

## Continuing Appropriations Act Includes FDA Reauthorization of User Fees

*The Act reauthorizes FDA's user fee programs but omits several proposed reforms to the FDA regulatory framework, setting the stage for further negotiations in Congress.*

### Key Points:

- Congress authorized FDA to increase the total amount of annual user fees for all product categories compared to prior user fee authorization programs.
- No material reforms to the Federal Food, Drug, and Cosmetic Act are attached to the reauthorization, although Congress may consider such reforms later this year.

On September 30, 2022, President Biden signed the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (the Act), which contains the FDA User Fee Reauthorization Act, reauthorizing the Food and Drug Administration's (FDA's) user fee programs through FY 2027.<sup>1</sup> The Act passed in the House of Representatives by a vote of 230-201 and in the Senate by a vote of 75-25.<sup>2</sup> Specifically, the Act reauthorizes FDA's prescription drug and biological product, generic drug, biosimilar biological product, and medical device user fee programs from FY 2023 through FY 2027.

Historically, reauthorization of FDA's user fee programs has been accompanied by material amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) intended to implement reforms to the FDA regulatory framework, and there had been several proposals to enact similar reforms in connection with this reauthorization. However, Congress did not reach an agreement as to the nature of such reforms ahead of the September 30, 2022, deadline to avert a government shutdown. The Act, in addition to reauthorizing FDA's user fee programs through FY 2027, provides for approximately 10 weeks of appropriations for most other government agencies,<sup>3</sup> setting the stage for renewed appropriations negotiations in Congress during the session between the November 2022 midterm elections and the beginning of the 118th Congress. Several members of Congress have identified this future omnibus appropriations bill as a vehicle for potential further reforms to the FDA regulatory framework, but whether Congress will be able to reach agreement on their passage in such a short time is unclear.<sup>4</sup>

This Client Alert provides a top-line overview of the key provisions of the reauthorization.

## Reauthorization of User Fees

Reauthorization of FDA's various user fee programs, together with FDA's targeted goals in its "commitment letters," set the stage for FDA to utilize fees collected from industry to support the agency's goals to provide timely reviews of product applications and associated regulatory activities. Specifically, the Act reauthorizes, through FY 2027, FDA's collection of user fees to fund the agency's activities with respect to: prescription drugs and biologic products under Prescription Drug User Fee Act (PDUFA) VII, generic drugs under the Generic Drug User Fee Amendments (GDUFA) III, biosimilar products under the Biosimilar User Fee Act (BsUFA) III, and medical devices under the Medical Device User Fee Amendments (MDUFA) V.<sup>5</sup>

### PDUFA VII

The Act reauthorizes PDUFA from FY 2023 through FY 2027.<sup>6</sup> PDUFA VII increases the FY 2023 annual base revenue for prescription drug user fees to \$1.15 billion, indexed through FY 2027 for inflation and other adjustments.<sup>7</sup> This represents an increase of roughly 4.5% from the \$1.10 billion annual base revenue in FY 2022.<sup>8</sup> Notably, the Act incorporates allergenic extract products licensed after October 1, 2022, into the user fee program.<sup>9</sup> Historically, these products were generally excluded from the user fee program.

FDA committed to several goals in its PDUFA VII commitment letter as part of the negotiation for reauthorization of the user fees.<sup>10</sup> Below is an overview of key points:

- **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) NDAs, non-NME NDAs, and original BLAs within 10 months of the receipt date (for non-NME NDAs) or the 60-day filing date (for NME NDAs and original BLAs). FDA also commits to review and act on 90% of *priority* NME NDAs, non-NME NDAs, and original BLAs within six months of the receipt date (for non-NME NDAs) or the 60-day filing date (for NME NDAs and original BLAs). 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 VI).
- **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 VI.
- **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 of receipt during drug development and within 90 days of receipt when submitted as part of an NDA or BLA. If FDA finds the proprietary name to be 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 the 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. Again, these performance goals are the same as those to which FDA committed for the previous five years under PDUFA VI.

