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FDA User Fee Reauthorization Act of 2022

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EXECUTIVE SUMMARY

On September 30, 2022, President Biden signed into law the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023, Pub. L. No. 117-180, 136 Stat. 2114 (2022), Division F of which—136 Stat. 2139—is titled the "FDA User Fee Reauthorization Act of 2022" ("FUFRA").[1] FUFRA primarily amends both the Federal Food, Drug, and Cosmetic Act ("FDC Act") and Public Health Service Act ("PHS Act"). In addition to reauthorizing for an additional five fiscal years—Fiscal Years ("FY") 2023-2027—several drug, biological product, and medical device user fee provisions that were scheduled to sunset on September 30, 2022, FUFRA reauthorizes—but only through December 16, 2022—several other statutory provisions that were scheduled to expire.

Unlike prior user fee reauthorizations, FUFRA does not include any "riders" addressing additional, non-user fee related statutory changes. The limited reauthorizations will likely force Congress back to the negotiation table later this year to pass additional legislation that would extend those provisions through Fiscal Year 2027. At that time, Congress may also consider various "riders" that were included in the House and Senate versions of the Food and Drug Administration's ("FDA's") user fee program reauthorizations.[2]

FUFRA includes five titles, the first four of which concern drug, biologic, and medical device user fee-related programs. Title V includes a potpourri of other statutory program reauthorizations.

This memorandum summarizes FUFRA—in particular, the provisions that are of most interest to our clients—and analyzes FUFRA's potential effects on the FDA- regulated industry. It is organized to summarize each title in the order presented in FUFRA. In addition to this memorandum, Hyman, Phelps & McNamara, P.C. will periodically report on various FUFRA issues on our firm's blog, the FDA Law Blog (www.FDALawBlog.net). You can register for e-mail updates on the blog.

I. PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2022

FUFRA reauthorizes the Prescription Drug User Fee Act ("PDUFA") through FY 2027. PDUFA was first enacted in 1992 to generate revenue from user fees paid by drug and biologic manufacturers in exchange for FDA's agreement to improve upon its historically slow review timelines (known as "Performance Goals") for sponsors submitting certain New

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[1] Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023, Pub. L. No. 117-180, 136 Stat. 2114 (2022), https://www.congress.gov/117/plaws/publ180/PLAW-117publ180.pdf.

[2] *See* Food and Drug Amendments of 2022, H.R. 7667, 117th Cong. (2022), https://www.congress.gov/117/bills/hr7667/BILLS-117hr7667eh.pdf; FDA Safety and Landmark Advancements Act of 2022, S. 4348, 117th Cong. (2022), https://www.congress.gov/117/bills/s4348/BILLS-117s4348rs.pdf.

Drug Applications ("NDAs") and Biologics License Applications ("BLAs"). PDUFA has been reauthorized every five years since 1992,[3] with the current iteration being the seventh PDUFA ("PDUFA VII"). This reauthorization continues a now familiar practice whereby the enacting legislation, FUFRA, captures select changes to the FDC Act's PDUFA provisions and incorporates by reference the Performance Goals, as negotiated through an iterative process that includes the FDA and numerous external stakeholders.

A. Significant Changes to PDUFA

The overall user fee-setting process and statutory definitions for those drug products and marketing applications covered by PDUFA were established in 1992 with the enactment of PDUFA I. Since that time, the methodology for setting user fees has been subject to some amount of revision with every PDUFA reauthorization, each intended to either provide new parameters around or new authority for FDA to increase the annual base fee. In contrast, the definition of human drug applications has remained a relative constant with the only substantive change being the addition of several new carveouts from the definition in 1997 under PDUFA II.

The current reauthorization, PDUFA VII, primarily maintains the existing user fee program structure, fee types, and methods for setting fees with a few exceptions. These exceptions include changes to the process for setting user fees: (1) codification of capacity planning adjustments first developed under PDUFA VI; and (2) addition of a new adjustment to support FDA strategic hiring and retention requests. *See* FUFRA § 1003(c). The capacity planning adjustment is determined annually using a four-step forecasting approach based on the FDA's anticipated workload and resource needs. *See* FUFRA § 1003(c)(3). The FY 2021 Prescription Drug User Fee Rates Notice in the *Federal Register* describes in detail the capacity planning adjustment methodology. *See* FDA, Notice, Prescription Drug User Fee Rates for Fiscal Year 2021, 85 Fed. Reg. 46,651 (Aug. 3, 2020). PDUFA VII incorporates this methodology and limits the bases for calculating the adjustment to FDA workload and activities related to core review functions (as described in the published notice) and certain PDUFA-related activities. *See* FUFRA § 1003(c)(3).

These new adjustments under PDUFA VII are just two parts of the overall fee structure, which, in brief, establishes a method for setting an annual total revenue from all PDUFA fees collected in a given fiscal year. The total revenue amount represents an

[3] *See* Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (1992) ("PDUFA I"); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, Title I, 111 Stat. 2296 (1997) ("PDUFA II"); Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, Title V, 116 Stat. 594 (2002) ("PDUFA III"); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, Title I, 121 Stat. 823 (2007) ("PDUFA IV"); Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, Title I, 126 Stat. 993 (2012) ("PDUFA V"); Food and Drug Administration Reauthorization Act of 2017, Pub. L. No. 115-52, Title I, 131 Stat. 1005 (2017) ("PDUFA VI").

annual base revenue plus adjustments for: (1) inflation; (2) strategic hiring and retention; (3) capacity planning; (4) operating reserves carry over; (5) additional direct costs; and (6) statutorily defined amounts meant to fund any new PDUFA initiatives. *See* FDC Act § 736(b)-(c), as amended by FUFRA § 1003(b)-(c). For FY 2023, the annual base revenue amount is $1,151,522,958 and adjusts annually for FYs 2024-2027 by adopting the previous fiscal year's total revenue amount (less adjustments for operating reserves and direct costs). *See* FUFRA § 1003(b)(2). Of the total revenue amount determined for a fiscal year, 20 percent is derived from application fees, and 80 percent is derived from annual prescription drug program fees. *See* FDC Act § 736(b)(2).

In contrast to the iterative changes made to the fee setting methodologies, PDUFA VII makes significant revisions to the types of products that are subject to PDUFA. These changes are intended to extend, for the first time, the benefits and costs of the user fee program to allergenic extract products, while adding and clarifying exemptions for other products.

