

FDA Reauthorization Act Aims to Speed Product Reviews Through User Fee Funding

Congress passes sweeping user fee reauthorization bill to fund increased FDA staffing and support commitments to product review timelines.

Key Points:

- Congress authorized FDA to collect increased total annual user fees for all product categories compared to previous user fee authorization programs.
- The bill also includes other provisions designed to expand access to generic drugs and products targeting life-threatening pediatric or rare diseases or conditions, and to improve the inspection process, among other goals.

On August 3, 2017, the Senate passed the Food and Drug Administration Reauthorization Act (FDARA or the Act) by a vote of 94-1.¹ The FDARA bill had previously passed in the House by unanimous consent.² President Trump is expected to sign the bill, which provides for user fees covering roughly 60% of the Food and Drug Administration (FDA)'s pre-market review costs.³ FDARA reauthorizes FDA's prescription drug, generic drug, biosimilar, and medical device user fee programs from Fiscal Year (FY) 2018 through FY 2022, and amends the Federal Food, Drug and Cosmetic Act (FDCA) to enact other reforms. The law's passage follows years of negotiations between FDA, industry, consumer groups, and other stakeholders. This *Client Alert* provides a top-line overview of the key provisions of the Act with an impact on industry.

Reauthorization of User Fees

A major piece of FDARA is its reauthorization of FDA's various user fee programs — which together with FDA's targeted goals in its "commitment letters" — sets the stage for FDA to utilize fees collected from industry to support efforts at providing timely reviews of product applications and associated regulatory activities. Specifically, FDARA reauthorizes, through FY 2022, FDA's collection of user fees for its activities with respect to prescription drugs and biologic products under the Prescription Drug User Fee Act (PDUFA) VI, for generic drugs under the Generic Drug User Fee Amendments (GDUFA) II, for biosimilar products under the Biosimilar User Fee Act (BsUFA) II, and for medical devices under the Medical Device User Fee Amendments (MDUFA) IV.⁴

PDUFA VI

FDARA reauthorizes PDUFA through FY 2022, effective October 1, 2017.⁵ PDUFA VI increases the FY 2018 annual base revenue from prescription drug user fees from US\$776.794 million to US\$878.59 million, indexed through FY 2022 for inflation and other adjustments.⁶ Consequently, FDARA authorizes FDA to collect an increased amount from industry through user fees than in prior years. The increased amount is in exchange for FDA's agreement, for the first time, to human drug review program hiring goals in addition to approval and transparency goals.⁷

Notably, FDARA eliminates application fees for supplemental applications, and consolidates the prescription drug establishment fee and prescription drug product fee into a single "product fee."⁸ The Act establishes a limit on the total number of program fees that FDA may assess per applicant per year to five.⁹ As with prior PDUFA authorizations, PDUFA VI allows FDA to grant fee waivers for small businesses submitting their first human drug application,¹⁰ and provides an application fee exemption for applications for orphan drugs.¹¹

FDA has committed to the following goals in its PDUFA commitment letter as part of the negotiation for reauthorization of the user fees:¹²