- **Split Real Time Application Review (STAR) Pilot Program.** FDA commits to establish the STAR pilot program for efficacy supplements across all therapeutic areas and review disciplines that meet specific criteria (e.g., the drug is intended to treat a serious condition with an unmet medical need; clinical evidence indicates the drug may demonstrate substantial improvement on a clinically relevant endpoint(s) over available therapies). The goal of the program is to shorten the time from complete submission to the action date. Accepted STAR applications will be submitted in two parts, with the components submitted approximately two months apart. The Part 1 submission initiates FDA's review and will contain (1) all components of the NDA/BLA efficacy supplement, except for final clinical study reports for the adequate and well-controlled investigation(s) and the eCTD module 2 clinical summaries; and (2) a document providing top-line results for each of the adequate and well-controlled investigations. The Part 2 submission initiates the PDUFA timeline and will include the clinical study reports for the adequate and well-controlled investigation(s) (e.g., Phase 3 studies), and the eCTD module 2 clinical summaries. The STAR program will be available to applicants beginning in FY 2023.
- **Rare Disease Endpoint Advancement (RDEA) Pilot Program.** FDA commits to establish a pilot program for supporting novel efficacy endpoint development for drugs that treat rare diseases by offering additional engagement opportunities with the agency to sponsors of development programs that meet certain criteria. FDA also commits to developing the staff capacity to enable and facilitate appropriate development and use of such novel endpoints. FDA will accept one proposal for the program in FY 2023, rising to a maximum of three proposals per year for the remainder of FY 2024-2027.
- **Real-World Evidence (RWE) Pilot Program.** By no later than December 31, 2022, FDA commits to establish a pilot "Advancing RWE Program" to improve the quality and acceptability of real-world evidence to support regulatory decision-making. Specifically, FDA commits to establish and publicly communicate a pilot program for sponsors to submit proposals regarding the use of real-world evidence to an investigational new drug (IND) application. This program is intended to (1) identify approaches for generating RWE that meet regulatory requirements in support of labeling for effectiveness or for meeting post-approval study requirements, (2) develop agency processes that promote consistent decision-making and shared learning regarding RWE, and (3) promote awareness of characteristics of RWE that can support regulatory decisions by allowing FDA to discuss study designs considered in the Advancing RWE Program in a public forum.
- **New or Expanded Meeting Types and Follow-Up Opportunities.** FDA agrees to the introduction of a new Type D meeting and expansion of the use of INTERACT (INitial Targeted Engagement for Regulatory Advice on CBER/CDER ProductS) meetings. Type D meetings allow discussion of up to two focused topics to provide faster feedback on certain issues (e.g., a general question about an innovative development approach that does not require detailed advice, a follow-up question raising a new issue after a formal meeting, etc.). INTERACT meetings occur early in a development program before a pre-IND meeting might be requested, with the goal of facilitating IND-enabling efforts where the sponsor is facing a novel issue that might otherwise delay progress in the absence of early FDA input. INTERACT meetings were previously limited to reviews led by the Center for Biologics Evaluation and Research (CBER). The PDUFA commitment letter expands the use of INTERACT meetings to appropriate questions for "all CDER and CBER products."<sup>11</sup> FDA commits to phasing in the performance goals for Type D and INTERACT meetings, beginning in FY 2023 by holding 50% of Type D and INTERACT meetings within 50 calendar days (for Type D meetings) or 75 calendar days

(for INTERACT meetings) from receipt of the meeting request, and increasing the percentage annually. FDA also formalizes the process for sponsors to submit clarifying questions to FDA for all meeting types following a meeting discussion or Written Response Only (WRO). FDA notes that clarifying questions should be sent in writing as a “Request for Clarification” to FDA within 20 calendar days following receipt of meeting minutes or a WRO, and FDA will issue a response in writing within 20 calendar days of receipt. By September 30, 2023, FDA will issue a revised draft of the existing draft guidance on “Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products” and will update relevant manual of policies and procedures (MAPPs) and standard operating procedures and policies (SOPPs) with information pertaining to INTERACT, Type D meetings, and the Request for Clarification follow-up opportunity.