Under PDUFA VII, the definitions of "human drug application" and "prescription drug product" have been revised to include allergenic extract products licensed on or after October 1, 2022. *See* FUFRA § 1002(a)-(b). However, the addition of allergenic extract products was accompanied by a specific carve-out from PDUFA's application and program fees for "skin-test diagnostic products." FUFRA § 1003(a). These diagnostics are defined to exempt certain skin hypersensitivity test products that use prick, scratch, intradermal and subcutaneous administration methods intended to aid in the diagnosis of certain allergies. *See* FUFRA § 1002(c).

In addition to the carve-out for skin-test diagnostics, PDUFA VII contains several other updates to the prescription drug program definition and annual fee exemptions, including a rewrite of the provisions meant to ensure that generic drugs are not subject to PDUFA's program fees. The revamped language works by exempting products that are "pharmaceutically equivalent" to those listed in FDA's Orange Book as well as certain large volume parenteral products. *See* FUFRA § 1003(a)(2)(B). The new language simply defers to FDA's regulatory definition of "pharmaceutical equivalence" incorporating by reference FDA's regulation at 21 C.F.R. § 314.3 (or any successor regulation). *See id.* In addition, a "special rule" clarifies that if a previously discontinued drug product is the subject of an approved drug application as of the first day of the fiscal year (October 1) and is subsequently removed from the discontinued products list during that fiscal year, such drug product will be subject to the annual program fee. *See* FUFRA § 1003(a)(2)(A)(iii). Further, the prescription drug product definition was revised to clarify that if an applicant submits a request that a drug be added to the FDA Orange Book's discontinued products list, said drug will be considered discontinued on the later of either the date the request is received by FDA or the planned future withdrawal date if one is identified. *See* FUFRA § 1002(b)(5).

Finally, PDUFA VII enacts procedural changes and clarifications affecting waivers,

reductions and exemptions from PDUFA fees. To receive public health and small business waivers or reductions, as well as those exemptions from the annual program fee available for certain orphan drugs, an applicant must submit the request, with citation to the relevant legal authorities, no later than 180 days after the fee is due. *See* FUFRA § 1003(e). In addition, the orphan drug exemptions to the annual program fee were revised to make clear that the $50,000,000 eligibility cap is on "gross annual revenues . . . for the last calendar year ending prior to the fiscal year for which the exemption is requested." *See* FUFRA § 1003(f)(2). Notably, the certification for a request for this exemption must now be supported by the applicant's United States tax returns or "as necessary, other appropriate financial information." *Id.*

B. FDA's PDUFA VII Performance Goals

FDA's PDUFA VII Performance Goals Letter (hereinafter referred to as "Goals Letter"),[4] summarized below, covers a wide range of drug development-related activities, including commitments regarding the human drug review program for various types of applications.

Review Performance Goals for Drug Marketing Applications. The Goals Letter sets the current review performance goals for various types of drug marketing applications as follows, which remain unchanged:

Table 1: Original and Resubmitted Applications and Supplements

SUBMISSION COHORT	STANDARD	PRIORITY
NME NDAs and original BLAs	90% in 10 months of the 60-day filing date	90% in 6 months of the 60-day filing date
Non-NME NDAs	90% in 10 months of the receipt date	90% in 6 months of the receipt date
Class 1 Resubmissions	90% in 2 months of the receipt date	90% in 2 months of the receipt date
Class 2 Resubmissions	90% in 6 months of the receipt date	90% in 6 months of the receipt date
Original Efficacy Supplements	90% in 10 months of the receipt date	90% in 6 months of the receipt date
Class 1 Resubmitted Efficacy Supplements	90% in 2 months of the receipt date	90% in 2 months of the receipt date
Class 2 Resubmitted Efficacy Supplements	90% in 6 months of the receipt date	90% in 6 months of the receipt date

[4] The PDUFA VII Performance Goals are *available at* https://www.fda.gov/media/151712/download.

Table 2

	PRIOR APPROVAL	ALL OTHER
Manufacturing Supplements	90% in 4 months of the receipt date	90% in 6 months of the receipt date

The NME NDA and Original BLA "Program." In an effort to promote transparency and communication between the FDA review team and the applicant, FDA reauthorized "the Program" for review of all New Molecular Entity New Drug Applications ("NME NDAs") and original BLAs, including applications that are resubmitted following a Refuse-to-File decision, received from October 1, 2022, through September 30, 2027 (*i.e.*, FYs 2022-2027). *See* PDUFA VII Performance Goals at 7.

The Program is intended to "promote the efficiency and effectiveness of the first cycle review process and minimize the number of review cycles necessary for approval, ensuring that patients have timely access to safe, effective, and high quality new drugs and biologics." *Id.*

The Program outlines a standard approach for review of NME NDAs and original BLAs, but allows for the FDA review team and the applicant to discuss and reach a mutual agreement on the timing and nature of interactions between the applicant and FDA through what is known as a "Formal Communication Plan." *Id.* The Formal Communication Plan specifies any elements of the Program that FDA and the applicant agree are unnecessary. *Id.*

The parameters of the Program include, among other things, a pre-submission meeting that is "strongly encouraged," a mid-cycle communication "to provide the applicant with an update on the status of the review of their application," and a late-cycle meeting at which the FDA review team, appropriate team leaders and supervisors, and the applicant discuss the status of the review of the application. *See id.* at 7-11. The goal for inspection times was reauthorized (6 months of original receipt for priority applications and within 10 months of the date of original receipt for standard applications). *See id.* at 11.

New Molecular Entity (NME) Milestones and Postmarketing Requirements ("PMRs"). FDA outlined an approach to communicating postmarketing drug safety issues, including timelines regarding PMRs for standard NME NDAs and original BLAs (no later than 8 weeks prior to the PDUFA action goal date) and priority NME NDAs and original BLAs (no later than 6 weeks prior to the PDUFA action goal date) with phased-in target percentages increasing each year until 80% in FY 2027. *See id.* at 12-13. Additionally, FDA plans to establish a process for reviewing sponsor-initiated requests for reviews of existing PMRs for release. *See id.* at 13-14.

