need. For example, a new drug that treats the underlying cause of cystic fibrosis in some patients with that rare genetic disease was approved in

January 2012 by the Division of Pulmonary, Allergy, and Rheumatology Products, several months ahead of the PDFUA goal date.

In addition, under the new Breakthrough Therapy (BT) program that was part of FDASIA, FDA has made an institutional commitment to work closely with sponsors to expedite the development and approval of new drugs for serious and life-threatening diseases that may provide a substantial improvement over existing therapies. This commitment includes involvement of senior FDA leadership in the review process. While almost half of the BT designations granted by FDA to date have been for drugs intended to treat hematologic and oncologic diseases, many other CDER review divisions have also granted BT designations and are committed to supporting the goals of the program, including utilizing all the available tools to expedite development and approval of these promising new drugs.

10. Since GDUFA does not provide review of predictability or metrics for backlog ANDAs or for ANDAs submitted during the first two years of GDUFA it is difficult to quantify the work the Agency has been doing. What has the FDA done to improve communication with industry in order for manufacturers to be able to predict when the FDA might take action on these applications?

FDA appreciates industry's need for predictability and has been collaborating with the Generic Pharmaceutical Association (GPhA) for the past several months to develop improvements in this regard. We have taken several steps in response to industry's concerns.

For example, FDA has begun to issue Complete Response (CR) letters to generic drug applicants. These CR letters outline deficiencies found after completion of an application review from all review disciplines (with or without inspection). These and Easily-Correctable Deficiency (ECD) letters convey deficiencies found during the review of an application.

FDA has also initiated assigning internal goal dates to applications to proactively align the application review with the goal due dates scheduled to be implemented in year three of GDUFA. We will inform industry about when to expect Agency action on specific applications.

In addition, FDA's Center for Drug Evaluation and Research (CDER) is developing a systematic process to provide meaningful status updates and also predict the likely timing of action on pending work. As an early step in this process, FDA published a Manual of Policies and Procedures (MAPP)[1] which, among other items, designates the Regulatory Project Manager as the primary point of contact for all inquiries on ANDA status. This policy is consistent with FDA practices in other Centers and other User Fee Programs. Designating one point of contact ensures centralized and streamlined communication flow, good communication practices, consistency in information provided, and appropriate documentation of communication. The Agency is also working on a MAPP to provide clarity and predictability regarding prioritization of different types of submissions, including those in the backlog and those submitted during Years 1 and 2 of GDUFA. We have been consulting with industry regarding prioritization.

Our goal is to address these issues systematically, rather than on a case-by-case basis. Prior to GDUFA, industry representatives placed a high volume of informal status inquiries to FDA

[1] See MAPP 5020.1: Responding to Industry Inquiries with respect to Abbreviated New Drug Applications in the Office of Generic Drugs.

reviewers, supervisors, and senior staff, and informally advocated to expedite review of the most commercially significant submissions. FDA responded to these inquiries on an ad hoc basis. This practice was highly resource-intensive and often inadequately documented. It could also result in differential treatment of similarly situated applicants, giving rise to fairness and consistency concerns.

Many of the steps we are taking to improve communications go above and beyond our negotiated GDUFA commitments, and constitute an extra effort to ease the generic drug industry's transition into a user fee environment for the first time. We welcome the opportunity to brief your staff on these improvements.

11. **Of the 234 new hires under GDUFA, will you breakdown approximately how many hires were on-board in each of Q I, Q2, Q3 and Q4 of FY 20 13? Are all 234 new hires actually on-board today? New hires is an important foundational goal of GDUFA, and actually one of the only goals for FY 2013 and FY 2014. Will you further explain why it took so long for the FDA to actually hire and on-board the 234 FTEs?**

FDA agrees that hiring new employees under GDUFA is an important foundational goal. As such, coordination within the Agency was essential in order to properly identify the necessary positions to meet the business needs for the generic drugs program. Numerous rounds of vetting and prioritization also took place to ensure that the Agency was properly prepared for these new hires. Additionally, to address the large number of similar positions, a corporate recruitment approach similar to that of the National Institutes of Health was developed to increase overall efficiency.

FDA is pleased to note that as of December 2013, almost all 234 new hires were on board. Recruitment efforts continue to bring new hires on board.

Hiring by Quarters for FY 2013:
Quarter 1 – 62
Quarter 2 – 25
Quarter 3 – 87
Quarter 4 – 60

12. **We recognize training is vital for new hires. Approximately how long does it take a new FDA Employee to become a fully productive ANDA reviewer or facility inspector?**

The length of time until a new reviewer or facility inspector becomes fully productive is dependent upon their experience level. With new hires of limited experience, it generally takes approximately two years for the new hire to reach this point. As part of the initial hiring strategy, FDA targeted recruitment and has hired staff with experience to shorten this time frame. For example, many of our new chemistry reviewers arrived at FDA with previous pharmaceutical industry experience, which should shorten the time it will take for them to be fully productive.

13. **Given the backlog of pending ANDAs and facility inspections (the tenets or principles on which GDUFA was negotiated, legislated and implemented), will you give the Committee an estimate on how many of these new hires are scientists dedicated to ANDA review? How many are to be facility inspections? And of the remaining 234 not accounted for in**

these two principle job functions, what job functions will they be providing related to GDUFA?

As of December 2013, an estimated 98 positions are dedicated to ANDA review. An estimated 80 positions in the Office of Regulatory Affairs are dedicated to facility inspections. The majority of the remaining positions will provide support in the form of information technology and administrative duties. Information technology support for the generics program will include the building of new IT systems, such as the one needed to track and monitor review times, as well as a billing system. Administrative positions will be dedicated to offer program support infrastructure, including staff, to bring on and train the new hires.

14. **For FY14, you have a goal of approximately 465 new hires. Please provide the breakdown by Quarter in FY 14 for on-boarding these new hires and the functional areas they are to be assigned.**

    Despite the slow start, I commend the FDA for being able to fill so many positions in the latter half of FY 13. Does the rapid hiring at the end of FY 13 mean that the FDA now has a well- established hiring process for the GDUFA program and will be able to meet this hiring goal earlier in the year for FY14? For example, it is my understanding that GDUFA is estimated to support the hiring of about 900 new FDA employees by the end of FY 15. How many of those new hires will be dedicated to actual technical review of pending ANDAs and inspectional review of facilities, as opposed to administrative functions within CDER?

As of August 2014, FDA has on-boarded 447 GDUFA hires, reaching 96% of the goal for FY2014. Approximately an additional 167 positions are pending. The FY2014 quarterly breakdown is as follows:

FY 2014 Breakdown of GDUFA Hires	
Quarter 1	90
Quarter 2	112
Quarter 3	185
Quarter 4 (as of August 2014)	60
TOTAL	447

The functional areas that the GDUFA hires support are review, inspection, administration and program support.

The Agency has an established hiring process. The Corporate Recruiting Process we have adopted allows FDA to announce positions for 120 days to fulfill multiple hiring demands for similar positions. This eliminates the need to create multiple and repetitive vacancy announcements. It also allows hiring managers to receive certificates of eligible candidates every 30 days without the delay of repeating the job announcement process. Further, the Agency continues to actively engage in outreach efforts to attract and identify potential candidates. FY 2013 had 98 of 234 positions dedicated to ANDA review, or 42 percent. In keeping with a similar average, we estimate that for FY 2014, there should be 187 new reviewer positions in the Office of Generic Drugs, or 40 percent of the 465 positions needed. We estimate that for FY 2015, the remaining 222 positions will be

added to equal the Agency goal of 921. Staying consistent to the previous years, 40 percent for FY 2015 would be 89 new hires dedicated to ANDA review.

15. Over the past several years, the U.S. Food and Drug Administration (FDA) has been tasked with the evaluation and the weighing of the appropriate use of opioid analgesic drug products. For the millions of American patients experiencing an acute medical need or living with chronic pain, opioids, when prescribed appropriately, can allow patients to manage their pain as well as significantly improve their quality of life.

At the same time, this Committee has become increasingly concerned about the abuse and misuse of opioid products, which have reached epidemic proportions in certain parts of the United States. The value of, and access to, these drugs for patients in pain is unquestioned. My concern is that the FDA has yet to establish nor has yet determined how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse.

Abuse Deterrent Formulations (ADFs) for scheduled narcotics show significant promise to reduce prescription drug abuse. While not yet perfect, even the FDA has recognized that the ADF technology as applied to the recently approved reformulation of OxyContin is a significant step in protecting patient's access while curbing abuse of this powerful opioid.

With the foregoing in mind:

a. When does the agency expect to finalize its draft labeling guidance?

FDA shares your concerns regarding prescription drug abuse, including the abuse of opioid analgesics. We are strongly committed to finding ways to reduce abuse and misuse of these medications. The draft guidance addresses both the evaluation and labeling of abuse-deterrent opioids. We intend to finalize the guidance as soon as possible. The evaluation of abuse-deterrent formulations (ADFs) is a new and evolving area of scientific and regulatory investigation, and FDA recently participated in a scientific meeting to hear comments about issues pertaining to ADFs. In addition, FDA is directly supporting research into ADFs, both through the conduct of research in FDA laboratories and also by supporting independent scientific research at Purdue University and the University of Maryland. FDA is also working with the manufacturers as they develop new ways to prevent misuse and abuse. FDA believes that these new approaches are important to understand, and we are doing what we can to support their development and use.

b. Will you consider the approach outlined in the draft labeling guidance to be equally applicable to products other than opioids?

At the present time, we are focusing our policies on the opioid drug products. Certain other categories of prescription drug products, such as stimulants used for Attention-Deficit/Hyperactivity Disorder, are also subject to misuse and abuse. However, the draft guidance is focused on opioids, as their patterns of abuse are different from those of non-opioid drugs, and the abuse of opioids poses a greater public health risk.

c. Does FDA believe that it has sufficient existing authority to incentivize development of abuse deterrent products?

FDA understands the importance of finding ways to reward the development of successful ADFs (for example, by approving labeling, which includes accurate descriptions of a product's abuse-deterrent properties). For example, applications for abuse-deterrent products generally will be eligible for fast track and priority review. The FD&C Act also provides for certain periods of marketing exclusivity, if the applicable criteria are met.

If FDA concludes that an extended-release/long-acting (ER/LA) opioid drug product has abuse-deterrent properties, the Agency has authority under current law to require a generic version of that product to also have abuse-deterrent properties.

d. If so, will the FDA utilize all of its existing authorities to create incentives for such products?

FDA continues to work to encourage the development of ADFs of opioids through a variety of actions, including meetings with sponsors, guidance, and accelerated reviews, wherever appropriate.

e. Why did the FDA approve a new product, Zohydro, without requiring an ADF in the formulation? Can Zohydro in its approved form be crushed and snorted or crushed diluted and injected?

FDA approved Zohydro ER after concluding that its benefits outweigh its risks, notwithstanding the fact that the product does not have abuse-deterrent properties. We approved this product because it offers a new option for the management of pain severe enough to require daily, around-the-clock, long-term treatment and for which alternative treatment options may be inadequate. In addition, as a single-entity hydrocodone product, it is not associated with the liver toxicity risk of the combination hydrocodone products that include acetaminophen. Zohydro ER is the first opioid to have strengthened labeling to help prescribers identify the select group of patients for whom it could be beneficial. Like all opioids, Zohydro ER has the potential for misuse and abuse, and the strengthened labeling also warns prescribers and patients about the risks of Zohydro ER and strongly recommends careful monitoring to reduce the risks of misuse and abuse. FDA takes the safety of Zohydro ER and all opioids very seriously and will actively monitor their utilization to identify any emerging issues.

All opioids are subject to abuse, including those that have abuse-deterrent properties. We expect that some people intent on abusing these drugs will be able to circumvent many of the abuse-deterrent formulations currently on the market or in development. In addition, no products or technologies have yet proven successful at deterring oral abuse—the most common form of opioid analgesic abuse. As noted previously, FDA believes the new warnings and education for prescribers and patients will help support appropriate prescribing and follow up for patients.

f. Does the FDA believe that there will be an expanded use of ADFs without an Agency mandate to include such formulations in new NDAs/ ANDAs?

We believe that there are ways to expand the development and use of ADFs using our existing authorities. FDA is actively discussing and supporting the development of ADFs when manufacturers meet with the Agency to discuss development of new products. In those meetings, FDA reinforces our goals to encourage the development of robust and successful ADFs for opioids, wherever possible. In addition, as discussed above, FDA anticipates that appropriately describing a product's abuse-deterrent properties in approved labeling will assist prescribers and payers in making decisions about which products to use and increase the use of products with ADFs.

16. In January, the FDA issued a draft guidance for industry on development and labeling for abuse deterrent formulation ("ADF") products. Although the draft guidance lists the basic concepts of FDAs perspective on ADFs, from technology manufacturers the paper lacks both clarity and detail necessary to support the development and broad application of ADF technology for abused products. For example,

a. Some of the references and examples made in the guidance are applicable to only a subset of technology approaches and not relevant to others.

The scientific and regulatory concepts set forth in the draft guidance should be applicable to a wide range of technologies in addition to those discussed directly in the document. Recognizing that the technologies being used are all different, the intent of the Guidance is to provide a framework about the types of non-clinical and clinical studies that we believe will be most useful in assessing ADFs, as well as how FDA will assess these studies and include them, when appropriate, into labeling.

b. There is no detailed guidance on differential requirements for immediate release opioids and combination products.

Given the higher public health risk posed by ER/LA opioids as a result of the higher amounts of opioids in each dose, the focus of FDA has been on the development of ADFs for these products. However, many of the scientific and regulatory concepts set forth in the draft guidance will be applicable to immediate release (IR) products. Also, the evaluation and labeling of combination products (such as an opioid agonist and antagonist combined in a single product, e.g., morphine sulfate/naltrexone) are discussed explicitly in several sections of the draft guidance document.

c. A perspective on how to address newly introduced ADF products that do not have a non-ADF predecessor version or reference product is missing.