- **Chemistry, Manufacturing, and Controls (CMC) Developments.** FDA commits to (1) enhancing CMC communications between FDA and sponsors during drug development and application review, (2) enhancing inspection communication for applications other than supplements, (3) issuing draft guidance on alternative tools to assess manufacturing facilities named in pending applications, (4) facilitating the CMC readiness of products with accelerated clinical development timelines, and (5) advancing the utilization and implementation of innovative manufacturing technologies. Notably, as part of the fourth commitment to CMC readiness, FDA commits to (a) issue a new MAPP by the end of 2022 on approaches to address challenges in expediting CMC development activities for CDER-regulated products to align with accelerated clinical development timelines, and (b) conduct a CMC Development and Readiness Pilot (CDRP), starting in FY 2023, to facilitate the expedited CMC development of products under an IND application, where warranted, based on the anticipated clinical benefit of earlier patient access to the products. For sponsors participating in the CDRP, FDA will provide additional, specific CMC advice during product development by providing two additional CMC-focused Type B meetings and an additional limited number of CMC-focused discussions based on readiness and defined CMC milestones.
- **Preapproval Review of Postmarketing Requirements (PMRs).** FDA commits to establish the following pre-approval process enhancements and guidelines in PDUFA VII: (1) for *standard* NME NDAs and original BLAs, FDA will communicate details on anticipated PMRs no later than eight weeks prior to the PDUFA action goal date, and (2) for *priority* NME NDAs and original BLAs, FDA will communicate details on anticipated PMRs no later than six weeks prior to the PDUFA action goal date. These communications will summarize FDA’s preliminary evaluation of required postmarketing studies, including the study purpose, critical study design elements, timelines for discussions and engagement on the PMR for the remainder of the review cycle, and the specific serious risk (for 505(o)(3) PMRs). FDA’s performance goals for standard and priority NME NDAs and original BLAs will be phased in, rising from 60% in FY 2023 to 70% in FY 2024, and finally to 80% in FY 2025-2027.

### GDUFA III

With respect to generic drugs, the Act reauthorizes GDUFA from FY 2023 through FY 2027.<sup>12</sup> FDA is authorized to collect user fees in FY 2023 in the amount of \$582.50 million annually, adjusted each year thereafter for inflation and other adjustments.<sup>13</sup> This is an increase of approximately 9.6% from \$531.37 million post-adjustment in FY 2022.<sup>14</sup> Notably, the Act provides for annual operating reserve and capacity planning adjustments in addition to an inflation adjustment. By contrast, GDUFA II only provided an adjustment for inflation.<sup>15</sup>

FDA committed to several goals in its GDUFA III commitment letter.<sup>16</sup> Below is an overview of key points:

- **Abbreviated NDA (ANDA) Review Performance Goals.** FDA commits to review and act on 90% of *standard* original ANDAs within 10 months of submission date, provided that the applicant certifies in its ANDA that the facility listed in the submission is ready for inspection; and 90% of *priority* original ANDAs within eight months of submission date, provided that the applicant submits a complete and accurate “Pre-Submission Facility Correspondence” (PFC) no later than 60 days prior to submission. FDA commits to act on 90% of priority original ANDAs within 10 months if certain limitations apply (e.g., a PFC is not submitted within the 60-day period, the PFC is found to be incomplete or inaccurate or significantly different from the information in the ANDA, or the agency determines that an inspection of the relevant site(s) is required based on its assessment of a final bioequivalence study report). FDA will also extend the review goal to 15 months for original ANDA applicants if the applicant certifies in its ANDA that the facility listed in the submission is not ready for inspection, and will not engage in substantive review of such ANDA until an amendment is submitted certifying that all facilities are ready for inspection (although the performance goal may later be shortened to eight months from the date of the submission for a priority ANDA or 10 months for a standard ANDA if the applicant submits an amendment certifying that all facilities are ready for inspection). If the sponsor fails to submit such an amendment within 30 days of the goal date, FDA will reset the goal date for an additional 15 months.
- **ANDA Amendment Review Performance Goals.** FDA commits to review and act on 90% of *standard* major ANDA amendments within eight months of the submission date, if preapproval inspection is not required; 90% of *priority* major ANDA amendments within six months of submission date, if preapproval inspection is not required; and 90% of *standard* and *priority* minor ANDA amendments within three months of submission date. For major ANDA amendments for which preapproval inspection is required, FDA commits to review 90% of such submissions within the following timeframes: standard major ANDA amendments within 10 months of submission; and priority major ANDA amendments within eight months, provided that the applicant submits a PFC no later than 60 days prior to submission and such correspondence is found to be complete and accurate, or 10 months if certain limitations apply (e.g., the PFC is incomplete or inaccurate). These timelines are also the same as those to which FDA committed for the previous five years under GDUFA II.
- **Review Goals for Prior Approval Supplements (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 date; *priority* PASs, four months of submission date; standard PAS major amendments, six months of submission date; and priority PAS major amendments, four months of submission date. 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 date; and priority PASs and priority PAS major amendments within eight months of submission date, provided that the applicant submits a PFC no later than 60 days prior to submission and such correspondence is found to be complete and accurate, or 10 months if certain limitations apply (e.g., the PFC is incomplete or inaccurate). In addition, FDA commits to review 90% of standard and priority minor PAS amendments within three months of submission. Again, these timelines are the same as those to which FDA committed for the previous five years under GDUFA II.
- **Product-Specific Guidance.** FDA will continue to issue product-specific guidance identifying the methodology for generating evidence needed to support ANDA approval for “complex products” and non-complex drug products approved in NDAs that contain a new chemical entity (NCE). “Complex products” are defined as generally including “[p]roducts with complex active ingredients (e.g.,

peptides, polymeric compounds, complex mixtures of active pharmaceutical ingredients (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.”<sup>17</sup>

- **ANDA Assessment Meeting Program.** FDA commits to establish an ANDA Assessment Meeting Program to provide advice to ANDA applicants as they work to meet the standards for ANDA approval. The program will offer both Mid-Cycle Review Meetings and Enhanced Mid-Cycle Review Meetings to give applicants the opportunity to ask the agency about deficiencies identified in discipline review letters (DRLs). Applicants will also have the ability to request a post-complete response letter (CRL) scientific meeting to seek scientific advice on possible approaches to address deficiencies identified in a CRL related to establishing equivalence.

### BsUFA III

The Act reauthorizes BsUFA from FY 2023 through FY 2027.<sup>18</sup> BsUFA III increases the FY 2023 annual base revenue for biosimilar products to \$43.38 million, indexed through FY 2027 for inflation and other adjustments,<sup>19</sup> an increase of approximately 2% over the \$42.49 million post-adjustment in FY 2022.<sup>20</sup> Notably, the Act removes applications for allergenic extract products from the list of applications excluded from the scope of the term “biosimilar biological product applications.”<sup>21</sup>

FDA committed to several goals in its BsUFA III commitment letter.<sup>22</sup> Below is an overview of key points:

- **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. These timelines are the same as those to which FDA committed for the previous five years under the prior BsUFA reauthorization (BsUFA II).
- **Supplement Categorization.** FDA commits to a new categorization scheme for biosimilar application supplements. Biosimilar supplements will now be placed in six categories, A-F, as follows: (A) supplements seeking to update the labeling for a licensed biosimilar or interchangeable product with regard to safety information that has been updated in the reference product labeling and is applicable to one or more indications for which the product is licensed; (B) supplements seeking licensure for an additional indication when the submission does not include new data sets (other than analytical in vitro data obtained by certain means if needed to support the scientific justification for extrapolation), provided that certain requirements apply; (C) supplements seeking to remove an approved indication for a licensed biosimilar or interchangeable product; (D) supplements seeking licensure for an additional indication for a licensed biosimilar or interchangeable product when the submission: (1) contains new data sets (other than efficacy data, data to support a supplement seeking an initial determination of interchangeability, or only analytical in vitro data obtained by certain means), or (2) does not contain new data sets (other than analytical in vitro data obtained by certain means) but is subject to section 505B(a) of the FDCA and the supplement does not contain an up-to-date agreed initial pediatric study plan; (E) supplements seeking licensure for an additional indication for a licensed biosimilar or interchangeable product and containing efficacy data sets; and (F) supplements seeking an initial determination of interchangeability.