- **New Drug Application (NDA) and Biologics License Application (BLA) Review Performance Goals.** FDA commits to review and act on 90% of standard new molecular entity (NME), non-NME NDAs, and original BLAs within 10 months of the 60-day filing date. FDA also commits to review and act on 90% of priority NME, non-NME NDAs, and original BLAs, within six months of the 60-day filing date. FDA further commits to review and act on 90% of Class 1 and Class 2 resubmitted original applications within two months and six months of receipt, respectively. These timelines are the same as those to which FDA committed for the previous five years under the prior PDUFA reauthorization (PDUFA V).
- **Review Performance Goals for Supplements.** FDA commits to review and act on 90% of standard efficacy supplements within 10 months of receipt; 90% of priority efficacy supplements within six months of receipt; 90% of Class 1 resubmitted efficacy supplements within two months of receipt; and 90% of Class 2 resubmitted efficacy supplements within six months of receipt. FDA also commits to review and act on 90% of manufacturing supplements requiring prior approval within four months of receipt and 90% of all other manufacturing supplements within six months of receipt. Again, these timelines are the same as those to which FDA committed for the previous five years under PDUFA V.
- **Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs.** FDA commits to apply a transparency and communication program to the review of NME NDAs and original BLAs, with the goal of minimizing the number of review cycles necessary for approval.
- **Proprietary Name Review Performance Goals.** FDA commits to review 90% of proprietary name submissions, and to provide sponsors notice of tentative acceptance or non-acceptance within 180 days during drug development and within 90 days when submitted as part of an NDA or BLA. If FDA finds the proprietary name unacceptable, the sponsor may submit a written request for reconsideration with supporting data or request a meeting within 60 days. FDA commits to review the request for reconsideration of a new proprietary name submission in accordance with these same review performance goals for new proprietary name submissions. For proprietary names that received tentative acceptance prior to an application, FDA commits to conduct a supplemental review at the time of application under the same performance goals as other NDA or BLA proprietary name submissions.

GDUFA II

FDARA reauthorizes GDUFA through FY 2022, effective October 1, 2017.¹³ FDA is authorized to collect user fees in FY 2018 in the amount of US\$493.6 million, annually adjusted each year thereafter for inflation. This is an increase from US\$323 million post-adjustment in FY 2017.¹⁴

Similar to PDUFA VI, GDUFA II eliminates application fees for Prior Approval Supplements (PASs).¹⁵ GDUFA II also adds a generic drug applicant “program fee,” the amount of which depends on the number of approved abbreviated new drug applications (ANDAs) the applicant owns (including ANDAs for discontinued products, but excluding ANDAs for which the applicant has requested withdrawal).¹⁶ To effectuate this requirement, GDUFA II requires all persons that own an ANDA, or a designated affiliate, to submit a list of all approved ANDAs owned by the applicant and its affiliates.¹⁷

FDA has committed to the following goals in its GDUFA II commitment letter:¹⁸

- **Addressing FDA’s ANDA Review Backlog.** FDA commits to review and act on 90% of standard original ANDAs within 10 months of submission; 90% of priority original ANDAs within eight months, provided that the applicant completes a “pre-submission facility correspondence” two months prior to submission; 90% of standard major ANDA amendments within eight months, if preapproval inspection is not required; and 90% of standard and priority minor ANDA amendments within three months.
- **Review Goals for PASs and PAS Amendments.** FDA commits to review 90% of PASs and PAS amendments for which preapproval inspection is not required within the following timeframes: standard PASs within six months of submission; priority PASs, four months; standard PAS major amendments, six months; and priority PAS major amendments, four months. For PASs and PAS amendments for which preapproval inspection is required, FDA commits to review 90% of such submissions within the following timeframes: standard PASs and standard PAS major amendments within 10 months of submission; and priority PASs and priority PAS major amendments within eight months of submission, provided that the applicant submits a “pre-submission facility correspondence” at least two months prior to the date of submission and such correspondence is found to be complete and accurate and remains unchanged, or 10 months if no such “pre-submission facility correspondence” is submitted or if the correspondence is found to be not complete and accurate and remains unchanged. In addition, FDA commits to review 90% of standard and priority minor PAS amendments within three months of the date of submission of the amendment.
- **Complex Product Meetings.** FDA commits to issue guidance clarifying policies and procedures for product development meetings, pre-submission meetings, and mid-review cycle meetings for sponsors of “complex products,” defined as generally including “[p]roducts with complex active ingredients (e.g., peptides, polymeric compounds, complex mixtures of APIs, naturally sourced ingredients); complex formulations (e.g., liposomes, colloids); complex routes of delivery (e.g., locally acting drugs such as dermatological products and complex ophthalmological products and otic dosage forms that are formulated as suspensions, emulsions or gels) or complex dosage forms (e.g., transdermals, metered dose inhalers, extended release injectables); [c]omplex drug-device combination products (e.g., auto injectors, metered dose inhalers); and [o]ther products where complexity or uncertainty concerning the approval pathway or possible alternative approach would benefit from early scientific engagement.”¹⁹
- **Inactive Ingredient Database Enhancements.** FDA commits to providing the means for users to perform electronic queries of the “inactive ingredient database,” which is public database of inactive ingredients present in FDA-approved products, by October 1, 2020.