The development of an ADF product that lacks a non-ADF predecessor is not discussed specifically in the draft guidance, but we believe the scientific and regulatory concepts discussed in the draft guidance document may be applicable to such development programs. As discussed in the draft guidance, FDA will take a flexible, adaptive approach to the evaluation and labeling of potentially abuse-deterrent products. FDA will evaluate each potential ADF on a case-by-case basis and work with the sponsors of novel products to

provide product-specific advice. For example, we believe that non-clinical and human studies comparing the new ADF formulation to the drug substance can help to predict the effect of the ADF on abuse. When the data predict or show that a product's potentially abuse-deterrent properties can be expected to—or actually do—result in a meaningful reduction in that product's abuse potential, FDA will approve inclusion of these data, together with an accurate characterization of what the data mean, in product labeling.

d. Last, there is not any structured guidance on how FDA is going to assess ANDA applications in the context of the guidance requirements.

FDA is currently developing guidance on the approach we intend to take when assessing generic forms of opioids when there are approved innovators that are demonstrated to be abuse-deterrent, and that guidance will be published in draft form as soon as possible.

Although technology developers and manufacturers started developing ADF technologies more than ten years ago, the FDA claims that the science of abuse deterrent formulation assessment is new and requires case-by-case assessment. This position lacks the clarity and reliability necessary for companies that require continuous funding and investment for their technology development.

Will you give this Committee a specific date by when the FDA will finalize the guidance for ADF development labeling, including addressing the missing pieces I just mentioned?

We intend to finalize the guidance as soon as possible.

17. Do you believe that FDA is lacking legislative authority to reject approval for non-ADF extended release opioid products?

Please see responses to Question 15e and f (above).

18. Does the FDA believe it should be able to continually progress the opioid market into one where all opioids will have to have ADF technology to protect and minimize misuse and abuse?

FDA strongly supports the development and broader use of effective opioids with abuse-deterrent properties. As explained in previous responses, however, we do not believe it is feasible or appropriate to require all products in the class to have abuse-deterrent properties, at this time. In light of the need for further data and scientific development in this nascent and rapidly evolving area, FDA intends to continue to take a product-by-product approach to regulatory decisions concerning the safety and effectiveness of opioid products.

23. Please provide the Agency's Social Media budget and strategy plan to the Committee.

FDA strives to present clear, accurate, timely, and relevant information to Americans in the same online spaces as many other purveyors of health and safety information. To do this effectively, we proactively embrace new technologies on an ongoing basis. As a public health and regulatory agency, FDA must provide the public with clear, concise, and accurate information on a wide range of important public health initiatives. In doing so, the Agency uses multiple communication

channels, including social media. FDA encourages the use of social media technologies to enhance communication, collaboration, and information exchange in support of our mission to protect and promote public health. Expanding our external interactions increases the potential for our stakeholders to gain a better understanding of the work and actions that the Agency takes regarding all FDA-regulated products.

For example, FDA uses Twitter regularly to distribute information on product approvals, Warning Letters, recalls, policy announcements and other relevant information. More than 800,000 followers have signed up to receive these tweets, many of which are forwarded, extending their reach to millions. FDA posts similar information to its Facebook page, which is tracked by nearly 95,000 people.

With regard to budget, there is no specific dollar amount allotted to social media within FDA; rather, social media is incorporated into the communication budgets of FDA's Office of External Affairs (OEA) and the various FDA centers.

OEA is responsible for setting the Agency-wide social media strategy as well as ensuring its governance. OEA is currently in the process of developing a strategy to optimize the use of social media in order to further the Agency's mission.

24. It has been the agency's policy and practice that in vivo (human) clinical testing is required to establish bioequivalence for most locally acting topical drugs. What scientific determination did FDA make to justify its departure from this prior policy and practice when it issued its new draft bioequivalence guidance for cyclosporine ophthalmic emulsions?

Under FDA's regulations, bioequivalence (BE) may be demonstrated by several in vivo and in vitro methods. The selection of a specific method used to establish BE will depend upon the purpose of the study, analytical methods available, and the nature of the drug product. FDA issues product-specific guidance documents that set forth recommended approaches for establishing BD for specific drugs.

On June 20, 2013, FDA published a *Federal Register* notice announcing the availability of draft guidance for industry, containing BE recommendations for cyclosporine ophthalmic emulsion. The draft BE guidance addresses two methods for BE studies, an in vitro method and an in vivo method.

The draft guidance recommends that an in vitro method may be used when the proposed generic drug and the reference listed drug (RLD) formulations are qualitatively and quantitatively the same, with respect to active and inactive ingredients. The draft guidance further provides that an in vivo method, i.e., a BE study with clinical endpoints, for cyclosporine ophthalmic emulsion, is requested when the generic drug has a different inactive ingredient, a difference of more than 5 percent in the amount of any inactive ingredient compared to that of the RLD, or unacceptable data from in vitro comparative studies.

FDA opened a public docket to collect comments on the draft guidance from industry, stakeholders, and the general public. FDA will carefully consider all submitted comments on the draft BE guidance for cyclosporine ophthalmic emulsion.

26. The Federal Food, Drug, and Cosmetic Act (Act) stipulates that the critical distinction between a drug and a medical device is that a medical device "does not achieve its primary intended purpose through chemical action within or on the body of man." The plain language of the Act indicates that a device may have more than one primary intended purpose. In 2011, however, FDA issued a draft guidance titled "Classification of Products as Drugs and Devices & Additional Product Classification Issues" indicating that if a product has "multiple therapeutic effects," each would be considered a "primary intended purpose." By designating all purposes as primary, this statement appears to be inconsistent with the plain language of the Act. The draft guidance also states that if any of these intended purposes were achieved through a chemical action within or on the body of a man, the product would not meet the definition of a medical device. This change in policy has resulted in products that would have been historically regulated in the U.S. as devices being regulated as devices in the rest of the world, but regulated as drugs in the United States. I have several questions regarding this draft guidance and how FDA is classifying medical devices:

a. Given that there are numerous products classified as devices that have some chemical action within or on the body of man, would you agree that the draft guidance reflects a substantial policy change by requiring a product to be classified as a drug if any of its intended purposes are achieved through a chemical action within or on the body of a man?

As you note, FDA issued the Draft Guidance on "Classification of Products as Drugs and Devices and Additional Product Classification Issues"[2] and related Draft Guidance on "Interpretation of the Term Chemical Action in the Definition of Device under Section 201(h) of the Federal Food, Drug, and Cosmetic Act"[3] in 2011. These draft guidance documents concern classification of products as drugs and devices. The Agency is currently working to finalize these draft guidance documents.

The Agency does not interpret the statutory definition of device in section 201(h) of the FD&C Act, 21 U.S.C. § 321(h), to exclude all products that exhibit chemical action within or on the body of man. A product that exhibits chemical action within or on the body of man may meet the device definition, provided that the product "does not achieve its primary intended purposes through" such chemical action. Thus, for example, if a product's chemical action contributes to an effect other than a primary intended purpose of the product, the product could fall within the scope of the device definition.

b. Would you agree that similar products should be regulated in the same manner and that the substantial policy change could have an impact on new products being regulated similarly to products on the market prior to issuance of the draft guidance?

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[2] Available at *http://www.fda.gov/RegulatoryInformation/Guidances/ucm258946.htm.*
[3] Available at *http://www.fda.gov/RegulatoryInformation/Guidances/ucm259059.htm.*

FDA strives to regulate similar products in a similar manner. Further, as explained in the draft guidance documents referred to in the response to Question a. (above), FDA classifies products in accordance with the statutory definitions established by Congress. Differences in product composition or intended uses, or both, can affect product classification. Due to such factors, products that appear to be similar may, in fact, not be similar and, thus, have different classifications.

Finalizing the above-referenced draft guidance documents will help regulated entities understand what factors affect product classification so that they can make informed judgments regarding how their products would be classified and what questions they may wish to address with the Agency. It is an important initiative to the Agency to enhance predictability and transparency for industry.

c. The plain language of the Act indicates that a device may have more than one primary purpose. The 2011 FDA draft guidance appears to arbitrarily depart from this plain language. What is the rationale for doing so?

We agree that a device may have more than one primary intended purpose. We intend to make this point clear in the final guidance.

d. This draft guidance has not been finalized but appears to have been implemented by FDA. Would you agree that a draft guidance document should not be implemented until final?

FDA must implement its statutes and regulations, regardless of whether it chooses to issue guidance in an effort to provide greater detail and transparency to industry and other stakeholders. The draft guidance documents referred to in the response to Question a. (above) are meant simply to provide more detail regarding FDA's implementation of its existing statutory and regulatory obligations. Indeed, the process for classifying a product as a drug, device, biological product, or combination product in response to a request for designation has a 60-day time limit for issuing a decision (*see* 21 U.S.C. § 360bbb-2). Therefore, FDA applies current interpretations of the applicable statute and regulations, including applicable case law, to engage in case-by-case decisions on requests for designation within the statutorily mandated time period. FDA also follows its regulations at 21 CFR 10.115 in developing guidance documents.

e. The FDA recently applied its revised interpretation of the Act set out in the 2011 draft guidance to classify a portable body shower as a drug rather than a medical device. The U.S. District Court for the District of Columbia found that the FDA designation of the product as a drug was based on a "doubly grandiose" interpretation of the phrase "primary intended purpose." When and how will FDA revise the 2011 draft guidance to reflect the ruling?

The product to which you refer—Diphoterine Skin Wash—is not a "portable body shower." It is comprised of a pressurized canister that delivers a diphoterine solution onto the skin as an aerosolized mist. It is intended to help prevent or minimize accidental chemical burn injuries. The diphoterine solution is expected to react with harmful chemicals to neutralize

them, draw chemicals from the interior to the exterior of the skin, and displace chemicals from the body. The device canister aids in delivery of the diphoterine solution by allowing its ready delivery onto the skin. FDA classified the product as a combination product consisting of a drug constituent part (the diphoterine solution) and a device constituent part (the aerosol spray canister). Further, consistent with section 503(g)(1) of FD&C Act and FDA's implementing regulations, because the primary mode of action of the combination product is attributable to the drug solution, FDA designated CDER as the lead Center for premarket review and regulation of the product.

As you note, in September 2012, the U.S. District Court for the District of Columbia remanded the Diphoterine Skin Wash classification decision to the Agency for further consideration. Upon reconsideration, the Agency issued a revised classification decision that includes a detailed discussion of the scientific grounds for FDA's determination, and which we believe complies with the court's order.[4] As FDA works to finalize the draft guidance documents referred to in the response to Question a., the Agency will make revisions as necessary in light of the U.S. District Court for the District of Columbia's September 2012 ruling.

f. Despite the court ruling, FDA has persisted in its determination that the portable body shower be classified as a drug. In response to the ruling, FDA created a new "meaningful contribution" standard for determining if a product is a device. Please explain how FDA developed its "meaningful contribution" test and what criteria FDA will apply in determining whether that test is met. How is it that FDA can reinterpret statute seemingly at will?

As noted above, the product to which you refer—Diphoterine Skin Wash—is not a "portable body shower." It is comprised of a pressurized canister that delivers a diphoterine solution onto the skin as an aerosolized mist. It is intended to help prevent or minimize accidental chemical burn injuries. The diphoterine solution is expected to react with harmful chemicals to neutralize them, draw chemicals from the interior to the exterior of the skin, and displace chemicals from the body. The device canister aids in delivery of the diphoterine solution by allowing its ready delivery onto the skin. FDA classified the product as a combination product consisting of a drug constituent part (the diphoterine solution) and a device constituent part (the aerosol spray canister). Further, consistent with section 503(g)(1) of the FD&C Act and FDA's implementing regulations, because the primary mode of action of the combination product is attributable to the drug solution, FDA designated CDER as the lead Center for premarket review and regulation of the product.

FDA did not improperly create a new test, but gave effect to the existing statutory language. As explained in the Agency's decision on remand concerning the Diphoterine Skin Wash classification, the statutory definition of device in section 201(h) of the FD&C Act excludes a product that "achieve[s] its primary intended purposes through chemical action within or on the body of man." The device definition does not expressly state how much chemical action suffices for a product to be excluded. To give effect to the statutory language—and to clarify that a *de minimis* amount of chemical action would not exclude a product from the device definition—FDA interprets the device definition to exclude a product if chemical action "meaningfully contributes" to the product's primary intended purposes. In other

[4] https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2011cv1187-26

words, if chemical action meaningfully contributes to a primary intended purpose, the primary intended purpose is achieved through the chemical action.

FDA's reasoning for determining that the diphoterine solution in the Diphoterine Skin Wash product does not meet the device definition is more fully explained in the classification determination issued on remand and referred to in response to Question e. (above). For further information on this matter, we refer you to the court docket (Case No. 1:13-cv-01177 (RMC)).

g. What impact will such draft guidance and the new "meaningful contribution" test have on regulatory predictability? How can manufacturers be sure guidance will not be further revised without their input?

As explained in response to Question f. (above), in using "meaningfully contributes" in its remand decision, FDA did not improperly create a new test but gave effect to the existing statutory language and clarified that a *de minimis* amount of chemical action would not exclude a product from the device definition. Further, the draft guidance documents referred to in the response to Question a. (above) are intended to enhance transparency for stakeholders concerning the factors that FDA may consider in its product classifications. FDA believes that providing greater transparency through guidance that explains the factors that may be considered in product classifications will help to enhance regulatory predictability.