- **Supplement Review Performance Goals.** FDA commits to performance goals for review of these categories of supplements. FDA commits to review and act on original and resubmitted Category A supplements within three months of receipt, with the percentage of supplements reviewed in this time depending on the year (i.e., 70% in 2023, 80% in 2024, and 90% in 2025-2027). The same percentages apply for original and resubmitted Category B, C, and D supplements, but Category B and C supplements will be reviewed within four months of receipt, and Category D Supplements within six months of receipt. FDA further commits to review and act on 90% of original Category E and F supplements within 10 months of receipt, and 90% of resubmitted Category E and F supplements within six months of receipt.
- **Original Manufacturing Supplements Performance Review Goals.** Similar to the previous BsUFA reauthorization, FDA commits to reviewing 90% of manufacturing supplements requiring prior approval within four months of receipt. FDA also commits to review and act on 90% of all other manufacturing supplements within six months of receipt.
- **New or Revised Biosimilars Guidance Documents.** FDA commits to publish or update guidance documents on a number of topics of interest to stakeholders. By September 30, 2023, FDA commits to issuing the following: (1) a revised draft of the existing draft guidance document on “Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products,” (2) a draft guidance document on the use of alternative tools to assess manufacturing facilities named in pending applications, and (3) a draft guidance document on labeling for interchangeable biosimilar biological products. By the end of FY 2023, FDA will also publish a draft guidance document and/or a MAPP on classifying supplements to a licensed 351(k) BLA for purposes of determining review timelines. By September 20, 2024, FDA will publish draft guidance documents on the following: (1) promotional labeling and advertising considerations for interchangeable biosimilar biological products, and (2) the nature and type of information, for different reporting categories, a sponsor should provide to support post-approval manufacturing changes to approved biosimilar and interchangeable biosimilar biological products. By the end of FY 2024, FDA will publish new draft or revised guidance documents for review staff and industry with considerations relevant to biosimilar biologic-device combination products. And by September 30, 2025, FDA will publish a draft guidance document describing considerations for developing presentations, container closure systems, and device constituent parts for proposed interchangeable biosimilar biological products.
- **New Meeting Type.** FDA introduces a new meeting type—Type 2a—in its commitment letter. Similarly to the new PDUFA Type D meetings, Type 2a meetings are intended to focus on a narrow set of no more than two issues, requiring input from no more than three disciplines or review divisions. To request a Type 2a meeting, sponsors must first have had a biosimilar initial advisory (BIA) meeting or biosimilar biological product development (BPD) meeting with FDA. Those meetings were previously classified as Type 2 meetings under BsUFA II and now will be classified as Type 2b meetings under BsUFA III. A Type 2b meeting is a BPD meeting to discuss a specific issue (e.g., proposed study design or endpoints) or questions where FDA will provide advice regarding an ongoing biosimilar biological product development program.
- **Regulatory Science Pilot Program.** Starting in FY 2023, FDA will pilot a regulatory science program focused on two demonstration projects: (1) advancing the development of interchangeable products, and (2) improving the efficiency of biosimilar product development. The first project will investigate and evaluate the data and information (including RWE) needed to meet the safety standards for determining interchangeability. The second project will focus on progressing research to advance the efficiency of biosimilar product development, enhance regulatory decision-making based on the latest

scientific knowledge, and advance the use of innovative scientific methodologies and experience with biosimilars.