- **Resource Management and Planning and Performance Reporting.** FDA commits to developing a resource management planning function and modernized time reporting approach. FDA agrees to obtain an independent evaluation of options for a new methodology to assess the resource needs of the generic drug review program, and how to monitor those needs on an ongoing basis. This evaluation will be published for public comment by the end of FY 2020.

BsUFA II

FDARA also reauthorizes BsUFA through FY 2022, effective October 1, 2017.²⁰ In FY 2018, FDA is authorized to collect US\$45 million in user fees.

As with PDUFA VI and GDUFA II, BsUFA II removes product application fees for supplemental applications.²¹ BsUFA II also removes biosimilar biological product establishment fees, and instead assesses a new “biosimilar biological product program fee,” which applies to each biosimilar product identified in an approved biological product application (excluding discontinued products).²² BsUFA II also limits the total number of program fees per applicant per year to five.²³ Similar to the changes made in PDUFA VI, BsUFA II requires FDA to develop and implement a new capacity planning methodology to more accurately reflect changes in resource and capacity needs of the process for the review of biosimilar applications.²⁴

FDA has committed to the following goals in its BsUFA II commitment letter:²⁵

- **Application Review Performance Goals.** FDA commits to review and act on 90% of original biosimilar application submissions within 10 months of the 60-day filing date and 90% of resubmitted original biosimilar applications within six months of receipt.
- **Supplements with Clinical Data Review Performance Goals.** FDA commits to review and act on 90% of original supplements with clinical data within 10 months of receipt, and 90% of resubmitted supplements with clinical data within six months of receipt.
- **Original Manufacturing Supplements Performance Review Goals.** In FY 2017, FDA commits to reviewing 70% of manufacturing supplements requiring prior approval within four months of receipt, rising annually to 90% of such supplements within four months by FY 2022. FDA also commits to review and act on 90% of all other manufacturing supplements within six months of receipt.
- **Biosimilars Guidance.** FDA commits to publish or finalize guidance on a number of topics of interest to stakeholders. By December 31, 2017, FDA commits to publish draft guidance describing statistical considerations for the analysis of analytic similarity data intended to support a demonstration that a biosimilar product is “highly similar” to the reference product, and by March 31, 2019, a draft guidance describing processes and further considerations related to post-approval manufacturing changes for biosimilars. FDA also commits to publish a revised draft guidance on “Good Review Management Principles and Practices for PDUFA Products” to ensure that it encompasses all review activities for biosimilar and interchangeable products, no later than the end of FY 2018. In addition, FDA commits to work toward publication of the following revised draft or final guidances by May 31, 2019: “Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product,” “Nonproprietary Naming of Biological Products,” and “Labeling for Biosimilar Biological Products.” Ahead of schedule from the date identified in the commitment letter, FDA’s BsUFA commitment letter, FDA published interchangeability guidance in January 2017, ahead of its commitment to do so by December 31, 2017.
- **Hiring and Retention.** FDA agrees to target hiring 15 full-time employees in FY 2018.

- **Strengthening Staff Capacity.** FDA agrees to strengthen its staff capacity to develop new biosimilars regulations and guidance, to deliver information concerning the date of first licensure and date of expiry of reference product exclusivity for inclusion in the “Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations,” known as the Purple Book, and to facilitate development of new policies and guidance by review staff.