FDA follows its good guidance practices regulation in 21 CFR 10.115, which requires, with certain exceptions, opportunity for public comment on draft guidance. Like other stakeholders, manufacturers may offer input on guidance development through comments on draft guidance, as they have done on the draft guidance documents referred to in the response to Question a (above). Further, as provided in 21 CFR 10.115(g)(5), stakeholders are welcome to offer comments on any guidance at any time for the Agency's consideration.

h. How do you propose we use reasonable efforts to harmonize its classification of products as drugs and medical devices with other global regulatory agencies?

FDA has initiated efforts to work on product classification and related issues directly with foreign regulatory agencies and also through international bodies in which both foreign regulators and the regulated industry participate. Challenges for these efforts include differences in the legal authorities that these regulatory bodies implement, including how products are classified and regulated. FDA remains committed to pursuing international regulatory coherence consistent with U.S. law and the promotion and protection of the public health.

i. Could requiring companies to comply with US drug regulations, when they are required to comply with medical devices regulations in all other countries for the identical product, place an unreasonable burden on the companies and could prevent introduction of important products to U.S. patients?

Some products that are regulated as drugs in the United States are regulated as devices in other countries and vice versa. FDA classifies products in accordance with the statutory definitions in force in the United States. We seek to implement our regulatory programs for drugs and devices in a manner that is consistent with U.S. law and our mission to protect the

public health, without imposing undue burden. We have developed regulatory programs to facilitate the development and availability of important products for U.S. patients. These include drug and device review programs. We remain committed to pursuing efforts with foreign counterparts to pursue regulatory coherence to minimize regulatory burden consistent with U.S. law and the promotion and protection of the public health.

27. Has the agency taken any specific action to promote the development of treatments related to Duchenne Muscular Dystrophy? Specifically, has the agency considered using its accelerated approval process authority in FDASIA to promote the development of Duchenne Muscular Dystrophy given the challenges of designing and populating a Phase III clinical trial with these patients? What successes, challenges and setbacks has the agency encountered in this area?

FDA has been working closely and extensively with Duchenne Muscular Dystrophy (DMD) drug developers, advocacy groups, researchers, and others to assist in the development of products to treat DMD. Some of these efforts have included (but are not limited to):

- Frequent meetings and communications with drug developers
- Intensive discussions with drug developers regarding suitable clinical trial designs and appropriate clinical trial endpoints
- Participation in scientific meetings and educational programs with researchers and advocacy groups
- Meetings with parents of boys with DMD

As with other rare diseases, there are a number of challenges associated with drug development in DMD. The number of patients available for participation in clinical trials is small. The progression of the disease tends to be slow, and the pace of progression varies from patient to patient on the basis of age and other factors, many of which are not understood. It has been difficult to select a reliable method for evaluation of patients that would demonstrate the positive effects of a drug treatment and be applicable to all patients. Although our understanding of the pathophysiology of the disease is improving, it is still incomplete. We are making progress toward understanding the role of biomarkers in assessing the state of the disease, but our knowledge is still evolving. Finally, DMD is a disease that predominantly affects children, a vulnerable population requiring special protections.

Regarding use of the accelerated approval pathway, drugs and biological products (both referred to as "drugs") may be granted accelerated approval upon determination that the drug:

> "...is for a serious or life-threatening disease or condition... upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments."[5]

[5] 21 U.S.C. 506(c)(1)

We consider DMD to be a serious and life-threatening disorder and recognize that there are currently no approved drugs specifically for its treatment. We are aware that there are substantial unmet medical needs for this disease and of the urgent needs of the patients.

We note that drugs granted accelerated approval must meet the statutory standards for safety and efficacy, which generally requires evidence obtained from adequate and well-controlled clinical trials. It is largely the type of endpoints used to reach that standard that differs between the two approval pathways: accelerated approval typically relies on endpoints for which validity is not fully established or for which there is greater uncertainty about the correlation of the endpoint with the ultimate outcome. In addition, accelerated approval is subject to the requirement that the drug be studied further to verify and describe its clinical benefit. Consequently, the accelerated approval mechanism does not permit circumventing the regulatory requirements: 1) to conduct an adequate and well-controlled trial with a surrogate endpoint or an intermediate clinical endpoint prior to the product's approval, and 2) to conduct a confirmatory clinical trial to verify and describe the drug's clinical benefit after the approval.

A number of products have been in development for DMD, and we continue to actively engage with sponsors of drugs for treatment of DMD and the patient community.

The Honorable Frank Pallone, Jr.

1. **How much has the biosimilars program received in user fees in FY 13 and FY 14 to date?**

   Biosimilar User Fee Act (BsUFA) fees collected in FY 2013 and FY 2014 as of December 24, 2013:

   -FY 2013 (33 initial biosimilar product development (BPD) fees)-$6,464,040
   -FY 2014, as of December 24, 2013 (31 invoices billed for FY 2014 + 8 initial BPD fees) ($1,735,280 + $6,724,210) = $8,459,490

2. **For FY2013, the FDA committed to find the $20 million "trigger" monies from within their FY2013 appropriations if additional monies were not appropriated by Congress for biosimilars. Has that occurred?**

   Yes. In FY 2013, FDA allocated and obligated $28,040,547 in appropriated funds (excluding user fees) for the process, for the review of biosimilar biological product applications.

3. **What is FDA's commitment for 2014, and subsequent years through 2017?**

   Assuming that the commitment in this question refers to the amount of budget authority and not to performance commitments, the FDA spending trigger will be adjusted each fiscal year as specified in statute (see §§744G(1) and 744H(e)(2)(B) of the FD&C Act). This adjustment takes into account inflationary increases in the overall economy, using the Consumer Price Index. Thus, the commitment for FY 2014 will be $20,000,000, multiplied by the adjustment factor applicable to FY 2014.

The Honorable Marsha Blackburn

1. **FDA's draft bioequivalence guidance for cyclosporine ophthalmic emulsions has been questioned by patient and provider groups, such as the American Academy of Ophthalmology, the American Glaucoma Society, the American Society of Cataract and Refractive Surgery, and the American Optometric Association. As health and safety concerns have been raised, does the agency plan to publicly withdraw the draft guidance and reconsider the matter?**

   Under FDA's good guidance practices (21 CFR 10.115), the intent of a draft guidance is to describe FDA's thinking and scientific recommendations on a particular topic and solicit input from the public on those recommendations. Typically, FDA announces the availability of draft guidance in the *Federal Register* and opens a public docket to collect comments on the topic from industry, stakeholders, and the general public; FDA reviews these comments and prepares a final version of the guidance document that incorporates suggested changes, when appropriate. FDA will carefully consider all submitted comments on the draft BE guidance for cyclosporine ophthalmic emulsion.

2. **How much has the agency collected in user fees for the biosimilars user fee program in FY2013 and how much has been collected thus far in this fiscal year?**

   BsUFA fees collected in FY 2013 and FY 2014 as of December 24, 2013:

   -FY 2013 (33 initial biosimilar product development (BPD) fees)-$6,464,040
   -FY2014 as of December 24, 2013 (31 invoices billed for FY 2014 + 8 initial BPD fees) ($1.735,280 + $6,724,210) = $8,459,490.

The Honorable Gene Green

1. **Section 575 of the FDA Safety and Innovation Act allows the FDA to designate new medical gases after "taking into account any investigational new drug application ... for the same medical gas submitted" under certain conditions. This is a very broad power to be exercised by the Secretary of the Department of Health and Human Services. Once designated, the gas and its use would be immediately generic and available for use by all companies, undermining the significant financial and resource investments made by companies or universities in bringing new medical gases to market. These entities typically have the legal protections provided to the medical drug industry for intellectual property related to INDs. But, this power, if exercised, would eliminate those protections. I understand that the FDA declined to address this important issue in its "Guidance for Industry: Certification Process for Designated Medical Gases," stating: "This document does not discuss how FDA plans to implement its new authority to designate gases... "**

   Moreover, in a written response to Members of this Subcommittee inquiring about this issue, the FDA acknowledged that these concerns are real and that the exercise of this authority could "lead to losses for the persons or entities that have invested resources in that IND ... and could disincentiveize others from pursuing IND... applications for new

medical gases in the future." Yet the response also leaves ample room for FDA to exercise its authority and do just that.

Will you assure Congress that the FDA does not intend to undermine pending and legitimate INDs by listing the medical gas in question under its section 575 (H) authority? Upon finding a pending and legitimate IND, will you allow the IND process to proceed normally, enabling an entity to bring the medical gas to market, protect its research and realize its investment?

We interpret the statutory requirement to "tak[e] into account" any IND or investigation new animal drug (INAD) applications before deeming a medical gas a "designated medical gas" to mean that we should carefully consider the possible negative impacts on new drug development prior to taking such action. We will weigh these potential impacts against the public health benefits of designating a new medical gas, and we note that we cannot pre-judge the outcome of this review for any particular medical gas.

The Honorable Michael C. Burgess

1. **It is my understanding that early clinical trials for many rare diseases are only being conducted outside the United States. Many times, the challenge is differences in how the flexibility in international guidelines are applied in the U.S. for first in human studies. How can the FDA improve its flexibility to ensure that U.S. patients have access to these potentially lifesaving clinical trials?**

From October 1, 2012, to October 1, 2013, CDER received approximately 350 initial IND applications for clinical trials in rare diseases.[6] Of these applications, approximately 95 percent moved forward after the required 30-day review period. That is, only a small number of rare disease initial IND applications were subject to clinical hold[7] on first submission to FDA.

FDA does not have access to numbers and types of INDs (or similar regulatory submissions) submitted to international regulatory agencies, and the rules governing initiation of clinical trials vary by country and/or region. FDA does not have access to data on how many IND applications are submitted first to rest-of-the-world versus the United States (and vice versa).

The reasons for submitting an initial clinical trial to one country or another are many and are under the control of the drug sponsor. For example, first-in-human trials for new products for rare diseases are usually very small (e.g., may include fewer than 10 patients) and are commonly

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[6] Point of clarification: CDER receives tens of thousands of IND submissions every year, which includes submissions across the spectrum of clinical development from first administration of a product to human subjects through to late IND phase and post-marketing application updates. Approximately 5,000-6,000 of these IND submissions are "initial" INDs, which include first-in-human and first-in-disease applications, as well as repurposing of drugs (both approved, usually for other purposes, and drugs in development for which there may be existing human experience). October 1, 2012, was the date when it was possible to approximate rare versus common disease IND applications in CDER's database.

[7] 21CFR 312.42, Clinical holds and requests for modification. "A clinical hold is an order issued by FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation." Clinical hold can be imposed for one or more of the following reasons: 1) human subjects are or would be exposed to an unreasonable and significant risk of illness or injury, 2) the clinical investigators are not qualified to conduct the IND, 3) the investigator brochure is misleading, erroneous, or materially incomplete, 4) the IND does not contain sufficient information required under regulations (312.23 IND content and format) to assess the risks to human subjects, 5) the IND is for the study of an investigational drug intended to treat a life-threatening disease that affects both genders and men or women with reproductive potential are excluded from eligibility.

conducted at only one or two centers initially. In some cases, sites may be selected based on where experienced treatment centers and/or experts reside, or that may have close geographic proximity to the drug sponsor, in addition to other scientific considerations.

As explained in FDA's regulations, for drugs intended to treat life-threatening and severely debilitating illnesses, FDA "has determined that it is appropriate to exercise the broadest flexibility in applying the statutory standards, while preserving appropriate guarantees for safety and effectiveness."[8] FDA has a long and well-documented history of applying flexibility to the development of new products that applies to early IND phases, through to marketing application review. This is evidenced by the fact that most novel products are approved in the United States first prior to rest of the world, and FDA has approved more orphan drugs than any other international regulatory agency. FDA is ready and willing to engage with drug sponsors to discuss initiation of clinical trials for drugs to treat rare diseases under a U.S. IND. FDA has the best developed mechanism for providing drug development advice than any regulatory agency in the world. Each year CDER conducts over 2,000 formal meetings to discuss drug applications; the vast majority of those meetings occurring during the development phase and many occurring before an IND is submitted (so-called pre-IND meetings).

We continue to work closely with drug developers through formal meetings and use of expedited programs, such as fast track and Breakthrough Therapy (BT) designations, to try to find efficient pathways forward for drug development, while not subjecting patients to unreasonable risks.

We additionally note that patient access to investigational agents outside of a clinical trial (Expanded Access or EA) is an additional option for patients with serious diseases who may not qualify for a clinical trial. There are several considerations for EA; however, important among them being that the drug's sponsor must be willing to supply the drug and that EA not interfere with the commercial development of the product.[9] We remain willing to work with drug developers to explore all available avenues for drug development and access, as appropriate, for rare serious disorders.

2. **What is the FDA assessment to date of the impact of Breakthrough therapy designation to expedite the availability of life-saving medicines to patients? Given that many more breakthrough therapy designations have been granted than was anticipated-has this had an impact on the availability of resources for each designation (i.e. are they able to actually spend as much additional time on each as they had intended)? Has the high number of designations led to a prioritization of certain products with the designation over others with the designation?**

As of July 11, 2014, FDA granted 56 designations under the BT program, and six drugs with BT designation have been approved by FDA. Many of the drugs that have received BT designation so far under the new program have been relatively late in their development, including in some cases, drugs for which a marketing application had already been submitted and, therefore, could not fully benefit from this new program's features. With time, FDA expects that most of the new BT designations will be for drugs that are early in their clinical development, which will provide a

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[8] 21 CFR 312.80 Drugs intended to treat life-threatening and severely debilitating illnesses.

[9] Guidance for Industry, Expanded Access to investigational drugs for treatment use—Qs & As. *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM351261.pdf.2013.*

better assessment of the impact of the BT designation in helping to speed the development and approval of these promising new drugs.

FDA has been surprised by the number of drugs that have qualified for designation; the number has far exceeded predictions that were made at the time the legislation was developed. Of course, having a larger number of promising new drugs for patients with serious and life-threatening diseases with unmet medical need is a good thing for patients and for public health. FDA is committed to continuing to fully implement the BT program and will work to balance this new program with other Agency priorities.