## MDUFA V

The Act reauthorizes MDUFA from FY 2023 through FY 2027.<sup>23</sup> For FY 2023, FDA is authorized to collect \$312.61 million in medical device user fees, an approximately 28.4% increase from \$243.47 million post-adjustment in FY 2022.<sup>24</sup> Notably, the Act includes a new performance improvement adjustment provision, which provides for increased fees in later years if FDA meets review goal timelines.<sup>25</sup> The Act also updates the user fee requirement to include *de novo* classification requests.<sup>26</sup>

FDA committed to several goals in its MDUFA V commitment letter.<sup>27</sup> Below is an overview of key points:

- Performance Goals for 510(k) Reviews.** FDA commits to issue a decision for 95% of 510(k) submissions within 90 “FDA Days,” defined as those calendar days when a submission is considered to be under review at the agency (as relevant to 510(k) submissions, following acceptance by the agency). For all 510(k) submissions not decided within 100 FDA Days, FDA commits to provide written feedback to the applicant regarding outstanding issues preventing FDA from issuing a decision. These timelines are the same as those to which FDA committed for the previous five years under the prior MDUFA reauthorization (MDUFA IV).
- Performance Goals for *De Novo* Reviews.** FDA commits to issue a decision for 70% of *de novo* requests within 150 FDA Days. However, this goal is subject to an improvement adjustment in FY 2025-2027 if FDA meets review goal timelines for FY 2023-2024.
- Performance Goals for Premarket Approval (PMA) Reviews.** Similarly to MDUFA IV, FDA commits to issue a decision within 180 FDA Days of the date of receipt that enables the submission to be filed for 90% of the following types of submissions: original PMAs, Product Development Protocols (PDP), Panel-Track Supplements, and Premarket Reports. Again, these timelines align with those to which FDA committed for the previous five years under MDUFA IV. A PDP is a method of gaining marketing approval that combines the clinical evaluation of a device with the development of necessary information for marketing approval.<sup>28</sup> More specifically, a PDP is a form of contract between FDA and a sponsor that describes the agreed-upon details of design and development activities, the outputs of those activities, and the acceptance criteria for those outputs.<sup>29</sup> When FDA declares that a PDP has been completed, the sponsor is considered to have an approved PMA.<sup>30</sup>
- Performance Goals for Pre-Submissions.** Similarly to MDUFA IV, FDA commits that, within 15 calendar days of receipt of a Pre-Submission, the agency will communicate to an applicant whether the application has been accepted, and if applicable, regarding scheduling of a meeting or teleconference. FDA also commits to provide written feedback in response to a Pre-Submission the earlier of 70 calendar days after receipt or five calendar days prior to a scheduled meeting for the following: in FY 2023, 90% of Pre-Submissions if there are fewer than 3,585, or 75% of Pre-Submissions if there are up to 4,300 submissions; for FY 2024, 90% of Pre-Submissions if there are fewer than 4,060, or 80% of Pre-Submissions if there are up to 4,300 submissions; and for FY 2025-2027, 90% of Pre-Submissions up to 4,300 submissions.
- Substantive Interactions.** FDA again commits to the following performance goals for communicating with applicants through a Substantive Interaction: (1) for 510(k)s, within 60 calendar days of receipt of the submission for 95% of submissions, and (2) for PMAs, within 90 calendar days of the filing date of the application for 95% of submissions. For *de novo* requests, at the applicant’s request and as

resources permit, if a final decision has not been rendered within 180 FDA Days, FDA will discuss with the applicant all outstanding issues with the submission preventing the agency from reaching a decision.