Split Real Time Application Review (STAR) Pilot Program. FDA plans to establish a

new Split Real Time Application Review ("STAR") pilot program, beginning in FY 2023, with the goal of shortening the time from date of complete submission to the regulatory action. *Id.* at 14, 17. The STAR pilot program applies to efficacy supplements for therapies where there is clinical evidence indicating the drug may demonstrate substantial improvement on a clinically relevant endpoint(s) over available therapies, the application is for a drug intended to treat a serious condition with an unmet medical need, no aspect of the submission is likely to require a longer review time, and there is no need for a foreign manufacturing site inspection. *See id.* at 14-15.

Under the STAR pilot program, the applicant will split the application into Part 1, containing all components of the NDA/BLA efficacy supplement except final clinical study reports and clinical summaries, along with a document providing topline results for each of the adequate and well-controlled investigations, and Part 2, containing the remainder of the supplement not yet submitted. *See id.* at 16. Part 1 will be submitted approximately 2 months, and not longer than 3 months, in advance of Part 2. *See id.* The PDUFA timeline will begin upon receipt of Part 2 and FDA intends to follow the expedited review timeline, taking action at least 1 month earlier than the applicable PDUFA goal date. *See id.* at 15. FDA also intends to conduct a public workshop by the end of Q2 in FY 2026 to discuss the potential value and feasibility of expanding this program to select NME NDAs and BLAs. *See id.* at 16.

Expedited Reviews. If an application reviewed in the Program is for a product that has received a priority review designation and the FDA review team identifies it as meeting an important public health need, or the application is an efficacy supplement in the STAR pilot program, the review team plans to act at least 1 month before the PDUFA goal date, unless prevented by deficiencies in the application, in which case FDA will revert to the normal priority review approach. *See id.* at 17.

Review of Proprietary Names to Reduce Medication Errors. FDA set review goals for proprietary names during development (as early as end-of-phase two), and during its review of a marketing application. *See id.* at 17. For proprietary name review during drug development, FDA has set a goal to review 90% of proprietary name submissions filed within 180 days of receipt. *See id.* For proprietary name review during application review, FDA has set a goal to review 90% of NDA/BLA proprietary name submissions filed within 90 days of receipt. *See id.*

Major Dispute Resolution. For procedural or scientific matters involving the review of human drug applications and supplements that cannot be resolved at the signatory authority level, FDA has set a goal of providing answers to 90% of appeals within 30 calendar days from the Center's receipt of the appeal. *See id.* at 18.

Clinical Holds. FDA has set a goal to respond to 90% of sponsors' complete responses to a clinical hold within 30 days of the Agency's receipt of the submission. *See id.* at 19.

Special Protocol Question Assessment and Agreement. FDA set procedures and performance goals for the evaluation of certain protocols and issues to assess design adequacy upon specific request by sponsors. *See id.* at 19-20. The Goals Letter specifies that the sponsor seeking FDA agreement on the design of certain study protocols should submit a limited number of specific questions about the protocol design and regulatory requirements. *See id.* at 19. Within 45 days of receipt, according to the procedures in the Goals Letter, FDA will provide a written response to the sponsor that includes an assessment of the protocol and answers to questions posed by the sponsor. *See id.*

Protocols that qualify for this program include: carcinogenicity protocols, stability protocols, and Phase 3 protocols for clinical trials that will form the primary basis of an efficacy claim. *See id.* at 19-20. The Goals Letter states that "[t]he fundamental agreement here is that having agreed to the design, execution, and analyses proposed in protocols reviewed under this process, the Agency will not later alter its perspective on the issues of design, execution, or analyses unless public health concerns unrecognized at the time of protocol assessment under this process are evident." *Id.* at 20. FDA has set a goal of completing and returning 90% of special protocol assessments to the sponsor within the specified timeframe. *See id.*

Meeting Management Goals. FDA set procedures and performance goals for meeting management administration (e.g., responding to meeting requests, scheduling meetings, receipt of meeting background packages). The Goals Letter describes the different meeting types with two new additions. *See id.* at 20-21. Type D meetings, which are focused on a narrow set of issues (typically not more than two), could include follow-up questions that raise a new issue after a formal meeting or a general question about an innovative development approach that does not require extensive advice. *See id.* at 21. Type D meetings should not require input from more than 3 disciplines or Divisions. *See id.* The other new addition is INitial Targeted Engagement for Regulatory Advice on CBER/CDER ProducTs ("INTERACT") meetings, which are intended for novel questions and unique challenges early in development, prior to the filing of an IND. *See id.* A sponsor needs to have selected a specific investigational product or product-derivation strategy to evaluate in a clinical study before requesting an INTERACT meeting. *See id.*

Table 3 indicates the timeframes for FDA's response to a meeting request. FDA plans to respond to meeting requests and provide notification within the response times noted below for 90% of each meeting type. *See id.* at 22-23. Other than for the two new additions, the response times are unchanged.

Table 3

Meeting Type	Response Time (calendar days)
A	14
B	21
B(EOP)	14
C	21
D	14
INTERACT	21

For any type of meeting, the sponsor may request written responses rather than a face-to-face or teleconference meeting, and FDA will make a determination regarding which it views as more appropriate. *See id.* at 23. For pre-IND, Type C, Type D, and INTERACT meetings, FDA may grant written responses despite a request for a face-to-face meeting, and will notify the requester of the date it intends to send the written response in the response to the meeting request. *See id.* If the sponsor believes a face-to-face pre-IND meeting is valuable and warranted, the sponsor may provide a rationale in a follow-up correspondence, and FDA will convert the meeting where possible from written response only ("WRO") to a face-to-face meeting for requests that include novel approaches to clinical development and/or where there are not well-established precedents. *See id.*

Table 4 indicates the timeframes for the scheduled meeting date following receipt of a formal meeting request, or in the case of a written response, the timeframes for the Agency to send the written response. *See id.* at 23-24. If the requested date for any meeting is greater than the specified timeframe, the meeting date should be within 14 calendar days of the requested date. *See id.* at 23. FDA plans to hold 90% of meetings within the timeframe for Type A, B, B(EOP) and C meetings and to send 90% of written responses within the timeframe for each of these meeting types. *See id.* at 24. The Agency will use a phased-in approach for performance goals in scheduling Type D and INTERACT meetings, beginning with 50% within the applicable timeframes in Table 4 by FY 2023 and 90% by FY 2027. *See id.* Other than for the two new types of meetings, the scheduling times are unchanged.