3. What is the FDA assessment to date of the impact of "The Program" for NMEs and Original BLAs to expedite the availability of life-saving medicines to patients?

The PDUFA V goals letter, agreed to by FDA and the regulated industry, states that the goal of the Program is to "...improve the efficiency and effectiveness of the first cycle review process and decrease the number of review cycles necessary for approval..." The idea behind the Program was that better pre-submission planning, submission of complete applications, improved communication and transparency between the applicant and review team during review, and additional review time will improve the efficiency of the first review cycle, which may decrease the number of additional review cycles prior to approval. The Program began with applications received on or after October 1, 2012. Therefore, to date, only a few applications have completed the review process and received an action from FDA. The early indications are that the Program has been implemented as agreed and that the specific opportunities for communication between FDA and applicants have contributed to review efficiency and are valued by both parties. FDA and industry will have a more complete assessment of the Program when the interim assessment in FY 2015 better characterizes the range of experience in the Program.

4. What is the FDA assessment to date of the impact of the Patient-Centered Drug development goals in the FDA performance goals and other patient-centered components of FDASIA?

By the end of FY 2013, FDA had conducted four meetings on patient-focused drug development (PFDD). The meetings addressed the severity of disease and the unmet medical need for myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), lung cancer, HIV, and narcolepsy. Based on the overwhelmingly positive feedback that FDA has received from patient advocates who participated in the meetings to date, and their positive reviews of the meeting reports published to date, we believe that this initiative is achieving its aim to increase the opportunity for direct and informative input from patients to FDA drug review considerations. FDA conceptualized PFDD to ensure that the Agency heard from patients outside the context of a specific drug under Agency review. The PFDD meetings are serving that purpose. FDA announces all PFDD meetings in a *Federal Register* notice that includes specific questions on which the Agency seeks feedback from the patient community. FDA obtains this feedback at the meeting and through a public docket for written submissions. In some cases, patient groups have used these questions to create survey instruments of their patient communities. This information helps FDA characterize the context in which regulatory decisions are made for each disease area discussed in a PFDD meeting. This context is an important part of regulatory decision-making and is represented in a PFDD report written by FDA that summarizes what we heard in PFDD meetings and submissions to the docket. The 'Voice of the Patient' reports are available at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm368342.htm.*

5. **I am concerned about the recent FDA decision to recommend the upscheduling of hydrocodone combination products. Patient access continues to be a concern for patients, as well as physicians if hydrocodone-containing medications are indeed rescheduled.**

   a. **The FDA has made its recommendation to reschedule these medications. However, the agencies' report justifying your recent decision has not been made public. When will this report be sent to HHS? When will this report be made public?**

The scientific and medical evaluation and scheduling recommendation (which recommends up-scheduling of hydrocodone combination products, and with which the National Institute on Drug Abuse concurred) was prepared by FDA and sent to HHS on December 11, 2013. HHS transmitted the document to DEA on December 16, 2013. On February 27, 2014, DEA published a notice of proposed rulemaking to reschedule hydrocodone combination products from Schedule III to Schedule II, with a public comment period that ended April 27, 2014. DEA's notice can be found at this website: *http://www.gpo.gov/fdsys/pkg/FR-2014-02-27/pdf/2014-04333.pdf*. Both the DEA and HHS analyses are available in their entirety in the public docket for this proposed rule (Docket No. DEA–389) at *http://www.regulations.gov/#!documentDetail;D=DEA-2014-0005-0001*. On August 22, 2014, DEA published the final rule rescheduling hydrocodone combination products from schedule III to schedule II of the Controlled Substances Act. *http://www.gpo.gov/fdsys/pkg/FR-2014-08-22/pdf/2014-19922.pdf*.

   b. **I am not aware that the FDA has access to new scientific research showing that rescheduling would address prescription drug abuse and diversion of these drugs. Will you provide us with any new information on any new scientific data FDA has that suggests rescheduling these products will substantially curb misuse and abuse?**

As an initial matter, it is important to clarify that FDA prepared the scientific and medical evaluation and scheduling recommendation for hydrocodone combination products under the requirements of the Controlled Substances Act (CSA) and the Food and Drug Administration Safety and Innovation Act (FDASIA), neither of which requires that scheduling recommendations be supported by evidence that rescheduling a drug would address abuse and diversion and substantially curb misuse or abuse. However, FDASIA did require that, in preparing the scientific and medical evaluation and scheduling recommendation required under the CSA,[10] the Secretary of HHS must solicit input from a variety of stakeholders on the health benefits and risks, including the potential for abuse and

[10] The Secretary of HHS is required to consider eight factors in the scientific and medical evaluation:

1. The drug's actual or relative potential for abuse
2. Scientific evidence of the drug's pharmacological effects
3. The state of current scientific knowledge regarding the drug or other substance
4. The drug's history and current patterns of abuse
5. The scope, duration, and significance of abuse
6. What, if any, risk there is to the public health
7. The drug's psychic or physiologic dependence liability
8. Whether the substance is an immediate precursor of a substance already controlled

the impact of the upscheduling of hydrocodone combination products. To satisfy this requirement, FDA held an advisory committee meeting on January 24-25, 2013, which provided opportunity for public comment. The Advisory Committee itself included members with scientific expertise in areas relevant to opioid abuse, including representatives from the National Institute on Drug Abuse, the Centers for Disease Control and Prevention, and a patient representative. The Committee voted 19 to 10 to recommend that hydrocodone combination products be placed into Schedule II. In addition to public commentary at the meeting, 768 comments were submitted to the Docket and to two other related dockets by patients, patient groups, advocacy groups, and professional societies.

FDA recognizes that the rescheduling recommendation, if implemented by DEA, is only one piece of the many activities that are needed to address opioid abuse. We agree with the important need to continue to monitor the impact of the action to minimize the unintended negative impact of patients who need pain relief.

c. Will you provide us with any new scientific data the agency has that addresses the potential impact rescheduling will have on patient access to these medications?

There are differences in the laws and regulations that govern how drugs under schedules II and III may be prescribed and refilled. However, fully predicting the public health impact of this action, including the impact on access by legitimate patients, is complicated by the many factors that shape prescribing patterns for hydrocodone, including reimbursements by payers, guidelines promulgated by societies, patterns of prescription, and laws enacted at various levels of government. An example of this is the challenge that can be seen in trying to predict how the decision to reschedule will be interpreted and responded to by prescribers. At the Advisory Committee held in January to discuss this issue, some commenters voiced the hope that rescheduling would reset the understanding of prescribers about the potential adverse effects of misuse of hydrocodone combination products. Others voiced concerns that rescheduling would drive the increased prescription of more single-entity products containing a higher dose of opioids (e.g., oxycodone, oxymorphone, methadone). Still, others voiced concerns about the impact of rescheduling on the availability of treatments for pain patients.

FDASIA did require that, in preparing the scientific and medical evaluation and scheduling recommendation for hydrocodone combination products, the Secretary of HHS solicit input from a variety of stakeholders on the health benefits and risks, including the potential for abuse and the impact of the upscheduling of hydrocodone combination products. As discussed above, the scientific and medical evaluation and scheduling recommendation, is generally made public as part of DEA's rulemaking process.

d. How can the FDA prevent the rescheduling from having a negative impact on patients in nursing homes who need opioid analgesics?

While DEA is charged with the enforcement of the provisions under Schedule II of the CSA, FDA has discussed the issues regarding appropriate access to pain medicines, including opioids, with groups that represent the health care professionals that care for patients in nursing homes and other extended care facilities and agrees that is it is important to continue to work to assure that appropriate access to pain medicines for appropriate patients is maintained.

6. **In April, you determined that OxyContin was an abuse deterrent formulation. You later made a determination that Opana reformulation did not meet your standard. Then you recently approved Zohydro, an extended release ER single entity hydrocodone with no abuse deterrent products and that industry, both innovator and generic, need to have a clear understanding of FDA's standard. I am concerned that the current regulatory requirements are so confusing that innovators may just walk away from developing abuse deterrent formulations. When you approve non-deterrent products it seems like a step backwards. Will you provide more detail on the standard that is being applied by the FDA in this realm?**

Please see the above responses to Questions 15e and f from the Honorable Joseph R. Pitts, which explain FDA's case-by-case approach to evaluation of opioids with and without abuse-deterrent properties. Under FDA's current approach, abuse potential is one aspect of a product's safety that FDA considers, together with all other appropriate factors, in determining whether a product's benefits outweigh its risks. As the science of abuse deterrent technologies continues to develop, we will continue to evaluate our approach to regulatory decisions concerning these products.

While FDA strongly supports a transition to abuse-deterrent opioids, we do not believe it is feasible or in the interest of public health to require all products in the class to be abuse-deterrent, at this time. In light of the need for further data and scientific development in this nascent and rapidly evolving area, FDA intends to continue to take a product-by-product approach to regulatory decisions concerning the safety and effectiveness of opioid products.

Regarding your concern that our regulatory approach may deter innovation, we can report that we are observing a lot of development activity in the area of ADF development. We believe that our current policy provides sufficient incentives for the development of abuse-deterrent drug products while preserving access to a range of therapeutic agents for patients in pain.

7. **Section 901 of the FDA Modernization Act of 1997 (FDAMA) as amended by the FDA Safety and Innovation Act (FDASIA) creates a clear pathway for treatments for rare diseases to receive accelerated approval. The first criteria is that the disease be rare and life threatening. As you know, Duchenne Muscular Dystrophy affects approximately one in every 3,500 boys and is always fatal. In your view, does Duchenne meet this criteria?**

Please see FDA's response to Question 27 from the Honorable Joseph R. Pitts.

We additionally note that the first requirement for a product to be considered for accelerated approval is that a product be for a serious or life-threatening disease or condition. While there is no requirement that the disease be rare, in recent years the accelerated approval pathway has been used most frequently for rare conditions (see FDA response to Question 2 from the Honorable Gus Bilirakis).

<u>The Honorable Phil Gingrey</u>

1. **On June 12, 2013, in the Federal Register, FDA published a proposed rule titled "Establishing a List of Qualifying Pathogens under the Food and Drug Administration**

Safety and Innovation Act." In section C of the Proposed Rule, the Agency states that"... inclusion of a pathogen on the list of 'qualifying pathogens' does not determine whether a drug proposed to treat an infection caused by that pathogen will be given QIDP designation." In the same section of the Proposed Rule, the Agency further states "... the development of a treatment for an infection caused by the pathogen included in the list of 'qualifying pathogens' is neither a necessary nor a sufficient condition for obtaining QIDP designation ... " In essence, does the Agency consider the list as having any real bearing to qualified infectious disease product (QIDP) designation?

As explained in the Proposed Rule, which was finalized on June 5, 2014, the statutory standard for inclusion on FDA's list of qualifying pathogens is different from the statutory standard for QIDP designation:

- QIDP designation, by definition, requires that the drug in question be an "antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections" (section 505E(g) of the FD&C Act, as amended by FDASIA).
- "Qualifying pathogens" are defined according to a different statutory standard; the term "means a pathogen identified and listed by the Secretary…that has the potential to pose a serious threat to public health" (section 505E(f) of the FD&C Act, as amended by FDASIA).

Therefore, a drug intended to treat a serious or life-threatening bacterial or fungal infection caused by a pathogen that is not included on the list of "qualifying pathogens" may be eligible for designation as a QIDP, while a drug that is intended to treat an infection caused by a pathogen on the list may not necessarily be eligible for QIDP designation if the proposed use is not for a serious or life-threatening infection. While many drugs that are granted a QIDP designation are likely to be active against one or more qualifying pathogens, a qualifying pathogen may cause some infections that are not serious or life-threatening, and for these uses, a drug would not be eligible for a QIDP designation. The list of qualifying pathogens provides examples of the types of pathogens that cause infections for which treatment might be eligible for QIDP designation.

2. **21 USC 355E(g) provides the definition of QIDP: "The term 'qualified infectious disease product' means an antibacterial or antifungal drug for human use intended to treat serious or life- threatening infections, including those caused by-(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or (2) qualifying pathogens listed by the Secretary under subsection (f)." Participants in the legislative process greatly debated this definition, predominantly because the term "serious or life-threatening" is not defined in statute, only in guidance, and therefore could be modified in the future. On the other hand, the statute not only defined "qualifying pathogens," it also set up an elaborate and formal process for determining pathogens that can make the "qualifying pathogen" list. Thus, by stating that "serious or life-threatening infections" include those caused by "qualifying pathogens," Title VIII of FDASIA provided some certainty and transparency early in the clinical development process about which products could be eligible for QIDP designation. If the Agency's proposed interpretation of the statute stands, would not the intended certainty or transparency be lost, and the "qualifying pathogen" list would serve no real purpose and carry no weight whatsoever, making it inconsistent with the intent of Congress?**

The statute provides considerable certainty and transparency in the QIDP designation process. By linking QIDP designation to serious and life-threatening infections, Congress has set a clear benchmark that FDA has significant experience in implementing, with respect to other programs. In addition, by not limiting the definition of QIDP to infections caused by qualifying pathogens, Generating Antibiotic Incentives Now could be implemented immediately after enactment, without having to wait to complete the process of rulemaking to establish a list of qualifying pathogens. In fact, the first QIDP designations were granted on September 8, 2012, just two months after the enactment of FDASIA, and 35 designations have been made within 18 months of enactment.

Moving forward, dependence on the qualifying pathogen list for QIDP designation would be neither practical nor timely. Antimicrobial resistance is constantly changing. Due to the time it takes to complete rulemaking, the list of qualifying pathogens will not necessarily reflect new and emerging public health threats. In contrast, drugs intended to treat serious or life-threatening bacterial or fungal infections caused by pathogens associated with emerging public health threats can be designated as QIDPs without waiting for such pathogens to be added to the list of qualifying pathogens.