- **Total Product Life Cycle (TPLC) Advisory Program (TAP Pilot).** FDA will establish the TAP Pilot, which is intended to demonstrate the feasibility and benefits of process improvements to FDA's early interactions with participants and FDA's facilitation of interactions between participants and stakeholders that support the vision for TAP. Through the TAP Pilot, FDA will provide for several types of strategic engagement for innovative devices of public health importance (e.g., providing for more timely premarket interactions; engaging in earlier identification, assessment, and mitigation of product-development risk; and facilitating regular, solutions-focused engagement between FDA review teams, participants, and other stakeholders beginning early in device development). In FY 2023, FDA will enroll up to 15 products in a "soft launch" of the TAP Pilot, which will increase annually until it reaches up to 325 total products enrolled through FY 2027.
- **Guidance Document Development.** FDA plans to apply user fee revenues to ensure timely completing of draft guidance documents. Specifically, FDA will strive to finalize, withdraw, reopen the comment period, or issue a new draft guidance document for 80% of draft guidance documents within three years of the close of the comment periods, and 100% of draft guidance documents within five years of the close of the comment periods (as resources permit).

## Takeaways

The Act, along with FDA's performance goals and other commitments in its commitment letters, set the stage for FDA to continue to collect user fees from industry, and to utilize such fees to support the agency's goals to provide timely reviews of product applications and associated regulatory activities. However, many of the Act's provisions will not take effect immediately, including the establishment of the specific FY 2023 user fees, which FDA will set after publishing notice in the Federal Register.

The short-term appropriations provisions of the Act also set the stage for potential further reforms to the FDA regulatory framework. Specifically, the House and Senate each passed separate stand-alone bills that, if enacted, would have reauthorized FDA's user fee programs (i.e., the Food and Drug Administration Safety and Landmark Advancements Act of 2022, the Food and Drug Administration Simple Reauthorization Act of 2022, and the Food and Drug Amendments of 2022) before the user fee program's September 30, 2022, expiration.<sup>31</sup> Each of these bills included legislative riders that, if passed, would have reformed several key FDA regulatory frameworks, including accelerated approval, orphan drug exclusivity, therapeutic equivalence, premarket review of diagnostic tests, dietary supplements, and cosmetics manufacturing, among others. However, Congress did not reach an agreement on the riders to include in a stand-alone, final reauthorization bill. Instead, Congress reauthorized FDA's user fee programs through the Act without such material reforms to the FDA regulatory framework. This marks the first time since 1997 when Congress included the reauthorization of PDUFA in the passage of a continuing appropriations bill.<sup>32</sup>

Although the Act omits many of the material reforms to the FDCA proposed in connection with user fee reauthorization negotiations, members of Congress have signaled that such proposed reforms may be considered for inclusion in an omnibus appropriations bill during the session between the November 8, 2022, midterm elections and the swearing-in of the new Congress on January 3, 2023.<sup>33</sup> Industry should continue to closely monitor not only FDA's implementation of the Act, but also other legislative and administrative developments in connection with these proposed reforms.

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#### Endnotes

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<sup>1</sup> See, [Bills Signed: H.R. 6833, S. 3895, S. 3969, S. 4900, White House Briefing Room](#) (Sept. 30, 2022).

<sup>2</sup> H.R. 6833, 117th Cong. (2022).

<sup>3</sup> See Section 106.

<sup>4</sup> See, e.g., *Pallone on FDA User Fees*, Energy & Commerce Newsroom (Sept. 26, 2022), [https://insidehealthpolicy.com/sites/insidehealthpolicy.com/files/documents/2022/sep/he2022\\_2552.pdf](https://insidehealthpolicy.com/sites/insidehealthpolicy.com/files/documents/2022/sep/he2022_2552.pdf) (Representative Pallone stated as follows: "All four corners committed to returning to the negotiating table ahead of the December government funding deadline to revisit these key priorities. I'm going to continue pushing to advance as much of the House-passed legislation as possible."); *Burr, Murray Statement on Agreement to Reauthorize FDA User Fee Programs, Continue Work on Additional Critical Priorities*, U.S. Senate Committee on Health, Education Labor & Pensions Chair's Newsroom (Sept. 27, 2022), <https://www.help.senate.gov/chair/newsroom/press/murray-burr-statement-on-agreement-to-reauthorize-fda-user-fee-programs-continue-work-on-additional-critical-priorities> (Senators Murray and Burr stated as follows: "We are glad to announce an agreement to reauthorize the FDA user fee programs, which will ensure that FDA can continue its important work and will not need to send out pink slips. However, there is more work ahead this Congress to deliver the kinds of reforms families need to see from FDA, from industry, and from our mental health and pandemic preparedness efforts. As part of our agreement, we and our House counterparts are committed to continuing that work, and including strong, bipartisan legislation in a robust end of year package.").