MDUFA IV

FDARA reauthorizes MDUFA, effective October 1, 2017.²⁶ For FY 2018, FDA is authorized to collect US\$183.28 million in user fees, an increase from US\$140.762 million post-adjustment in FY 2017.²⁷ For the first time, MDUFA IV adds a user fee for submission of a *de novo* classification request.²⁸

FDA has committed to the following goals in its MDUFA IV commitment letter:²⁹

- **Performance Goals for 510(k) Reviews.** FDA commits to issue a decision for 95% of 510(k) submissions within 90 calendar days of the submission’s acceptance for filing. For all 510(k) submissions not decided within 100 calendar days, FDA commits to provide written feedback to the applicant regarding outstanding issues preventing FDA from issuing a decision.
- **Performance Goals for *de novo* Reviews.** FDA has set the goal of issuing a decision within 150 calendar days of receipt for 50% of *de novo* requests received in FY 2018. This is the first time that FDA has committed to performance goals for *de novo* submissions.
- **Performance Goals for PMA Reviews.** FDA commits to communicate all deficiencies to 95% of applicants within 60 days of receipt of an application accepted for filing review, and will issue a decision for 90% of submissions not requiring an Advisory Committee review within 180 calendar days.
- **Performance Goals for Pre-Submissions.** For the first time, FDA has also adopted performance goals with respect to its pre-submission program. FDA commits that within 15 days of receipt of a pre-submission, FDA will communicate to an applicant whether the meeting request has been accepted, and if applicable, regarding scheduling of a meeting or teleconference. FDA commits to provide written feedback in response to a pre-submission the earlier of 70 days after receipt or five days prior to a scheduled meeting for at least 1,530 pre-submissions received in FY 2018. This commitment rises annually, reaching 1,950 for FY 2022. FDA also will update its guidance, “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff” by October 1, 2018.
- **Approach to Deficiency Letters.** FDA commits that when issuing a major deficiency letter, the Agency will base that letter upon a complete review of the application and will include all deficiencies. All deficiency letters will include the basis for the deficiencies including, as relevant, the specific scientific issue and the information to support FDA’s position.

Other Key FDARA Provisions Affecting Product Development and Review

FDARA contains a number of other provisions in addition to the user fee reauthorization programs, that may also significantly impact the development and review of FDA-regulated products, including several designed to expand access to generic drugs or products targeting life-threatening pediatric or rare diseases or conditions.

Drug Product Pre-Approval Inspections

Section 806 of FDARA requires the Department of Health and Human Services, within six months of FDARA's enactment, to develop and implement a protocol for expediting review of timely responses to reports of observations from certain pre-approval inspections. The provision requires the protocol to apply to cases in which (1) the inspectional observations are the only barrier to approval of the application; and (2) the drug that is the subject of the application is a drug for which there are three or fewer approved ANDAs and for which there are less than six tentatively approved ANDAs, or for which the drug is listed on FDA's drug shortage list. The protocol will also address expedited re-inspection of facilities and establish a six-month timeline for completion of review of applicants' responses to the reports of inspectional observations. This provision is intended to address public criticism that FDA's delays in closing out pre-approval inspections have caused significant approval delays for important novel and generic drugs.

Pediatric Drug Provisions

Within one year of FDARA's enactment, FDA is required to develop and implement a plan to achieve earlier submission of pediatric studies by applicants, to enable earlier discussion of proposed pediatric study requests, to issue written requests for pediatric studies earlier in the development period, and — as appropriate — to speed the timeline for the completion of studies pursuant to a written request.³⁰ FDARA requires FDA, upon an applicant's request, to discuss preparation of the pediatric study plan for product candidates intended to treat serious or life-threatening diseases or conditions within 30 calendar days of receipt of the request, or by the end-of-Phase 1 meeting, whichever is later, and to discuss the initial pediatric study plan no later than 90 calendar days after receipt.³¹ FDARA establishes that, three years from its enactment, FDA may require an NDA or BLA applicant for a new active ingredient intended for the treatment of an adult cancer to study the product candidate in children, if the product candidate is directed at a molecular target relevant to the growth or progression of a pediatric cancer.³² Such pediatric studies should be designed to yield dosing, safety, and efficacy data.³³ FDARA also requires FDA to issue draft guidance regarding clinical pharmacology considerations for neonatal studies for drugs and biologics.³⁴