3. **Since clinical data is usually limited on resistant infections and generic companies are not about to conduct new clinical trials for old drugs, isn't it critical that FDA also use all the tools at its disposal to set and update breakpoints, tools like pharmaco-metric and pharmaco-dynamic data (PK PO), nonclinical data, and state-of-art statistical methods to both update old breakpoints and as well as to set new breakpoints for products before the FDA for approval?**

As clinical data regarding antibacterial drug susceptibility and available clinical outcome information is often limited, particularly in the case of older antibacterial drugs, FDA considers all available and relevant information, including in-vitro microbiology data, data from animal models of infection, and statistical modeling using PK/PD information to inform the establishment of susceptibility test interpretive criteria. For a particular drug, the amount and quality of any of these four types of information may vary.

4. **The 2012 GAO report found that the Agency was way behind in updating breakpoints. Will you provide the Committee with an update? How many marketed antibiotics are there in the U.S. for which the breakpoint for the product label has neither been confirmed nor updated? What is the agency's plan for getting this done as well as what is FDA's process and plans to update breakpoints moving forward?**

FDA continues to work with pharmaceutical companies so that they can update the susceptibility test interpretive criteria (breakpoints) in their drug labels as expeditiously as possible. There are 207 RLDs for antibacterial drugs for human use marketed at this time. Labeling regarding susceptibility test interpretive criteria has been reviewed and updated for approximately 150 of those drugs, as of June 30, 2014. For the remainder, discussion of FDA recommendations with pharmaceutical companies is in progress or scientific review is underway. The current process of relying upon pharmaceutical companies to submit supplements to update the susceptibility test interpretive criteria in their labels is not optimal for a number of reasons:

- Many antibacterial drugs are very old, and they are now marketed only by generic firms. These companies often do not have staff with the technical expertise to evaluate and update the susceptibility test interpretive criteria.

- This approach to updating labeling is very resource-intensive from FDA's perspective. The labeling of each RLD has to be addressed separately when, in fact, the interpretive criteria are often the same for all products containing a specific drug substance, so there is a great deal of duplicate effort.

- In addition to the RLDs, there are approximately 400 additional generic systemic antibacterial drugs. It is expected that each generic firm will update their label when the RLD label for that generic antibacterial drug product is updated. The collective resources that are required of the pharmaceutical companies to update their drug product labeling and the associated FDA resources are/will be considerable, while most of this work will be to simply duplicate work previously performed to update the RLD label.

In 2009, FDA published a guidance for industry, "Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices," that lays out a process for updating susceptibility test interpretive criteria in accordance with the requirements of FDAAA. This process involved the recognition by FDA of susceptibility test interpretive criteria established by standard development organizations. This recognition would be published in a *Federal Register* notice, and sponsors would be required to either update their labeling to be in conformance with these standards or submit data to support alternative criteria.

The process outlined in the guidance would still require the management of changes to susceptibility test interpretive criteria through labeling supplements. However, it has become increasingly clear that the package insert may not be the best place to document the current susceptibility test interpretive criteria. FDA would welcome the opportunity to discuss processes that may be more likely to ensure that most up-to-date and accurate susceptibility test interpretive criteria information is made available to clinical laboratories and health care providers.

5. **The 2012 GAO report found that FDA had not taken any regulatory action against companies that failed to respond to the agency's efforts to obtain updated breakpoint information. Has the FDA taken any regulatory action against such companies since the publication of the GAO report and if not, why not? What type of regulatory action can the FDA take in this situation?**

FDA has not taken regulatory action against the companies that have not yet updated their susceptibility test interpretive criteria. Generally, taking action against a sponsor who failed to update the susceptibility interpretive criteria in its labeling would be resource- and time-intensive. FDA believes that working with the sponsor to update the labeling would generally be more efficient and obtain a more optimal result.

As explained in our 2009 guidance for industry, "Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices," under existing regulations, a sponsor is responsible for updating its drug product's

labeling whenever new information becomes available that causes the labeling to become false or misleading and, therefore, misbranded.

6. **Antibiotic products have a number of challenges in terms of their development that may lead to clinical data not entirely reflective of when a new QIDP candidate may actually work.**

   In antibiotic development, the least sick individuals tend to be in clinical studies to assure that such patients have NOT been exposed to other antibiotic products before the study product is introduced. This "exclusion criteria" that helps power a pivotal clinical trial may also ironically reduce or even exclude the enrollment of patients with resistant infections.

   In other words, a significant amount of potentially relevant clinical data cannot be collected and, therefore, a newly established clinical breakpoint for QIDP product could be inappropriately high. Do you agree that this potential exists, that is setting a new breakpoint too high? How does FDA propose to deal with this situation, whereby the data in clinical studies may be skewed to the least sick patients and then the need for new QIDP product with breakpoints that are not set so high that the sickest do NOT have access to life saving antibiotics?

A number of options for the inclusion of seriously ill patients with unmet medical need in clinical trials are described in the draft Guidance for Industry, "Antibacterial Therapies for Patients with Unmet Medical Need for the Treatment of Serious Bacterial Infections" (available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM359184.pdf).*

In a more streamlined development program targeting serious bacterial infection in patients with unmet need, clinical trial data regarding antibacterial drug susceptibility to the investigational drug and clinical outcome to inform establishment of susceptibility test interpretive criteria may be limited. FDA will also consider other available information, including in-vitro microbiology data, data from animal models of infection, and statistical modeling using PK/PD information, and weigh this information along with the available clinical data in working with the company to establish susceptibility test interpretive criteria for their drug product.

7. **In order to maximize the effectiveness of the GAIN Act, will you clarify that the establishment of breakpoints for such QIDPs would utilize both clinical and additional forms of evidence, as well as rely upon advanced statistical methods as appropriate, to ensure their breakpoints are set appropriately and, importantly, not set too high especially in light of the unique circumstances confronting QIPD product development already outlined?**

FDA weighs all available and relevant information, including clinical data, in-vitro microbiology data, data from animal models of infection, and statistical modeling using PK/PD information to inform the establishment of susceptibility test interpretive criteria. We note that the quantity and quality of all of these different types of information may vary among drug development programs.

8. **What steps is the FDA now taking to assure that breakpoints for new QIDPs rely on these other sources of non-clinical data and what has been industry's response?**

The draft Guidance for Industry, "Microbiological Data for Systemic Antibacterial Drug Products – Development, Analysis, and Presentation" (available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM182288.pdf)* recommends that pharmaceutical industry sponsors obtain in-vitro microbiology data and data from animal models of infection, and perform statistical modeling using PK/PD information in the development of proposed breakpoints. This information is submitted and considered in the review of a new drug application for an antibacterial drug.

9. **Advisory Committee decisions are not binding on the FDA, but three years ago, the Anti-Infective Drugs Advisory Committee decided that "It would not be the best use of resources for FDA to duplicate the work CLSI when, essentially, the same experts would be utilized ... [and] One suggestion was that the Agency should have a working group to routinely evaluate published and unpublished data for each drug class... If interpretation of the data differs among FDA and CLSI, it should be brought before the [Advisory] Committee."**

   Would it not be appropriate for FDA to rely on such outside expert findings with regard to breakpoints? And isn't it actual practice now for physicians and other health care providers to rely on CLSI and other expert third party breakpoint findings because this information is more up to date and reflective of scientific knowledge than what's on the FDA label for many antibiotic products?

Prior to this Advisory Committee meeting, FDA published a guidance for industry, "Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices," that describes a process by which FDA would recognize certain susceptibility test interpretive criteria "developed by one or more nationally or internationally recognized standard development organizations." In addition to FDA's recognition of these standards, it would be more efficient and effective for the susceptibility test interpretive criteria to be removed from the package insert; the FDA web site would then serve as the standard reference for FDA-recognized breakpoints.

FDA would welcome the opportunity to discuss processes that may be more likely to ensure that most up-to-date and accurate susceptibility test interpretive criteria information is made available to clinical laboratories and health care providers.

10. **The growing resistance of several bacterial strains to all or nearly all antibiotics currently approved is a public health emergency. Recently, the Centers for Disease Control and Prevention (CDC) issued an alarming report on this topic, noting that each year at least 2 million Americans acquire a serious infection resistant to one or more antibiotics designed to treat that infection. CDC warned if we do not take steps now, we could be entering a "post antibiotic era."**

The FDA has indicated that it agrees that product innovation is one of the keys to solving this situation. In addition to the GAIN Act, what other specific incentives might work to significantly grow antibiotic innovation?

Antibacterial drugs provide value not only in their ability to treat common infections, but also in their support of other life-saving medical interventions such as surgery, chemotherapy for cancer patients, organ transplantation, and the care of premature infants. As a nation, we need to begin to think in terms of promoting the establishment of a sustainable and robust antibacterial research and development enterprise, while also preserving the effectiveness of the antibacterial drugs we have, so that sufficient therapeutic options will be available when future microbial threats emerge. Given the limited number of antibacterial drugs currently in development and the continued and increasing public health threat posed by life-threatening, drug-resistant pathogens, the Agency agrees that additional approaches to help encourage antibacterial drug development should be considered.

One approach to encouraging antibacterial (as well as antifungal) drug development is contained in the recently introduced H.R. 3742, the Antibiotic Development to Advance Patient Treatment Act (ADAPT Act). This approach would establish a distinct pathway for the development of drugs that are intended for use in patients with unmet medical need (i.e., patients with serious or life-threatening infections and few or no available treatment options) based on a streamlined development program. If such legislation were passed, it would be important that such drugs, which are intended for a limited population of patients, include within their labeling a simple and clear way to identify them (e.g., using a distinct labeling statement and/or logo) so that the health care community could self-limit their use to situations where the drugs' risk/benefit profile is clinically supported. It also would be important that the promotional materials for such products undergo pre-dissemination review.

12. **As part of the 2012 MDUFA Goals letter, FDA agreed to new performance metrics for 510(k) and CLIA Waiver dual submissions. An important part of the commitment letter that FDA signed with industry is the issuance of a Guidance by FDA that will help industry understand the requirements of successfully completing dual 510 (k) and CLIA waiver applications.**

    These two provisions will aid the public health through quicker review times and potentially more tests available to doctors and patients. A number of rapid tests for diseases listed in the CDC's recent report on antibiotic resistant pathogens are either in the review process or are nearing the point of submission.

    We understand FDA believes this Guidance will be delayed because of issues related to the information technology required for its application tracking system. What are those issues and why would this delay the issuance of a Guidance designed to facilitate the overall management of these applications? As part of dual submissions with a 510(k) application, can CLIA waivers be tracked manually if 510(k)s are tracked electronically? What are FDA's plans to meet the obligations of this FDA/industry agreement if Guidance is not issued?

The 2012 MDUFA Goals letter (the "MDUFA III commitment letter")[11] did not specify a timeline associated with publishing the CLIA-related guidance.

However, the Center for Devices and Radiological Health (CDRH) has prepared an update to the Guidance for Industry and FDA Staff: "Administrative Procedures for CLIA Categorization."[12] This updated guidance includes changes to the administrative procedures for CLIA categorizations as well as administrative procedures for CLIA Waiver by Applications and Dual 510(k)/CLIA Waiver by Applications. The Agency published this guidance in March 2014 to coincide with the launch of CDRH's new IT system for tracking all CLIA work, so that performance can be reported as accurately as possible. The guidance includes administrative procedures that are specific to the new IT system.

Of note, the MDUFA III commitment letter refers to a pre-submission prior to submission of a Dual 510(k)/CLIA Waiver by Application. FDA has been reviewing the Pre-submissions that the Agency has received to date and will continue to provide feedback to, and participate in discussions with, sponsors, with regard to any potential Dual 510(k)/CLIA Waiver by Application plans through the Pre-submission program. Such feedback/discussion is actually tailored to the sponsor's specific device, and therefore, is more substantive than the type of information presented in guidance documents. In addition, FDA has been applying the CLIA Waiver by Application performance goals, as outlined in Section II(E) of the MDUFA III commitment letter, since October 1, 2013, the start of MDUFA III.

<u>The Honorable Leonard Lance</u>

1. **To be in compliance with FDASIA, the FDA must allow for novel approaches to use pathophysiologic and pharmacologic evidence to support the use of a biomarker endpoint when the low prevalence of disease makes the existence of other types of data impractical to collect. What kinds of novel approaches is the FDA planning to take to allow for the use of surrogate endpoints in clinical trials for rare diseases?**

FDA is open to and promotes the use of surrogate endpoints and biomarkers in clinical development programs for both common and rare diseases. As explained in our regulations, for drugs intended to treat life-threatening and severely debilitating illnesses, FDA "has determined that it is appropriate to exercise the broadest flexibility in applying the statutory standards, while preserving appropriate guarantees for safety and effectiveness."[13] FDA has a long and well-documented history of applying flexibility to the development of new products for rare diseases, which includes the use of biomarkers and surrogate endpoints in clinical trials, as well as other tools such as non-traditional trial designs. We continue to work with drug sponsors to find ways to apply this flexibility, where appropriate.

Rare disease drug approvals also have a long history of use of biomarkers as surrogate endpoints to support approvals, including traditional and accelerated approvals, and in recent years, many rare

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[11] FDA, "MDUFA Performance Goals and Procedures" (April 18, 2012), available at *http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf.*

[12] FDA, "Guidance for Industry and FDA Staff; Administrative Procedures for CLIA Categorization" (March 12, 2014), available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070889.pdf*

[13] 21CFR 312.80, Drugs intended to treat life-threatening and severely debilitating illnesses.

disease clinical development programs have relied upon surrogate biomarkers (please see response to the Honorable Gus Bilirakis, Questions 2 and 3 and Appendix 1, for a listing of recent rare disease approvals).

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.[14] 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).