Table 4

Meeting Type	Meeting Scheduling or Written Response Time
A	30 calendar days from receipt of meeting request
B	60 calendar days from receipt of meeting request
B(EOP)	70 calendar days from receipt of meeting request
C	75 calendar days from receipt of meeting request
D	50 calendar days from receipt of meeting request
INTERACT	75 calendar days from receipt of meeting request

Table 5 lists the timing of the Agency's receipt of the sponsor background package for each meeting type. *See id.* at 25. Other than for the two new types of meetings, the deadlines are unchanged. However, for Type C meetings that are requested as early consultations on the use of a new surrogate endpoint to be used as the primary basis for approval in a proposed context of use, the meeting background package is due at the time of the meeting request. *See id.*

Table 5

Meeting Type	Receipt of Background Package
A	At the time of the meeting request
B	30 calendar days before the date of the meeting or expected written response
B(EOP)	50 calendar days before the date of the meeting or expected written response*
C	47 calendar days before the date of the meeting or expected written response*
D	At the time of the meeting request
INTERACT	At the time of the meeting request

* If the scheduled date of a Type B(EOP) or C meeting is earlier than the timeframes specified in Table 4, the meeting background package will be due no sooner than 6 calendar days and 7 calendar days following the response time for Type B(EOP) and C meetings specified in Table 3, respectively.

FDA intends to send 90% of preliminary responses to the sponsor's questions contained in the background package no later than five calendar days before the meeting date for Type B(EOP), D, and INTERACT meetings. *See id.* For Type C meetings, FDA plans the same timeframe, but there is no accompanying performance goal. *See id.* Not later than three calendar days following the sponsor's receipt of FDA's preliminary responses for a Type

B(EOP), D, INTERACT, or C meeting, the sponsor must notify FDA of whether the meeting is still needed, and if so, the agenda for the meeting. *See id.* at 25-26.

FDA plans to issue 90% of meeting minutes within 30 calendar days of the date of the meeting for Type A, B, B(EOP), C, and D meetings. *See id.* at 26. For INTERACT meetings, the preliminary responses will be annotated and resent within 30 calendar days if the advice changes as a result of the meeting. *See id.* The Goals Letter states, however, that in order to qualify for the performance goals described above, the sponsor must submit a written request to the review division which contains: (1) a statement of the purpose of the meeting; (2) a list of specific objectives/outcomes; (3) a proposed agenda; (4) a list of planned external attendees; (5) a list of requested Center attendees; and (6) the date that the meeting background package will be sent to the Center. *See id.* The Agency must also concur that the meeting will serve a useful purpose. *See id.*

Sponsors may submit clarifying questions to FDA for all meeting types to ensure the sponsor's understanding of FDA feedback. *See id.* at 27. No new issues may be raised in these questions. *See id.* The questions should be submitted in writing as a "Request for Clarification" to FDA within 20 calendar days following receipt of meeting minutes or a WRO, and FDA intends to respond in writing within 20 calendar days of receipt. *See id.*

The Regulatory Science Program and Expediting Drug Development. As part of the PDUFA VII Performance Goals, FDA will extend its regulatory science program "[t]o ensure that new and innovative products are developed and available to patients in a timely manner." *Id.* at 27.

In order to develop better communication between FDA and sponsors during the drug development process, FDA will maintain a dedicated drug development communication and training staff in CDER and CBER. *See id.* The staff will serve as a "liaison" to facilitate interactions between sponsors and each Center by serving as a point of contact for sponsors who have general questions about drug development or who are having difficulty communicating with the review team for their IND. *See id.* at 27-28. The communication staff will also provide training on best practices for communication with sponsors. *See id.* at 28.

FDA plans to convene a public workshop by the end of July 2024 to discuss best practices for meeting management, including issues related to lessons learned from the COVID-19 pandemic. *See id.* The workshop will include experience and metrics related to all PDUFA meeting activities. *See id.* Based on the discussion at the public meeting, FDA will update public documents, as appropriate, including publishing revised draft or final version of the guidance on "Best Practices for Communication Between IND Sponsors and FDA During Drug Development" 18 months following the public workshop. *See id.*

To further expedite the development and review of drug and biological products, the Breakthrough Therapy Program will continue to be prioritized through the retention of

current resources that allow FDA to continue to work closely with sponsors throughout the designation, development, and review process. *See id.* at 29.

CDER's Rare Diseases Team staff will continue to be integrated into review teams for rare disease development programs and application review. *See id.* at 29-30. Their "unique expertise on flexible and feasible approaches to studying and reviewing such drugs" is intended to foster the advancement of the development of drugs for rare diseases. *See id.* at 30. The Goals Letter states that CBER's Rare Disease Program Staff will also ensure its review offices consider such flexible and feasible approaches in review. *See id.* The rare disease staff will also continue to provide training to all CDER and CBER review staff related to the development, review, and approval of drugs for rare diseases. *See id.* All staff activities must be included in the PDUFA annual performance report. *See id.*

FDA intends to establish the Rare Disease Endpoint Advancement ("RDEA") pilot program to provide selected sponsors with the opportunity for repeated, intensive interactions with the Agency for the purpose of supporting the advancement of rare disease treatments. *See id.* at 30-31. FDA has committed to developing staff capacity to enable and facilitate the appropriate development and use of novel endpoints in this context. *See id.* at 31. Endpoints will be considered eligible for proposal submission to RDEA if they meet the following criteria: (1) the development program must be active, at least to the extent of initiating a natural history study, and address a rare disease or, potentially, a common disease where innovative or novel endpoint elements could be applicable to a rare disease; and (2) the proposed endpoint is a novel efficacy endpoint intended to establish substantial evidence of effectiveness for a rare disease treatment. *See id.* at 31-32.