Finally, FDARA expands Section 505A(o) of the FDCA, which currently allows ANDA holders to carve out patent- and exclusivity-protected information about a product's pediatric use, such that 505A(o) will now also pertain to 505(b)(2) applicants as well.³⁵

Orphan Drug Provisions

FDARA amends Section 527 of the FDCA to prospectively require, as a condition to granting orphan exclusivity to a product candidate designated as an orphan drug that is the same as a previously approved drug, that such product candidate demonstrate clinical superiority over the previously approved drug upon approval of that product candidate. A drug is defined as clinically superior when it "provides a significant therapeutic advantage over and above an already approved or licensed drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care." This provision provides FDA with new prospective authority, after the U.S. District Court for the District of Columbia held in *Depomed v. U.S. Department of Health and Human Services*, 66 F. Supp. 3d 217 (2014), that FDA's attempts to impose a similar requirement violated the plain terms of the Orphan Drug Act.

FDARA also reauthorizes FDA's grant program for orphan-designated drug through 2022, allowing FDA to continue to provide grants to sponsors of product candidates designated as orphan drugs.³⁶

Accelerating Access to Generic Drugs

FDARA provides two new forms of accelerated review and market exclusivity for certain categories of generic drugs:

- **Priority Review of ANDAs for Reference Products with Less than Three Approved Generics and for Those on a Drug Shortage List.** Section 801 of FDARA creates new eight-month priority review pathways for two categories of ANDAs: (1) ANDAs for which the reference product has less than three approved generics, and for which there are no blocking patents and exclusivities; and (2) ANDAs for products included on the drug shortage list. Section 801 also requires FDA to publish an updated list of all drugs for which all patents and periods of exclusivity have expired, and for which FDA has not approved an ANDA referencing the product. Prior to enactment of FDARA, FDA published the first iteration of this list on June 27, 2017.³⁷
- **Breakthrough-Like Review and Marketing Exclusivity for ANDAs Designated as “Competitive Generic Therapies.”** Section 803 of FDARA authorizes FDA to designate a generic product candidate as a “competitive generic therapy” upon request by the applicant when there is one or fewer approved generics for its reference product (not including discontinued products).³⁸ For product candidates designated as competitive generic therapies, FDARA authorizes FDA to hold meetings and provide interactive communications with the applicant regarding the development of the drug during the application review, to involve FDA officials at senior levels in the review process, and to assign a cross-disciplinary project lead to facilitate review of the application. FDARA also requires FDA to issue guidance on this pathway within 18 months after FDARA’s enactment. Finally, Section 808 of FDARA provides for 180-day marketing exclusivity for the first-approved “competitive generic therapy,” even if the sponsor of the product is not the first-to-file, provided that the approval-holder begins marketing the drug within 75 days of approval.

In addition, FDARA requires FDA, as appropriate, to provide review status updates to pending ANDA applicants upon request, indicating the categorical status of the application by each relevant review discipline.³⁹

Risk Evaluation and Mitigation Strategies (REMS)

FDARA Section 606 adds an additional element to the communications plan to health care providers that FDA may require an applicant to conduct as part of a REMS. Under the FDCA, a REMS may already require the holder of an approved application to send letters to healthcare providers, disseminate information about the REMS to encourage implementation or explain certain safety protocols, and/or disseminate information through professional societies about a drug’s serious risks and any protocols to assure safe use.⁴⁰ With the additional FDARA provision, a REMS communication plan may also now require the applicant to “disseminat[e] information to health care providers about drug formulations or properties, including information about the limitations or patient care implications of such formulations or properties, and how such formulations or properties may be related to serious adverse drug events associated with the use of the drug.”⁴¹