2. How will the FDA ensure the upcoming FDA Rare Disease meeting in January will improve the regulatory process for rare disease, when the FDA held a similar meeting in 2010 and issued a report with recommendations, but has yet to implement any of the recommendations more than three years later?

The Public Workshop on Complex Issues in Rare Disease Drug Development was a 3-day meeting that was held January 6-8, 2014.[15] [16] This meeting was held in response to 1) PDUFA V performance goals (Section IX.E.4[17]), and 2) FDASIA Sec 510.[18] Both PDUFA V and FDASIA multi-stakeholder (e.g., industry, FDA, Congress, advocacy) negotiations emphasized that the meetings should be collaborative, include discussions of difficult and complicated issues in rare and pediatric rare disease drug and biologic product and medical device development, and should involve diverse panels of experts from industry, academia, advocacy, and government. The main goals of the public meeting were to 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. Consistent with the FDASIA/PDUFA V negotiations, FDA convened the Public Workshop and included diverse panels of experts from across the broad rare disease stakeholder community (see Appendix 1, Public Workshop on Complex Issues in Rare Disease Drug Development roster).

Also consistent with the FDASIA/PDUFA V negotiations, the overall structure of the meeting and major topics addressed included the following:

1) Day 1: Complex Issues in Rare Disease Drug Development[19]

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[14] Guidance for Industry. Expedited Programs for Serious Conditions –Drugs and Biologics. Draft Guidance.
[15] FDA, Drugs. Public Workshop -- Complex Issues in Developing Drug and Biological Products for Rare Diseases. *http://www.fda.gov/Drugs/NewsEvents/ucm367820.htm*
[16] FDA, Medical Devices. Public Workshop – Complex Issues in Developing Medical Devices for Pediatric Patients Affected by Rare Diseases. *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm367656.htm*
[17] IX. Enhancing Regulatory Science and Expediting Drug Development, E. Advancing Development of Drugs for Rare Diseases
[18] Title V – Pediatric Drugs and Devices, Section 510 Pediatric Rare Diseases
[19] For the final workshop agenda for Days 1 and 2, please see the Public Workshop meeting page, available at *http://www.fda.gov/Drugs/NewsEvents/ucm367820.htm*

a. Session 1: Complex Issues for Trial Design: Endpoints
b. Session 2: Complex Issues for Trial Design: Study Design, Conduct, and Analysis
c. Session 3: Foundational Science
d. Session 4: Safety & Dosing

2) Day 2: Encouraging and Accelerating Development of New Therapies for Pediatric Rare Diseases

a. Session 5: Networks and Collaborations in Support of Pediatric Clinical Trials
b. Session 6: Tolerating Risk and Uncertainty in Pediatric Clinical Trials
c. Session 7: Pediatric Oncology
d. Session 8: Gene Therapy Trials in Pediatric Patients

3) Day 3: Complex Issues in Development of Medical Devices for Pediatric Patients Affected by Rare Diseases[20]

a. Session 1: What's Happening Clinically
b. Session 2: HUD/HDE Discussion
c. Session 3: Engineering Considerations
d. Session 4: Clinical Trials Issues Panel
e. Session 5: Needs Assessment
f. Session 6: Diagnostic Devices
g. Session 7: What Can be Done? Incentives and Otherwise

Issues encountered in rare disease drug development are multi-factorial and complex, and occur across the entire spectrum of rare disease research, beginning in early phase of basic scientific research, through translational scientific research and development, and then later on, into pre-clinical and clinical drug development. Since rare diseases have a long-standing history of under-representation in research and development (R&D), many of the approximately 7,000 rare diseases have no or very limited R&D ongoing, and most have no drug development in progress.

FDA's involvement generally begins when testing of investigational agents in human subjects begins, which typically occurs after many years of basic and translational scientific research have taken place. FDA recognizes and takes extremely seriously its role and responsibilities in the larger drug development process. We also recognize that scientific research and drug development can be greatly facilitated through collaborations of industry, investigators, patients, advocacy groups, and government. While this is true for all scientific research and drug development, the need to collaborate is especially critical for rare diseases where there are small numbers of patients with the individual disorders, opportunities for study and replication are known to be limited, there are few treating physicians and disease experts, and resources are grossly insufficient for the magnitude of the problem.[21] Thus, collaboration beginning early on and continuing throughout drug development, non-proprietary information sharing, and investment into and development of common tools (e.g., endpoint development, biobanking, natural history studies and registries) are especially important given the known limitations in opportunities for research and replication. Meetings, such as this Public Workshop, therefore, play an extremely important role in fostering

[20] For the final workshop agenda for Day 3, please see the Public Workshop meeting page, available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm367656.htm*

[21] There are an estimated 25-30 million Americans living with a rare disease, or approximately 1 in 10 people–this is a substantial public health concern. By comparison HIV affects fewer than 2 million Americans and cancer ~15 million Americans.

collaboration and cooperation, identifying knowledge gaps as well as best practices, and exploring areas where working towards common goals can be best applied. All of these important considerations contribute to the overall rare disease R&D environment.

Regarding the 2010 Open Public Hearing (OPH) on Rare Diseases:

An OPH on rare diseases was held June 29-30, 2010, the purpose of which was for the FDA rare disease internal review group to hear directly from the rare disease community on issues important to them regarding rare disease drug development. The internal review group was convened as part of a legislative requirement.[22] Comments from the OPH as well as all comments submitted to the docket were carefully considered by the review group, and incorporated into review group deliberations, which were later summarized in a report to Congress.[23] A summary of recommendations in three areas from the report is briefly summarized as follows:

1) Increase the foundation of biomedical and regulatory science required to support development and regulatory assessment of medical products for rare disease. This includes:

    a. Development of natural history studies and databases
    b. Identify, develop, and qualify novel biomarkers

2) Increase collaboration among rare disease stakeholders both within and outside FDA.

3) Gain a thorough understanding of the regulatory history of orphan drug products to help identify effective development approaches.

We have made substantial progress in all of the above-listed areas. Some of the progress includes (but is not limited to):

1) Development of Draft Guidance for Industry on common issues in rare disease drug development

2) Conducting a Natural History Studies Workshop in collaboration with NIH in 2012

3) Development of Draft Guidance for Industry on development of natural history studies

4) Creation of a collaborative taskforce for the development of natural history studies between CDER, the National Organization for Rare Disorders (NORD) and NIH's National Center for Advancing Translational Sciences (NCATS) Therapeutics for Rare and Neglected Diseases (TRND) program was formed in 2012 (ongoing).

5) Continuation of work on CDER's Critical Path Initiative (CPI). A draft guidance on the "Qualification Process for Drug Development Tools (DDT)" was published in October 2010,

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[22] Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2010, Public law 111-80, Section 740. This Act required FDA to establish an internal review group which "shall recommend to the Commissioner appropriate preclinical, trial design, and regulatory paradigms and optimal solutions for the prevention, diagnosis, and treatment of rare diseases".

[23] A report from the review group is available on FDA's website under the Critical Path Initiative. *http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/CriticalPathInitiative/UCM265525.pdf*

and this provides a description of a formal mechanism for CDER to advise external parties, of any type, how to efficiently develop DDTs that will be useful in drug development. Work on biomarkers, endpoints, and pharmacogenomics through CPI continues on an ongoing basis in numerous areas, such as through participation at conferences and meetings, scientific publications, guidance development and advice, and during individual product development meetings. In particular, CDER's Study Endpoints and Labeling Development program (SEALD) for clinical outcome assessments (COAs) and CDER's Office of Translational Sciences (OTS) for biomarkers are now available to work with outside groups to advance creation of these tools for development of rare disease therapies. Based upon experience with these efforts since then, a revised final DDT qualification guidance was published in January 2014.

6) Initiation of a program by CDER OTS, the Critical Path Innovation Meeting (CPIM), to foster early engagement with drug developers, researchers, advocacy groups, and other components of government who are developing innovative tools (e.g., biomarkers in the exploratory phase of their development and for evaluation under the Biomarker Qualification Program, natural history study designs and implementation, emerging technologies, or new uses of existing technologies, and innovative conceptual approaches to clinical trial design and analysis)

7) Development of an internal FDA staff rare-disease training course, which has occurred annually in CY 2011, 2012 and 2013, and 2014, with the next planned course to occur in March-April 2015. Thus far, hundreds of FDA staff have participated in this training.

8) Formation of an agency-wide Rare Disease Council with representation from CDER, CBER, CDRH, CFSAN and OC. This council, which meets monthly, was formed to foster collaboration between Centers, identify issues of cross-Center interest and develop strategies to address areas of common interest for rare diseases.

9) Co-development of an annual rare disease conference with NORD and the Drug Information Agency that has occurred since 2010. Approximately 300-400 members of the rare disease community (industry, advocacy, researchers, and government) have participated each year. FDA staff also participate in numerous scientific conferences on a variety of rare disease topics.

10) Formation of a CDER-NIH Clinical Center taskforce in 2012, to facilitate research-investigator initiated clinical trials. In addition to scheduled meetings and the development of "early engagement" meetings between CDER and NIH-CC (on a case-by-case basis), this taskforce has resulted in the following:

    a. An IND Regulatory Training program for research-investigators was held in 2013. Presentations from the training program will be made widely available through NIH's website in the future.

    b. FDA posted on its website an IND regulatory training toolkit for investigators.[24]

    c. Emergency IND regulatory tools have also been posted on FDA's website.[25]

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[24] FDA, Drugs. Investigator-Initiated Investigational New Drug (IND) Applications. *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm343349.htm*. 2013.

11) Construction of a CDER database of marketing applications has been completed, which includes extensive application-specific data for new molecular entity and original biologic product marketing applications submitted to CDER from 2007-present. This database allows detailed analyses of critical drug application characteristics (e.g., disease, endpoints, types of trials, regulatory precedents) to inform the development of guidance, advice, processes, and procedures for rare disease drug development. For example, a scientific manuscript on characteristics of rare disease drug applications at CDER was published in 2012.[26]

Since rare disease R&D requires the work and collaboration of so many people from diverse communities, it can be difficult to pinpoint definitive outcomes from one meeting alone. However, we feel that workshops such as the recent Public Workshop of 2014 will play an extremely important role in facilitating, encouraging, and accelerating continued R&D, and building communities and collaborations among rare disease stakeholders. A summary report and a pediatric rare diseases strategic plan will be issued approximately six months after completion of the Public Workshop. FDA remains fully committed to continuing to participate, as resources allow, in the many other collaborative workshops, meetings, and conferences with drug developers, researchers, advocacy groups, and other government agencies on a wide range of biomedical and regulatory science topics that occur throughout the years.

9. As you know, FDASIA included bipartisan language that I advanced with the help of your staff at FDA to resolve a 100-year old issue and create a pathway for medical gases to become approved drugs. I am proud that New Jersey is the home of numerous health care companies that manufacture medical gases used by millions of patients around the country. I am very eager to see the full implementation of these medical gas provisions.

For instance, FDASIA requires that FDA update its current regulations to take into account the unique characteristics of medical gases. FDA is required to report to Congress on the proposed changes in January 2014 and complete all changes by July 2016. FDA's current regulations have caused enforcement issues for decades both for FDA as the regulator and for the regulated community, including expiration dating and calculation of yield. These are issues that must be resolved through amendments to current regulation, as opposed to guidance, in order to provide certainty. I understand that safety organizations representing our New Jersey manufacturers have submitted extensive comments on the changes that are necessary to the current regulations. Will you provide me with an update on progress working with stakeholders to update the necessary federal regulations as well as assure this committee that FDA regulations will be updated to incorporate medical gases by the July 2016 deadline?

Your question refers to FDASIA Section 1112, which requires the Secretary of HHS to: 1) determine whether any changes to Federal drug regulations are necessary for medical gases, 2) submit a report to the Committee on Energy and Commerce and the Committee on Health, Education, Labor, and Pensions regarding any such changes, and 3) to make such changes within four years of the passage of FDASIA (July 9, 2016) "if the Secretary determines…that [such] changes…are necessary."

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[25] FDA, Drugs. IND Applications for Clinical Treatment of a Single Patient in Emergency Setting. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm343022.htm. 2013.

[26] Pariser AR, Slack DJ, Bauer LJ, et al. Characteristics of rare disease marketing applications associated with FDA product approvals 2006-2010. Drug Discov Today. 2012;17:898-904.

FDA is conducting an extensive review to determine if changes to the regulations are necessary. After considering numerous suggestions for regulation changes from the medical gas industry, we held a public meeting on this topic on December 6, 2013. We are currently working on the required report to Congress and will determine whether any changes to FDA regulations are necessary for medical gases.

10. **I am pleased to hear that certification of medical gas manufacturers is already underway, however I am concerned there is not yet final guidance in place resolving key issues like documentation for subsequent manufacturers. When can Congress expect to see final guidance on the medical gas certification process?**

We can assure you that work on this document is ongoing, but we do not have a specific date for issuance of a final guidance. We can report that we addressed the specific issue you mention—documentation expectations for downstream medical gas suppliers (typically transfillers)—with industry representatives at the December 6, 2013, meeting. Our staff is also generally available to discuss this or other specific issues with members of industry as they arise in the course of their regulatory compliance efforts or our regulatory enforcement practices.