The Goals Letter outlines how FDA intends to establish preference in selecting proposals for the RDEA Pilot Program, with a focus on those that have the potential to impact drug development more broadly. *See id.* at 31-32. FDA will select a limited number of qualified proposals into RDEA, increasing from a maximum of 1 proposal beginning in Q4 FY 2023 to a maximum of 1 proposal per quarter totaling up to a maximum of 3 proposals per year beginning in FY 2024. *See id.* at 32. Following submission of a proposal, FDA will notify the sponsor of a final selection decision no later than 60 days following the end of the FY quarter during which it is submitted. *See id.* Admitted sponsors may participate in up to 4 focused meetings to discuss endpoint development, each scheduled within 45 days following FDA's receipt of the request and complete briefing document. *See id.* at 33. FDA advice in the context of the RDEA Pilot Program does not constitute a regulatory decision and is not binding; regulatory approval is also not guaranteed for participants. *See id.* FDA intends to conduct up to 3 public workshops by the end of FY 2027 to discuss various topics relevant to endpoint development for rare diseases. *See id.* at 33-34. Novel endpoints developed through RDEA may be presented by FDA to the public in these workshops or elsewhere and may include disclosures previously agreed upon between sponsor and FDA. *See id.*

The Goals Letter also describes procedures and performance goals intended to advance

the development of drug-device and biologic-device combination product. *See id.* at 34-35. Sponsors conduct a Use-Related Risk Analysis ("URRA") to identify the need for risk mitigation strategies and to design a human factors ("HF") validation study. Based on an URRA, a sponsor may propose that an HF validation study is not necessary to support the safe and effective use of a drug-device or biologic-device combination product. *See id.* at 34. Sponsors should submit a request for review of their URRA with accompanying justification that a HF validation study is not needed to their IND. FDA intends to respond within 60 days of receipt for 50% of submissions by FY 2024, increasing up to 90% by FY 2026. *See id.* By the end of FY 2024, FDA intends to publish a new draft or revised guidance document describing considerations on such combination products. *See id.* at 35. A sponsor that submits an HF validation study protocol for FDA review should do so with specific questions, and FDA intends to respond within 60 days of receipt for 90% of submissions beginning in FY 2023. *See id.* at 35.

The Goals Letter also outlines FDA's plans regarding Real-World Evidence ("RWE") for use in regulatory decision-making. *See id.* at 36-38. This includes a pilot Advancing RWE Program established by the end of 2022 in which FDA will solicit applications twice a year for sponsors to submit regulatory questions they seek to address with RWE and the potential real-world data ("RWD") source to support that design prior to protocol development. *See id.* at 36. FDA will accept one to two proposals each cycle in FY 2023-2024 and one to four proposals each cycle in FY 2025-2027. *See id.* In this program, FDA will meet with sponsors up to four times to focus on data, design, and regulatory issues that have the potential to generate RWE in support of a proposed regulatory decision. *See id.* at 36-37.

Regulatory Decision Tools to Support Drug Development and Review. FDA intends to build on the success of Patient Focused Drug Development ("PFDD"), benefit-risk assessment in regulatory decision-making, and the drug development tools qualification pathway for biomarkers. *See id.* at 38. In support, the Goals Letter describes the Agency's intention to continue to strengthen capacity to facilitate development and use of Patient-Focused methods to inform drug development and regulatory decisions through internal trainings and external outreach. FDA will engage experts to support the review of patient experience data. *See id.* Through these efforts, FDA intends to develop a virtual catalog of standard core sets of Clinical Outcome Assessments ("COAs") and Related Endpoints to be available for public use. *See id.* at 39.

The Goals Letter describes FDA's intent to build on the success of "model-informed drug development" ("MIDD") approaches by announcing the continuation of the MIDD paired meeting program. *See id.* at 40. In this program, FDA will select up to 8 proposals per year for a pair of meetings with clinical pharmacology or biostatistical review components within CDER or CBER in partnership with clinical staff to support the development and application of exposure-based, biological, and statistical models derived from preclinical and clinical data sources. *See id.*

FDA has committed to enhancing its capacity to review complex adaptive, Bayesian, and other novel clinical trial designs. *See id.* at 41. FDA plans to do this by developing the staff capacity to enable processes to facilitate appropriate use of these types of methods, maintaining the paired meeting program for certain highly innovative trial designs, convening a public workshop by the end of the second quarter of FY 2024, and publishing a draft guidance by the end of FY 2025. *See id.* at 41-42.

Finally, FDA plans to enhance the drug development tools qualification pathway for biomarkers by retaining and enhancing staff capacity to enhance biomarker qualification review, piloting processes to engage external experts to support review of submissions, publishing information on its website regarding biomarker qualification submissions, and maintaining traditional channels for engaging FDA outside of the qualification pathway. *See id.* at 42-43.

Enhancement and Modernization of the FDA Drug Safety System. FDA will continue to use user fees to enhance and modernize the drug safety system.

In furtherance of this goal, FDA plans to develop draft guidance regarding REMS assessment reports by March 31, 2026, including the type of data that can support elimination of a REMS. *See id.* at 44. Additionally, FDA intends to provide feedback on REMS methodological approaches and study protocols used to assess a REMS program for products within 90 days of receipt 50% of the time in FY 2024, increasing up to 90% in FY 2026. *See id.*

FDA will continue to implement and integrate Sentinel and BEST (Biologics Effectiveness and Safety) Systems in FDA drug safety activity. *See id.* By the end of FY 2025, FDA intends to publish on its website an update on facilitation of public and sponsor access to Sentinel's distributed data network to conduct safety surveillance, and will continue to post study results, study parameters, and analysis code online. *See id.* at 45.

FDA also plans to use user fee funds to advance the analytic capabilities of the Sentinel Initiative by: (1) developing a consistent approach to post-market requirements and commitments during NDA and BLA review related to assessing the outcomes of pregnancies in women exposed to drugs and biological products and clarifying the optimal use and value of pregnancy registries and electronic healthcare data for assessing pregnancy safety; and (2) supporting the use of RWE to address questions of product safety and advancing our understanding of how RWE may be used for studying effectiveness. *See id.*

In support of these efforts, FDA intends to develop a framework on how data from different types of post-market pregnancy safety studies might optimally be used; hold a public workshop to facilitate determination of the ideal study design; and conduct 5 demonstration projects to address gaps in knowledge about performance characteristics of different study designs. *See id.* at 46-47.

Additionally, the Goals Letter states that FDA will develop new methods to support causal inference in Sentinel/BEST that could address product safety questions and advance the Agency's understanding of how RWE may be used for studying effectiveness. To this end, FDA will hold a public workshop on use of negative controls for assessing the validity of non-interventional studies and will initiate two methods development projects. *See id.* at 47.