As part of the FDARA debate, Congress considered including in the legislation language aimed at addressing competition concerns associated with REMS programs. The discussion was based on prior bills that aimed to facilitate generic and biosimilar developers’ access to samples of REMS-covered drugs to conduct necessary testing in support of approval, and also to reduce the delays associated with certain generic product approvals caused by prolonged negotiations between brand and generic applicants on a single, shared REMS program. While the final FDARA legislation ultimately did not address these issues,

the prior bills — the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act⁴² and Fair Access for Safe and Timely (FAST) Generics Act⁴³ — remain under consideration in Congress.

Drug Pricing and Shortage

Section 804 of FDARA requires an ANDA holder to notify FDA, typically within 180 days, of its intent to withdraw its product from sale or, upon approval, if the product will not be available for sale within 180 days. This codifies FDA's approach of interpreting its reporting requirements to require advance notice of manufacturing discontinuances that could lead to certain drug shortages. FDARA also requires that, within 180 days of enactment, all NDA and ANDA holders must notify FDA in writing of the marketing status of the drug. Failure to make one of the abovementioned notifications could result in FDA moving the drug from the active to the discontinued section of FDA's list of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the Orange Book.

Medical Device-Related Provisions

FDARA amends the FDCA to establish a risk-based approach to device inspections,⁴⁴ and to require improved notice and communications related to the device establishment inspection process.⁴⁵

In addition, FDARA requires FDA to develop a new pilot program no later than September 30, 2020 whereby the Agency will accept reports from accredited testing laboratories during premarket reviews as evidence that the device conforms to recognized consensus standards, with the intent of improving consistency in the way FDA applies standards in evaluating submissions.⁴⁶ In its MDUFA VI commitment letter, FDA commits to issue draft guidance regarding this pilot program by September 30, 2019 and final guidance within 12 months post-initiation of its pilot program.⁴⁷

FDARA also reauthorizes third-party review of 510(k) submissions, and requires FDA to issue draft guidance clarifying the factors FDA will use in determining whether a device is eligible for third-party review and to publish an updated list of class I and II device types or subsets that are eligible for third-party review.⁴⁸

Industry Response

FDARA passed with wide-reaching support from industry leaders. Pharmaceutical Research and Manufacturers of America (PhRMA) president and CEO Stephen J. Ubi released a statement calling reauthorization of the user fee acts "crucial to patients in need of life-saving treatments and enhancing the competitive market in biopharmaceutical innovation."⁴⁹ The Association for Accessible Medicines (AAM) released a statement, praising the GDUFA II and BsUFA II agreements for "put[ting] in place the framework for using the best processes and science available to approve new safe, effective and affordable generic and biosimilar medicines," and applauded the "strong bipartisan vote in the Senate."⁵⁰ And Biotechnology Innovation Organization (BIO) President and CEO James C. Greenwood stated that FDARA "ensures that the FDA continues to have the resources necessary to carry out its critical human drug review programs, while advancing important patient-centered policies that will help streamline the clinical trial process — the most time-consuming, complex and expensive step in the drug development process."⁵¹

Takeaways

President Trump is expected to sign FDARA without delay, though many of the Act's provisions will not take effect immediately, including the establishment of the specific FY 2018 user fees, which FDA will set after notice in the Federal Register. Companies should continue to closely monitor these legislative and administrative developments and FDA's implementation of FDARA once it becomes law, in order to efficiently and effectively navigate the evolving regulatory landscape.