The Honorable Bill Cassidy

1. **In the event a foreign and domestic manufacturer are similarly situated, such as in the case when both the foreign and domestic manufacturer would be providing an unapproved drug to mitigate a drug shortage, what criteria does FDA consider and use to determine which manufacturer will be permitted by the Agency to provide an unapproved product to mitigate the shortage?**

When there is a shortage of a medically necessary drug product,[27] FDA's practice has been to first communicate directly with the current manufacturers of the drug for the U.S. market, which may include both domestic and foreign manufacturers, to work on addressing the shortage. For example, the Agency has asked U.S.-approved manufacturers if they can increase or restart production; if a manufacturer's production has been impacted by quality problems, we have worked with the manufacturer to address those problems and where possible, develop a plan for the product to be released. In rare circumstances, when the current manufacturers that make the drug for the U.S. market have not been willing and able to meet patient needs and an ongoing shortage is anticipated, FDA has explored whether there are other manufacturers, domestic or foreign, already supplying the drug to other countries, who may be able to meet patient needs in the United States. FDA has worked with these manufacturers to determine if they have supplies available for the United States and are able to provide information to FDA to ensure that the drug is of adequate quality, is manufactured in a facility that meets FDA quality standards, and does not pose undue risks for U.S. patients. FDA has then used regulatory discretion to facilitate importation (if necessary) and distribution of the product, on a temporary basis, to meet critical patient needs

[27] A medically necessary drug product is a product that is used to treat or prevent a serious disease or medical condition, for which there is no alternative drug in adequate supply, that is judged by medical staff to be an appropriate substitute. Drug products that are in active shortage are listed on the FDA Drug Shortage Website, *http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm*.

during the shortage. The Agency has considered this option only in very limited circumstances. FDA has been reviewing certain aspects of our past practices with respect to importation, in light of the recent decision by the U.S. Court of Appeals for the District of Columbia in Cook v. FDA (733 F.3d 1 (DC Cir. 2013)).

4. **FDA plans to provide expedited entry for Secure Supply Chain Pilot participants, but does not clarify how much faster. Will FDA collect data on how the program impacts clearance rates?**

The Secure Supply Chain Pilot Program (SSCPP) includes an audit process for FDA to determine whether the program has an impact on expediting the importation of certain active pharmaceutical ingredients and finished drug products that are accepted into the program. During the audit process FDA will collect data on the rate of entry release for drugs participating in the pilot, compared with drugs subject to routine drug imports entry review.

5. **The Secure Supply Chain Pilot needs to cover a substantial portion of imports in order to enable FDA to focus its resources on high risk imports. Unfortunately, we are hearing from many qualified companies that the program is not compelling. For companies that plan to participate, the program will cover only a sliver of their imports. In terms of participation rates and amount of trade covered, what are FDA's metrics for success for this program? If FDA does not meet those metrics, is it prepared to pivot to a new, meaningful program, or will it allow the pilot to continue with only a few participants?**

This pilot program applies only to FDA-approved NDAs and ANDAs. The SSCPP is intended to assist FDA in its efforts to help prevent the importation of adulterated, misbranded, or unapproved drugs by allowing the Agency to focus its resources on imported drugs that fall outside the program and may pose risks. If, through our audit process, we find that these firms are capable of consistent compliance with the requirements of this pilot, we may expand the scope of the program to other drug areas. Our initial metrics for success focus on the ability of these firms to comply with the requirements of this pilot program and the FD&C Act, and not necessarily the rate of participation and the amount of trade covered. FDA understands the rate of participation in this program will be small due to its limited application to approved NDAs and ANDAs, but because this is a pilot program, it is adaptable and amenable to change based on the results of our program audit conducted throughout its two-year life cycle.

<u>The Honorable H. Morgan Griffith</u>

1. **While the Senate has now passed and the President has signed into law the Drug Quality and Security Act (H.R. 3204), I am still focused on the overwhelming need to protect patient safety and ensure the drugs patients are receiving are sterile and safe. Many patients rely on the availability of compounded medications to treat a variety of conditions. Without these medications, many patients may not be able to receive treatments they need. Recognizing that both contamination and lack of access may pose serious health risks to patients, how does FDA intend to balance these risks and both**

ensure safe compounded products while maintaining access to products for providers and patients, specifically including access to compounded products for office use?

FDA shares your interest in ensuring that patients receive the drugs they need and that those drugs that are required to be sterile are sterile and are safe. It is important to remember, however, that drugs made by compounders, including those made at human drug compounding outsourcing facilities, are not FDA-approved. When a drug is FDA-approved, patients are assured that FDA has reviewed the safety and efficacy of the drug product and the adequacy of the manufacturing process to produce a quality product prior to marketing. Compounded drugs do not provide such assurance. Therefore, when an FDA-approved drug is available, FDA recommends that practitioners prescribe the FDA-approved drug rather than a compounded drug, unless the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient as compared to the FDA-approved drug product.

Under the DQSA, hospitals and health care professionals can purchase compounded drugs without a prescription from a compounder that is registered as an outsourcing facility under section 503B of the FD&C Act. Section 503A requires, among other things, that to qualify for the exemptions under section 503A, there be a prescription for an identified individual patient. The Agency intends to exercise its authority, as appropriate to protect the public health, against compounded drugs that do not qualify for the exemptions in section 503A or section 503B, and drugs that are adulterated or misbranded or otherwise violate Federal laws.

2. **While the DQSA provides clarity on oversight authority for compounding pharmacies, it lacks some much needed clarity on the issue of office use. However, while office use is not mentioned in 503(a), it is expressly permitted under numerous state laws and regulations governing the practice of pharmacy. Will the FDA defer to a state regulatory agency when such a conflict between federal and state law exists?**

FDA is examining its compounding enforcement policies and practices in light of recent outbreaks and the new legislation. We anticipate communicating further with the public as that examination progresses.

3. **H.R. 3204 creates a new class of federally-regulated compounding facilities. These "outsourcing facilities," which will meet the highest possible drug safety standards, will be able to compound a variety of products for physician and patient use. How does the FDA plan to address who is responsible for regulation those entities which are acting like an outsourcing facility but have not voluntarily registered with the agency?**

If a compounder chooses not to register as an outsourcing facility and qualify for the exemptions under section 503B, the compounder could qualify for exemptions from the FDA approval requirements, the requirement to label products with adequate directions for use, and CGMP requirements by meeting the conditions in section 503A of the FD&C Act. Otherwise, it would be subject to all of the requirements in the FD&C Act applicable to conventional drug manufacturers. FDA anticipates that state boards of pharmacy will continue their oversight and regulation of the practice of pharmacy, including pharmacy compounding. The Agency also intends to continue to cooperate with state authorities to address compounding activities that may violate the FD&C Act.

4. **Does the agency intend to petition Congress to expand the definition of an outsourcing facility to include those entities and individuals engaged in the compounding and distribution of non-sterile medications?**

FDA is working to implement the new legislation and has no plans at this time to seek additional legislation.

5. **Does the agency intend to petition Congress to change current language of 503 (b) providing for voluntary registration of an outsourcing facility to a mandated registration?**

FDA is working to implement the new legislation and has no plans at this time to seek additional legislation.

6. **Are outsourcing facilities going to be required to follow Current Good Manufacturing Practices (cGMPs) or, as you indicated in your testimony before the Senate HELP Committee, does the agency intend to promulgate or use a different set of standards with which those firms will be expected to comply?**

Compounders that are registered as outsourcing facilities under section 503B of the FD&C Act are not exempt from section 501(a)(2)(B) of the FD&C Act, which requires compliance with current good manufacturing practice (CGMP). On July 1, 2014, FDA issued a draft interim guidance that describes FDA's expectations regarding compliance with CGMP requirements for facilities that compound human drugs and register with FDA as outsourcing facilities under section 503B of the FD&C Act. The guidance focuses on CGMP requirements related to sterility assurance of sterile drug products and the general safety of compounded drug products.

7. **Repackaging of drug products by outsourcing facilities was not an activity specifically covered in the Drug Quality and Security Act. Given the stringent safety, sterility, and inspection requirements on these facilities, as well as the strong need for access to repackaged sterile drug products by many physicians and patients, will the FDA allow outsourcing facilities to provide sterile repackaged drug products to physicians for administration to patients in treatment settings?**

The Agency is actively reviewing this issue and, in doing so, is taking into consideration the best interests of patients.

The Honorable Gus Bilirakis

5. **Will you tell the Committee what additional advice or guidance FDA plans on doing in the coming year in order for the industry to better understand the FDA's expectations, and encourage submission of applications for bio-similar products? Additionally, is the Agency currently developing, or does it intend to develop, any guidance with respect to unique non-proprietary names?**

FDA is carefully reviewing and considering the comments submitted to FDA's biosimilar guidance and public hearing dockets. We will take into consideration all received comments as we move forward in finalizing the draft guidance documents FDA published in 2012, and in developing future policies regarding biosimilar products and interchangeable products, including guidance on clinical pharmacology data to support a demonstration of biosimilarity to a reference product. FDA is currently considering the appropriate naming convention for biosimilar and interchangeable products licensed under the pathway established by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).

The Honorable Renee Ellmers

1. **North Carolina is home to thousands of high paying pharmaceutical jobs. We should help find smart ways to make these facilities more competitive. Unfortunately, FDA frequently but unpredictably detains complaint research compounds and active ingredients from highly compliant imports. Section 713 of FDASIA encouraged FDA to address this problem by distinguishing between highly complaint importers and high risk importers, hence the Secure Supply Chain pilot. The application window will close December 31. How have potential applicants reacted to the program? How many have applied? How many do you expect?**

Thus far, industry stakeholders have provided positive feedback and shown great interest in the SSCPP. We received approximately 40 SSCPP applications by the December 31, 2013, deadline.

Additional question asked at the hearing:

During the hearing, Members asked you to provide additional information for the record and you indicated that you would provide that information. For your convenience, descriptions of the requested information based on the relevant excerpts from the hearing transcript regarding these requests are provided below.

The Honorable Joseph R. Pitts

1. **Please submit the Agency's internal spreadsheet tracking all obligations you have under this FDASIA.**

Enclosed

FOOD AND DRUG SAFETY AND INNOVATION ACT (FDASIA) INTERNAL TRACKING SHEET

* User Fee Commitment Letter deliverables are identified using the following Section numbers: PDUFA - 100, MDUFA - 200, GDUFA - 300, BSUFA - 400. User Fee deliverables do not have "statutory" dates and the dates represent agreements in the Commitment Letters.

Item #	Title	Section *	Sub-Section	UFA Goals Letter	Goals Letter Citation	Deliverable Description	Deliverable Type	Statutory Deadline *	Targeted Completion Date **	FDA Completion Due Date **	Responsible Organization	Status ***	Date Completed	Publicly Tracked? (FDASIA-TRACK)	FDASIA TRACK Notes (Will be posted on public FDA-TRACK Website)	Public Website Contact
1		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/PrescriptionDrugUserFeeAct/325152.htm	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFeeAct/272170.htm
2		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 meta paper to facilitate discussion at the public meeting, which is available online at http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFeeAct/360080.htm	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFeeAct/272170.htm
3		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 near 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/DrugsNewsEvents/ucm367620.htm
4		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 the link http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFeeAct/ucm351029.htm	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFeeAct/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 3 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. Other Meeting dates 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 after Substantially complete, on track to meet due date	–	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	In process, 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 currently existing data standards and the involvement of existing standards development organizations to develop new standards or refine existing standards. FDA will obtain the 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 endpoint standards development within and across review divisions. FDA shall publish a proposed project plan for stakeholder review and comment by June 30, 2012. FDA shall update and publish its project plan annually. 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	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/DrugsDevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm287408.htm
11	I	100		PDUFA	XII B	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	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	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	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	XII B.2	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	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	XII B.1	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	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	XII 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	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/ucm351026.htm	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm351023.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	9-30-2014	9-31-2014	CDER	Scheduled to begin later	--	Y	Impacted by sequestration	http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
18	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	3/28/2013	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 2015, 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 Team 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 Completed 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 applications 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.2	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/default.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/default.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-2012-07-09/pdf/2012-16829.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/default.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	OPM	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 period[illegible] 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 8/1/2012 Completed http://www.gpo.gov/fdsys/pkg/FR-2012-08-01/pdf/2012-18711.pdf	Giles Miles giles.miles@fda.hhs.gov David Miller David.Miller@fda.hhs.gov
40	I	103	(2)(a)	NO		FDA shall establish fees for PDUFA and publish the fees and rationale for any adjustments in an FR notice. 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.	FR Notice	8/2/2012	8/3/2012	8/3/2012	OPM	Completed	8/1/2012	Y		
41	I	103	(2)(b)	NO			Public Report	9/30/2015	9/30/2015	9/30/2015	OPL	Scheduled to begin later	–	Y	Completed 1/31/2014	Giles Miles giles.miles@fda.hhs.gov http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeesReports/PerformanceReports/default.htm
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	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeesReports/PerformanceReports/PDUFAAudit394028.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 the 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		CDRH-FDASIA@fda.hhs.gov
44	II	200		MDUFA	I D (a)	FDA will update as 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 [illegible]	Final Guidance	–	9/1/2013	9/1/2013	CDRH	Undergoing FDA Clearance	–	Y	Completed 12/31/2012 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf	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		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 state that it plans on a structured process for managing Pre-Submissions draft guidance issued on 7/23/12.	Final Guidance	–	2/4/2014	2/4/2014	CDRH	Undergoing FDA Clearance	–	Y		CDRH-FDASIA@fda.hhs.gov
49	II	200		MDUFA	I 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 seeks 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 5 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 submit 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/OverviewMDUFAIII/UCM378282.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	9/30/2013	CDRH	Completed	9/22/2013	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/OverviewMedicalDeviceUserFeeandModernizationActMDUFMA/ucm105710.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	1 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	1 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 2012 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFA/ucm321367.htm	
70	II	203	(b)(4)	NO		FDA shall establish fees for MDUFA and publish the fees and rationale for any adjustments in an FR notice.	FR Notice	8/3/2012	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	DPL	Completed	1/31/2014	Y	Completed 1/31/2014 http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/MDUFMAucm383988.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	DPL	Completed	1/31/2014	N	Completed 1/31/2014 http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/MDUFMAucm383988.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/MedicalDeviceUserFeesandModernizationAct/UDUFMA/UCM339988.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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73	III	300		GDUFA	2 C	To maximize the number of applications that can be reviewed within the review 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.hhs.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.hhs.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.hhs.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.htm 367997.htm	www.fda.gov/gdufa AskGDUFA@fda.hhs.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.htm 367997.html	www.fda.gov/gdufa AskGDUFA@fda.hhs.gov
80	III	300		GDUFA	3 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.hhs.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 sites) 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 a timely basis.	Public Report	–	10/1/2012		CDER	Completed	10/2/2012	Y	http://www.accessdata.fda.gov/scripts/inspsearch	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.com/322629.htm
85	III	302		NO		FDA shall establish fees for GDUFA (drug master file fees and facility 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, 2012 http://www.gpo.gov/fdsys/pkg/FR-2012-10-25/pdf/2012-26256.pdf	http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees.com/322629.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. 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 sponsor (see section 512)	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/2013-00951.pdf	http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees.com/322629.htm
87	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	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			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.com/322629.htm	http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees.com/322629.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.com/322629.htm