Product Quality Reviews, Chemistry Manufacturing, and Controls ("CMC") Approaches, and Innovative Manufacturing Technologies. The Goals Letter describes the four essential components of CMC information requests (referred to as Four-Part Harmony – what was provided, what is the issue or deficiency, what is needed, and why it is needed). To promote FDA reviewers' use of Four-Part Harmony, FDA will update and conduct training on CDER's MAPP 5016.8 and CBER's SOPP 8401.1 describing the guidelines for the content of CMC information requests and will conduct training on CMC assessment procedures associated with mid-cycle and late-cycle review meetings. *See id.* at 48. FDA will also contract with an independent third party to assess current practices in communicating through product quality Information Requests ("IRs") during application review, and to identify best practices and areas for improvement. *See id.* at 48-49.

To enhance communication regarding pre-approval inspections, FDA intends to notify sponsors of its intent to inspect a manufacturing facility at least 60 days in advance, and no later than mid-cycle, when it determines it is necessary to conduct the inspection at a time when the product is being manufactured. *See id.* at 49. However, FDA reserves the right to conduct manufacturing facility inspections at any time during the review cycle, whether or not it has communicated its intent to inspect. *See id.*

By September 30, 2023, FDA plans to issue a draft guidance on the use of alternative tools to assess manufacturing facilities, incorporating best practices from the use of such tools during the COVID-19 pandemic. *See id.* at 49-50.

By the end of 2022, FDA intends to issue a new MAPP on approaches to address CMC challenges for CDER-regulated products with accelerated clinical development timelines. *See id.* at 50. Starting in FY 2023, FDA will initiate a CMC Development and Readiness Pilot (CDRP) to facilitate the expedited CMC development of products with accelerated clinical development timelines. *See id.* For participating sponsors, FDA will provide specific CMC advice during development by providing two additional CMC-focused Type B meetings and a limited number of CMC-focused discussions with the goal of ensuring a mutual understanding of what activities must be completed and what information should be provided at the appropriate timepoint. *See id.* at 51. FDA will conduct a public workshop focused on CMC aspects of expedited development and will subsequently issue a strategy document outlining its plans to incorporate lessons learned through the pilot program. *See id.* at 51-52.

FDA also plans to conduct a public workshop on the utilization of innovative

manufacturing technologies by the end of FY 2023. *See id.* at 52. Following the workshop, FDA will issue a draft strategy document for public comment outlining the actions it will take to facilitate the utilization of innovative manufacturing technologies. *See id.*

Cell and Gene Therapy Products. FDA intends to substantially strengthen staff capacity and capability in the Cell and Gene Therapy Program (CGTP), and to direct additional resources to sustain and expand the program. *See id.* at 53. CBER intends to evaluate, streamline, and harmonize CGTP procedures, processes, and interactions. *See id.* Staff will continue to participate in external collaborations in a variety of areas, including development of tools, technologies, and approaches that support development of such products. *See id.* at 54.

By the end of FY 2023, the Goals Letter states that FDA will convene a public patient focused drug development meeting to better understand patient perspectives on gene therapy products. *See id.* at 54. The Agency will continue to work with stakeholders to seek public input on questions and challenges faced by cell and gene therapy developers, including the use of novel endpoints and the role of less defined natural histories, and to facilitate development and approval for such products, including individualized therapies and rare disease. *See id.* at 54-55. By the end of FY 2025, FDA will issue a draft guidance on the evaluation of efficacy in small patient populations using novel trial designs and statistical methods, and how these concepts can be applied to more common diseases. *See id.* at 55. Additionally, by the end of FY 2024, FDA will issue a Questions and Answers draft guidance based on frequently asked questions and commonly faced-issues, and will convene a public meeting for capturing post-approval data followed by a draft guidance on the same topic. *See id.*

FDA intends to update the Guidance for Industry: Expedited Programs for Regenerative Medicine Therapies for Serious Conditions with additional thinking on post-approval requirements for products approved under accelerated approval, as well as on approaches and processes relating to CMC. *See id.* at 55-56. FDA also intends to convene a public meeting, followed by a draft guidance, to solicit the perspective of cell and gene therapy manufacturers on how sponsors might leverage internal prior knowledge and public knowledge in order to facilitate product development and application review. *See id.* at 56.

New Allergenic Extract Products. FDA will use user fee revenues to support the review of new allergenic extract products that have been incorporated in the PDUFA program by PDUFA VII. *See id.* at 56. Allergenic extract products licensed after October 1, 2022 will generally be included in user fees, and all performance goals, procedures, and commitments in the Goals Letter apply to such products. *See id.*

Continued Enhancement of User Fee Resource Management. FDA plans to build on the financial enhancements included in PDUFA VI and continue activities in PDUFA VII to ensure optimal use of user fee resources and alignment of staff to workload. *See id.* at 57.

No later than the second quarter of FY 2023, FDA plans to publish an implementation plan that will describe how resource capacity planning and time reporting will continue to be implemented. *See id.* By the end of FY 2025, an independent contractor will complete and publish an evaluation of the resource capacity planning capability, providing options and recommendations regarding continued enhancement. *See id.* at 57-58.

FDA has committed to assuring financial transparency and efficiency in the way user fees are administered, allocated, and reported. *See id.* at 58. To that end, FDA will publish a five-year financial plan not later than the second quarter of FY 2023 with annual updates in each subsequent year. *See id.* FDA will also hold a public meeting no later than the third quarter of each fiscal year to discuss the PDUFA five-year financial plan. *See id.*

FDA Hiring and Retention of Review Staff. FDA plans to set clear goals for human drug review program hiring and to utilize a qualified, independent contractor to conduct a targeted assessment of the hiring and retention of staff for the human drug review program. *See id.* at 59.

Information Technology. FDA will further enhance transparency of its IT activities and continue to ensure the usability and improvement of the electronic submissions gateway ("ESG") by: (1) holding quarterly meetings between FDA staff and industry about current challenges and needs; (2) holding annual public meetings to review PDUFA IT initiatives and to provide an opportunity for industry input; (3) engaging industry to provide feedback and/or participate in pilot testing in advance of implementing significant changes that impact industry's interaction with the enterprise-wide systems; and (4) and maintaining a current FDA Data Standards Catalog. *See id.* at 60.