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Endnotes

- ¹ Sen. Bernie Sanders (I-Vt.) was the sole Senator to vote against the measure.
- ² H.R. 2430, 115th Cong. (2017).
- ³ Office of Management & Budget, *Major Savings and Reforms, Budget of the U.S. Government Fiscal Year 2018*, at 39, (2017), <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/budget/fy2018/msar.pdf> (last accessed Aug. 8, 2017).
- ⁴ The roman numeral denotes the number of times the particular user fee act has been reauthorized.
- ⁵ Section 105.
- ⁶ 81 Fed. Reg. 49,674, 49,676 (July 28, 2016).
- ⁷ FDA, *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022*, at 40 <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf> (last accessed Aug. 8, 2017) [hereinafter “*PDUFA Reauthorization Performance Goals*”].
- ⁸ Section 102.
- ⁹ *Id.*
- ¹⁰ Revised 21 U.S.C. § 379h(d).
- ¹¹ Revised 21 U.S.C. § 379h(a)(1)(F).
- ¹² FDA, *PDUFA Reauthorization Performance Goals*, *supra* note 7, at 22.
- ¹³ Section 306.
- ¹⁴ For FY 2017, the base revenue amount was US\$299 million, adjusted to approximately US\$323.011 million. 81 Fed. Reg. 49,225, 49,226 (July 27, 2016).
- ¹⁵ Section 303.
- ¹⁶ Section 303.
- ¹⁷ *Id.*
- ¹⁸ FDA, *GDUFRA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022*, <https://www.fda.gov/downloads/forindustry/userfees/genericdruguserfees/ucm525234.pdf> (last accessed Aug. 8, 2017).
- ¹⁹ *Id.* at 25.
- ²⁰ Section 406.
- ²¹ Section 403.
- ²² *Id.*
- ²³ *Id.*
- ²⁴ *Id.*
- ²⁵ FDA, *Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022*, <https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsJFA/UCM521121.pdf> (last accessed Aug. 8, 2017).
- ²⁶ Section 306.
- ²⁷ 81 Fed. Reg. 49,987, 49,988 (July 29, 2016).
- ²⁸ Section 203.
- ²⁹ FDA, *MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022*, (2016) <https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf> (last accessed Aug. 8, 2017) [hereinafter “*MDUFA Reauthorization Performance Goals*”].
- ³⁰ Section 505.
- ³¹ Section 503.
- ³² Section 504.
- ³³ *Id.*
- ³⁴ Section 505.
- ³⁵ Section 608.
- ³⁶ Section 603.
- ³⁷ See FDA List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic, <https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/UCM564441.pdf> (last accessed Aug. 8, 2017).
- ³⁸ Section 803.
- ³⁹ Section 802.

⁴⁰ 21 U.S.C. § 355-1(e)(3).

⁴¹ Section 606.

⁴² S. 974, 115th Cong. (2017), H.R. 2212, 115th Cong. (2017).

⁴³ H.R. 2051, 115th Cong. (2017).

⁴⁴ Section 701.

⁴⁵ Section 702.

⁴⁶ Section 205.

⁴⁷ FDA, *MDUFA Reauthorization Performance Goals*, *supra* note 29, at 14.

⁴⁸ Section 206.

⁴⁹ Press Release, Pharm. Research & Mfrs. of Am., *PhRMA Statement on House Passage of PDUFA VI Reauthorization*, (July 12, 2017), <http://www.phrma.org/press-release/phrma-statement-on-house-passage-of-pdufa-vi-reauthorization> (last accessed Aug. 8, 2017).

⁵⁰ Press Release, Ass'n for Accessible Meds., *AAM Statement on Senate Passage of FDA User Fee Reauthorization (FDARA)*, (Aug. 3, 2017), <https://www.accessiblemeds.org/resources/press-releases/aam-statement-senate-passage-fda-user-fee-reauthorization-fdara> (last accessed Aug. 8, 2017).

⁵¹ Press Release, Biotechnology Innovation Org., *BIO Applauds House Passage of Food and Drug Administration Reauthorization Act (FDARA)*, (July 12, 2017), <https://www.bio.org/press-release/bio-applauds-house-passage-food-and-drug-administration-reauthorization-act-fdara> (last accessed Aug. 8, 2017).