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90	III	302		NO		FDA shall make available on its Web site a list of CMF 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/UCM332975.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 Completed 4/30/2014 http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/FinancialReports/GDUFA/ucm395903.htm	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/default.htm http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm322629.htm www.fda.gov/gdufa AskGDUFA@fda.hhs.gov
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 Scheduled to begin later	4/30/2014	Y		
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		-	Y		
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 Completed 4/30/2014 http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/FinancialReports/GDUFA/ucm395903.htm	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/default.htm http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm322629.htm www.fda.gov/gdufa AskGDUFA@fda.hhs.gov
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 Scheduled to begin later	4/30/2014	Y		
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		-	N	-	
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 http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/ucm320768.htm
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		

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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	402	(a)(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/AboutFDA/PublicInformation/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/MDUFMAucm383988.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/BsUFAucm395872.htm Completed 1/31/2014	http://www.fda.gov/AboutFDA/PublicInformation/UserFees/BiosimilarUserFeeActBsUFAucm320768.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/MDUFMAucm383988.htm	http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/default.htm
109	IV	403		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 meetings or written requests.	Other	7/9/2012	7/9/2012	7/9/2012	CDER	Completed	7/9/2012	N		pdr@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/UCM355309.pdf Additionally, an outline of procedures and timeline for review of PSPs and Written Requests by the Pediatric Review Committee can be found by this link http://ins.de.fda.gov.9003/downloads/CDER/OfficeofNewDrugs/ImmediateOffice/PediatricandMaternalHealthStaff/UCM355955.pdf	pdd@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 (j) 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		pdd@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/ucm027629.htm
114	V	505	(b)	NO		Amends FD&C Act Section 505B(1)(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		pdd@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/ucm027629.htm	pdd@fda.hhs.gov

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116	V	505	(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 the link: http://www.gpo.gov/fdsys/pkg/FR-2013-07-15/pdf/2013-16825.pdf	pdd@fda.hhs.gov
117	V	505	(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		pdd@fda.hhs.gov
118	V	505	(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	-	1/9/2018		DPT	Scheduled to begin later	-	Y		Debbie Avant debbie.avant@fda.hhs.gov
119	V	505		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 report must also be made publicly available on FDA's Internet website	Report to Congress	7/2/2016	7/5/2016	7/1/2016	DPT	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	1/6/2014	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/ucm367620.htm http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm367656.htm	http://www.fda.gov/Drugs/NewsEvents/ucm367620.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		Gavan Rao (MAY CHANGE)

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Item #	Title	Section *	Sub-Section	UFA Goals Letter	Goals Letter Citation	Deliverable Description	Deliverable Type	Statutory Deadline *	Targeted Completion Date **	FDA Completion Due Date **	Responsible Organization	Status ***	Date Completed	Publicly Tracked? (FDASIA-TRACK)	FDASIA TRACK Notes (Will be posted on public FDA-TRACK Website)	Public Website Contact
122	V	511		NO		The Office of Pediatric Therapeutics shall include an individual with expertise in pediatric epidemiology, and an individual with expertise 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	-	-		CPT	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 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	-	-		CPT	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 reissue 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 6/14/2013 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM379197.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 others, 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/ucm352246.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 submitting 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 submitting 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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Item #	Title	Section *	Sub-Section	UFA Goals Letter	Goals Letter Citation	Deliverable Description	Deliverable Type	Statutory Deadline *	Targeted Completion Date **	FDA Completion Due Date **	Responsible Organization	Status ***	Date Completed	Publicly Tracked?(FDASIA-TRACK)	FDASIA TRACK Notes (Will be posted on public FDA TRACK Website)	Public Website Contact
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	1/6/2014	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 systematically 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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* User Fee Commitment Letter (GUFA) are identified using the following Section numbers: PDUFA - 100, ANDUFA - 200, ISDUFA - 300, BSUFA - 400. User Fee deliverables do not have "Statutory" dates and the dates reflected agreements in the Commitment Letters.

Item #	Title	Section *	Sub-Section	UFA Goals Letter	Goals Letter Citation	Deliverable Description	Deliverable Type	Statutory Deadline *	Targeted Completion Date **	FDA Completion Due Date **	Responsible Organization	Status ***	Date Completed	Publicly Tracked?(FDASIA-TRACK)	FDASIA TRACK Notes (Will be posted on public FDA-TRACK Website)	Public Website Contact
138	VI	609	(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	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/ucm330695.htm	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		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 devices 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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FOOD AND DRUG SAFETY AND INNOVATION ACT (FDASIA) INTERNAL TRACKING SHEET

* User Fee Commitment Letter deliverables are identified using the following Section numbers: PDUFA - 700, MDUFA - 500, GDUFA - 300, BSUFA - 400. User Fee deliverables do not have "statutory" dates and the dates represent agreements in the Commitment Letters

Item *	Title	Section *	Sub-Section	UFA Goals Letter	Goals Letter Citation	Deliverable Description	Deliverable Type	Statutory Deadline *	Targeted Completion Date **	FDA Completion Due Date **	Responsible Organization	Status ***	Date Completed	Publicly Tracked?(FDASIA-TRACK)	FDASIA TRACK Notes (Will be posted on public FDA TRACK Website)	Public Website Contact
142	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/2012/07/10/2012-15021/unique-device-identification-system UDI Amendment to Proposed Rule 11/09/12 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/2014-00525.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	7/2/2014	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/OfficesOfficials/MedicalProductsandTobacco/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 extension 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	520	(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/2014/01/10/2014-00224/requirement-for-submission-of-information-on-pediatric-subpopulations-that-suffer-from-a-disease-or	CDRH FDASIA@fda.hhs.gov
150	VI	520	(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 Action (Proposed) Feb 19, 2013 Link to FR notice http://www.gpo.gov/fdsys/pkg/FR-2013-02-19/html/2013-03852.htm Link to draft guidance 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	Completed 09/05/2013	
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	9/9/2013	Y	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM367169.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 labelings shall identify the establishments used in production of components 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	5	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/UCM394063.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 blood components, under section 704. 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	SOP - New Template	-	7/15/2014	7/15/2014	ORA	In process on track to meet due date	-	N	Completed 7/15/2013 https://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
162	VII	707	(a)	NO		FDA will 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		FDASIAImplementationORA@fda.hhs.gov
163	VII	707	(b)	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	Final Guidance		12/22/2014	8/1/2014	ORA	In process and critical 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 at $2,500 or less	Proposed Rule	-	4/16/2014	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			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		FDASIAImplementationORA@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	4/26/2013	Y	Completed 4/26/2013 https://www.federalregister.gov/articles/html/raw_text/2013/08-10120.txt	FDASIAImplementationORA@fda.hhs.gov
168	VII	709	(b)(3)	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	FDASIAImplementationORA@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	9/27/2015	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	9/20/2015	CDER	In process on track to meet due date	-	Y		CDERCompliancePublic@fda.hhs.gov
173	VII	714	(b)	NO		Not later than 18 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	12/28/2014	OP	In process 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)(1)(B)	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	–	4/28/2015	12/28/2014	OP	In process and on track 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	–	drugrfa@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	–	5/19/2013	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	drugrfa@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 modifying 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/ucm379618.htm	drugrfa@fda.hhs.gov

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* User Fee Commitment Letter Sections are identified using the following Section numbers: PDUFA - 103, MDUFA - 209, GDUFA - 303, BSUFA - 409. User Fee deliverables do not have "statutory" dates and the dates represent requirements in the Commitment Letters.

Item #	Title	Section *	Sub-Section	UFA Goals Letter	Goals Letter Citation	Deliverable Description	Deliverable Type	Statutory Deadline *	Targeted Completion Date **	FDA Completion Due Date **	Responsible Organization	Status ***	Date Completed	Publicly Tracked?(FDASIA TRACK)	FDASIA TRACK Notes (Will be posted on public FDA TRACK website)	Public Website Contact
180	VIII	804	[illegible]	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 FDA shall submit a report to Congress on the process, 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	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/ucm320763.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		Report to Congress	Report to Congress	[illegible]/2017	7/[illegible]/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 Not later than December 31, 2014, FDA shall publish final guidance, after notice and opportunity for public comment, that addressed how data may be used for the efficient and streamlined development of antibacterial drugs to treat serious or life-threatening bacterial infections	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/UCM359164.pdf	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM359164.pdf
183	VIII	806	(b)	NO			Final Guidance	12/31/2014	12/18/2014	10/30/2014	CDER	In process or track to meet due date	–	Y		druginfo@fda.hhs.gov
184	X	921	(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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155	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
*56	IX	901	(c)	NO		(b) (1) 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	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	drug.info@fda.hhs.gov
157	IX	902	(a)	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	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	drug.info@fda.hhs.gov
158	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		drug.info@fda.hhs.gov
159	IX	903	a,b,c	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	7/26/2013	N	In the Center for Drug Evaluation and Research (CDER), the Division of Advisory Committees 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.	drugsinfo@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	-	Y		Claudia Gallo Claudia.gallo@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	a1	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/SignificantAmendments/FDCAct/FDASIA/UCM365544.pdf	Pamela.Scott@fda.hhs.gov
193	IX	907	b1	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		Jonica Bell@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 Gallo Claudia.gallo@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	-	-	-	OGPD	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	-	-		OGPD	Scheduled to begin later	-	N		druginfo@fda.hhs.gov

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*195	X	1001	a.	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 Products" issued. 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/2013-26956	http://www.fda.gov/DrugsDrugSafety/DrugShortages/default.htm
199	X	1001	(b)	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/2013/11/04/2013-26956/permanent-discontinuance-or-interruption-in-manufacturing-of-certain-drug-or-biological-products
200	X	1001	1	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/DrugsDrugSafety/DrugShortages/default.htm
201	X	1001	a	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 DEA to increase the quota	Other	7/9/2012	7/9/2012	7/9/2012	CDER	Completed	–	N		http://www.fda.gov/DrugsDrugSafety/DrugShortages/default.htm
202	X	1007		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	12/31/2013	CDER	Completed	2/6/2014	Y	Completed 2/6/2014 Drug Shortages Report to Congress - http://www.fda.gov/DrugsDrugSafety/DrugShortages/ucm384891.htm	http://www.fda.gov/DrugsDrugSafety/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 505(j)(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		CDERCompliancePub.cs@fda.hhs.gov

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204	X	1003	3	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	11/1/2013	Y	Completed 01 11 2013 http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm142338.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 assessment of aggregate quotas made by the manufacturer of a schedule II drug on FDA's drug shortage list. If the AG determines the quota 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		drug info@fda.hhs.gov
208	X	1006		NO		Attorney General shall submit a report to Congress identifying the number of requests it receives to assess 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		CDERCompliancePush@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 if FDA determines that any changes to the Federal drug regulations are necessary for medical gases pursuant to Sec. 1112 (a) (1). FDA shall issue revised 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-2012-N-0901-0002	CDERCompliancePublic@fda.hhs.gov
212	XI-B	1112	(b)	NO			Proposed Rule	7/8/2016	7/8/2016	10/30/2015	CDER	Scheduled to begin later	–	N		CDERCompliancePublic@fda.hhs.gov druginfo@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/ODP	In process, on track to meet due date	–	Y	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	–	7/1/2013	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/OC	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 OCI 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	1123		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. This 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/SignificantAmendments/ucm359356.pdf	Damian Tarver damian.tarver@fda.hhs.gov
220	XI-C	1124		NO		For fiscal years 2014 through 2018 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		Damian Tarver damian.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 (CIM)	Completed	11/4/2013	Y	Completed 11/4/2013	Carolyn Yancey Carolyn.Yancey@fda.hhs.gov Claudia Gallo Claudia.gallo@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		Jed Costanza jed.costanza@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		
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/OEP	Completed	7/10/2013	N	Final Report Issued 7/10/13: 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/SignificantAmendments/ucm360356.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/SignificantAmendments/StrategicPlanFDCAct/FDASIA/UCM360047.pdf	Patricia Stewart patricia.stewart@fda.hhs.gov
227	XI-C	1132	(b)(6)	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/UCM284580.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/UCM313764.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/SignificantAmendments/StrategicPlanFDCAct/FDASIA/UCM359590.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	10/24/2013	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 [illegible] 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 Electronic 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 [illegible] 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. DNC is working on publishing the "115" report on the web. DOJ 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-DNCDP	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 HJ	druginfo@fda.hhs.gov
237	XI-C	1142	(a)(1)	NO	NA	Not later than February 1 of each year, FDA must 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 Orlowski michael.orlowski@fda.hhs.gov
238	XI-C	1142	(a)(2)	NO	NA	Not later than 30 days after submitting any report under 712(a)(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	3/12/2014	N		Michael Orlowski michael.orlowski@fda.hhs.gov
239	XI-C	1142	(c)	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 Orlowski michael.orlowski@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		ACDMS	In process on track to meet due date Scheduled to begin later	–	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 5/30/2014) 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 Orkwis michael.orkwis@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		–	N		

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