FDA intends to establish a Data and Technology Modernization Strategy ("Strategy") that provides FDA's strategic direction for current and future state data-driven regulatory objectives. *See id.* The Strategy will reflect the vision in FDA's Technology and Data Modernization Action Plans. *See id.* FDA also plans to engage with stakeholders and international consortia on technology and initiatives that promote convergence in data interoperability and interpretability for current and future FDA initiatives. The Goals Letter states that in these efforts to promote convergence, it will seek to adopt international standards where feasible and appropriate. *See id.* at 61.

During PDUFA VII, CBER will retire its older IT systems and capabilities. In coordination with CDER and CDRH, CBER will accelerate its data and IT modernization to streamline and improve its ability to perform complex reviews and to access, utilize and protect data. *See id.* CBER intends to establish a multi-year modernization roadmap by the end of Q4 FY 2022 with a goal of concluding these activities by the end of FY 2027. *See id.* at 61-62.

FDA will provide historic and current metrics on ESG performance on the ESG website. *See id.* at 62. FDA will complete the ESG transition to the cloud by the end of FY

2025 with an improved architecture that supports greatly expanding data submission bandwidth and storage. *See id.*

FDA intends to initiate at least three demonstration projects to explore application of cloud-based technologies to streamline, improve and enable a variety of applicant-regulatory interactions. *See id.* at 62-64. These will be the building blocks informing and positioning FDA and regulated industry to take best advantage of third-party hosted capabilities in conjunction with their own infrastructure. *See id.* at 63. The demonstration projects and associated capabilities development will be completed by the end of FY 2027. *See id.* at 64.

Finally, FDA will assess its bioinformatics capabilities and annually ensure that IT resources are provided to support bioinformatics activities. *See id.* at 64. This is intended to address the increasing volume and diversity of bioinformatics and computational biology information and data CDER and CBER are seeing, such as Next Generation Sequencing. *See id.*

Bioinformatics. The Goals Letter states that FDA will develop additional expertise and staff capacity in both CDER and CBER to efficiently review and provide technical and timely feedback on information and accompanying data in submissions and to meet performance goals. *See id.* FDA will also assess and strengthen its computational infrastructure to support and advance its informatics platforms, allowing FDA to remain current with the most recent technology in the field. *See id.* To facilitate submission and review of bioinformatics and computational biology information, FDA will continue to develop data standards and revise guidance or issue draft guidance on the topic. *See id.*

Digital Health Technologies. A Digital Health Technology ("DHT") may be considered as a system that uses computing platforms, connectivity, software, and sensors for healthcare and related uses. *See id.* at 65. DHTs can allow for remote data acquisition from patients and clinical trial participants to measure a wide range of activities, behaviors, and functioning in real life settings that can inform clinical endpoints and enable the conduct of decentralized clinical trials ("DCTs"). *See id.*

Despite having limited experience evaluating novel DHT-based measurements in human drug development, FDA recognizes their potential and the need to build capacity and expertise to advise industry and to evaluate DHT outputs. *See id.* FDA will take several actions in furtherance of this goal. The Agency will establish a DHT framework document to guide the use of DHT-derived data in regulatory decision-making, establish a committee to support implementation of the commitments in this section of the Goals Letter, and will convene five public meetings with key stakeholders to gather input on issues related to DHTs. *See id.* at 65-66.

FDA plans to publish guidance on the use of DHTs in clinical trials, addressing validation of measurements made by DHTs, the development of novel endpoints using DHTs, the use of DHTs as new ways to measure existing endpoints, and approaches to using

patients' own DHTs such as cell phones or smart watches. *See id.* at 66. FDA will also publish guidance on regulatory considerations for Prescription Drug Use-Related Software, including information about software that may be described in labeling. *See id.* at 67.

The Goals Letter also describes an intention to build technical expertise, train staff, develop statistical methodology, and build review capacity. *See id.* at 67. By the end of Q2 FY 2023, FDA will enhance its internal systems to support review of DHT-related submissions. *See id.* In FY 2023, FDA will establish a secure cloud technology that will enable FDA to effectively receive, aggregate, store, and process large volumes of data from trials conducted using DHTs. *See id.* at 67-68.

FDA Performance Management. FDA will improve performance management by conducting studies to assess the PDUFA VII performance goals. *See id.* at 69.

Progress Reporting. FDA will include information on the Agency's progress in meeting the PDUFA VII performance goals in the annual PDUFA Performance Report. *See id.* at 70. FDA will also include information on user fee resource management in the annual PDUFA Financial Report. *See id.*

II. MEDICAL DEVICE USER FEE AMENDMENTS OF 2022

The Medical Device User Fee Amendments of 2022 ("MDUFA V") supplements FDA's funding of device regulation, with the goal of increasing the speed and efficiency of the Agency's review of new devices, as well as improving the safety and effectiveness of marketed devices. MDUFA was first enacted in 2002, and was reauthorized in 2007, 2012 and, most recently, in 2017 for FYs 2018-2022.[5]

A. Significant Changes to MDUFA

Baseline User Fees and Adjustment. FUFRA gradually increases baseline Medical Device Fees for FY 2023-2027. *See* FDC Act § 738(b), as amended by FUFRA § 2003(b)(2). The fee for a PMA in FY 2023 will be $425,000, increasing to $470,000 by FY 2027. *See id.* The fee for 510(k) applications in FY 2023 will be $19,870, increasing to at least $21,150 by FY 2027. *See id.* These increased fees are expected to produce an estimated revenue of more than $1.7 billion in industry payments during MDUFA V.