<sup>5</sup> The roman numeral denotes the number of times the particular user fee act has been reauthorized.

<sup>6</sup> Section 1004.

<sup>7</sup> Section 1003.

<sup>8</sup> See 86 Fed. Reg. 45,732, 45,732 (Aug. 16, 2021).

<sup>9</sup> Section 1002.

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- <sup>10</sup> See FDA, *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027*, <https://www.fda.gov/media/151712/download> (last visited Sept. 22, 2022).
- <sup>11</sup> See *id.* at 22.
- <sup>12</sup> Section 3002.
- <sup>13</sup> *Id.*
- <sup>14</sup> See 86 Fed. Reg. 40,582, 40,584 (July 28, 2021).
- <sup>15</sup> Section 3002.
- <sup>16</sup> See FDA, *GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027*, <https://www.fda.gov/media/153631/download> (last visited Sept. 22, 2022).
- <sup>17</sup> *Id.* at 45-46.
- <sup>18</sup> Section 4003.
- <sup>19</sup> Section 4003.
- <sup>20</sup> See 86 Fed. Reg. 40,567, 40,568 (July 28, 2021).
- <sup>21</sup> Section 4002.
- <sup>22</sup> See FDA, *Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027*, <https://www.fda.gov/media/152279/download> (last visited Sept. 22, 2022).
- <sup>23</sup> Section 2003.
- <sup>24</sup> See *id.*; 86 Fed. Reg. 41,477, 41,478 (Aug. 2, 2021).
- <sup>25</sup> Section 2003.
- <sup>26</sup> *Id.*
- <sup>27</sup> See FDA, *MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027*, <https://www.fda.gov/media/158308/download> (last visited Sept. 23, 2022).
- <sup>28</sup> FDA, *PMA Application Methods*, [https://www.fda.gov/medical-devices/premarket-approval-pma/pma-application-methods#:~:text=Product%20Development%20Protocol%20\(%C2%A7814.19\)&text=The%20PDP%20process%20provides%20the,effectiveness%20of%20a%20new%20device](https://www.fda.gov/medical-devices/premarket-approval-pma/pma-application-methods#:~:text=Product%20Development%20Protocol%20(%C2%A7814.19)&text=The%20PDP%20process%20provides%20the,effectiveness%20of%20a%20new%20device). (last updated Sept. 27, 2018).
- <sup>29</sup> *Id.*
- <sup>30</sup> *Id.*
- <sup>31</sup> See S.B. 4348, 117th Cong. (2022); H.R. 7667, 117th Cong. (2022); S.B. 4535, 117th Cong. (2022).
- <sup>32</sup> See Elise Reuter, *6 Questions for the MedTech Industry if Congress Doesn't Reauthorize FDA User Fees on Time*, MedTech Dive (Aug. 3, 2022), <https://www.medtechdive.com/news/Congress-FDA-user-fees-deadline-FAQ/628729/>.
- <sup>33</sup> John Wilkerson, *Burr Wants User Fee Policy Riders Included in Omnibus Appropriations*, InsideHealthPolicy (Sept. 20, 2022, 5:12 PM), <https://insidehealthpolicy.com/daily-news/burr-wants-user-fee-policy-riders-included-omnibus-appropriations>; Pallone on *FDA User Fees*, House Committee on Energy & Commerce (Sept. 26, 2022), <https://energycommerce.house.gov/newsroom/press-releases/pallone-on-fda-user-fees>.