Adjustments in establishment registration fees. FUFRA adds two new provisions relating to the adjustment in establishment registration fees. Beginning in FY 2025, after the

[5] Medical Device User Fee and Modernization Act of 2002 ("MDUFMA"), Pub. L. No. 107-250, 116 Stat. 1588 (2002); Medical Device User Fee Amendments of 2007, Pub. L. No. 110-85, Title II, 121 Stat. 823, 842 (2007) ("MDUFA II"); Food and Drug Administration Safety and Innovation Act ("FDASIA"), Pub. L. No. 112-44, 126 Stat. 993 (2012) ("MDUFA III"); FDA Reauthorization Act of 2017, Pub. L. No. 115-52, 131 Stat. 1005 (2017) ("MDUFA IV").

establishment registration fee is adjusted for inflation and volume, FDA may further increase the fee to account for resource needs to achieve the premarket submission performance goals set forth in the MDUFA V Commitment Letter. *See id.* FDC Act § 738(c)(4), as amended by FUFRA § 2003(c)(5). FUFRA also allows for the establishment registration fee to be decreased, however, if FDA does not meet certain specified hiring goals. *See id.* § 738(c)(5), as amended by FUFRA § 2003(c)(5). Specifically, in FY 2023 FDA must make 123 hires, in FY 2024 38 hires, and in FY 2025 22 hires, if there is no increase in the establishment registration fee under FDC Act § 738(c)(4) and 75 hires for FY 2025 if there is an increase. In addition, if FDA collects in excess fees and has an operating reserve, the establishment registration fee shall be decreased according the amounts designated in the law. *See id.* § 738(c)(6), as amended by FUFRA § 2003(c)(6).

Conformity Assessment Pilot Program. Voluntary consensus standards are technical standards by various parties including governments and standard setting organizations. These standards can play an important role in establishing the safety and performance criteria for many aspects of medical device design and manufacturing. These standards often support claims of safety and effectiveness in premarket submissions. Applicants currently have the option of including a Declaration of Conformity in their premarket submissions attesting that their devices conform to applicable consensus standards. However, these standards vary widely in terms of technical complexity; which makes it challenging for applicants and FDA reviewers to determine whether standards have been appropriately incorporated in regulatory submissions.

To explore a potential solution to this problem, FDARA enacted the Pilot Accreditation Scheme for Conformity Assessment. *See* 21 U.S.C. § 360d(d). The program aimed to enlist accredited laboratories with the expertise to evaluate device submissions according to consensus standards recognized by the Agency. FUFRA formalized the Accreditation Scheme meaning that it is no longer simply a "pilot," and device manufacturers can have tests conducted at recognized, accredited test labs and submit to FDA a determination from the test laboratory that their device conforms to the standards tested. *See* FDC Act § 514, as amended by FUFRA § 2005. FDA will rely on the results from the accredited test laboratory for the purpose of premarket review. *See id.* § 514, as amended by FUFRA § 2005. FDA shall report on the progress of the program annually on the Agency's website. *See id.* § 514, as amended by FUFRA § 2005.

B. FDA's MDUFA IV Performance Goals

Under the MDUFA IV Performance Goals and Procedures, FDA steadily increased the percentage of medical device submissions that met the review time goals from FYs 2018 to 2022. According to the MDUFA Performance Goals and Procedures for FY 2023-2027 ("MDUFA V Performance Goals"[6]), FDA will maintain these timeliness standards for PMA,

[6] The MDUFA V Performance Goals and Procedures are *available at* https://www.fda.gov/media/158308/download.

510(k) submissions, Pre-Submissions, and *De Novo* petitions.

For original PMAs, panel-track supplements, and premarket report applications, FDA's goals are as follows:

- Within 15 calendar days, communicate with the applicant regarding whether its application has been accepted for filing review. This goal is unchanged from MDUFA IV.

- Within 45 days of FDA's receipt of the application, communicate with the applicant regarding the application's filing status, including providing specific reasons for any refusal to file. This goal is unchanged from MDUFA IV.

- Within 90 calendar days of the filing date of the application, communicate with the applicant through a "Substantive Interaction"[7] for 95 percent of submissions. This goal is unchanged from MDUFA IV.

- Within 180 "FDA Days,"[8] issue a "MDUFA decision"[9] for submissions that do not require Advisory Committee input for 90 percent of submissions. This goal is unchanged from MDUFA IV.

- Within 320 FDA Days, issue a MDUFA decision for submissions that require Advisory Committee input for 90 percent of submissions. This goal is unchanged from MDUFA IV.

- For PMA submissions that receive a MDUFA decision of approvable, FDA will issue a decision within 60 days of the sponsor's response to the approvable letter, as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations. This goal is unchanged from MDUFA IV.

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7 A "Substantive Interaction" can be any form of communication through which FDA requests additional information, a major deficiency letter that notifies the applicant of substantive deficiencies in its application, or a communication stating that FDA has not identified any deficiencies. *See* MDUFA V Performance Goals at 34.

8 "FDA Days" are calendar days when a submission is considered to be under review at the agencies (i.e., the submission has been accepted or filed). FDA Days begin on either the date of receipt of the submission, or the date of receipt of the amendment or resubmission that permits the submission to be accepted or filed. *See id*. at 32.

9 A "MDUFA decision" is a final decision on the application. For original PMAs, these can be decisions that the application is approved, approvable, approvable pending GMP inspection, not approvable, withdrawn, or denied. For 180-day PMA supplements or real-time PMA supplements, a MDUFA decision can be that the application is approved, approvable, or not approvable. For 510(k)s, which are discussed below, the MDUFA decision can be that the product is substantially equivalent, or not substantially equivalent. *See id*. at 32-33.

MDUFA V Performance Goals at 5-7.

With regard to 180-day PMA supplements, FDA's goal is to communicate with applicants through a Substantive Interaction within 90 calendar days of FDA's receipt of the submission for 95 percent of submissions, and FDA will issue a MDUFA decision within 180 FDA Days for 95 percent of submissions. *See id.* at 7. This goal is unchanged from MDUFA IV. For real-time PMA supplements, FDA will issue a MDUFA decision within 90 FDA Days for 95 percent of submissions. *See id.* This goal is unchanged from MDUFA IV.

The 510(k) performance goals are unchanged from MDUFA IV with FDA's goals being:

- Within 15 calendar days, communicate with the applicant regarding whether the submission has been accepted for review.

- Within 60 calendar days, communicate with the applicant through a Substantive Interaction for 95 percent of submissions.

- Within 90 FDA Days, issue a MDUFA Decision for 95 percent of submissions.

Id. at 8-9. For PMAs and 510(k)s, the FDA review goals are not affected by the FY 2026 and 2027 fee adjustments discussed above. However, the shared outcome total time to decision is adjusted if the total time to decision goals are met for 510(k)s and PMAs and the fees are adjusted for performance improvements. *See id.* at 11.

With regard to *De Novo* petitions, FDA will a MDUFA decision within 150 FDA Days of receipt of the submission for 70 percent. *See id.* at 7. If the *De Novo* decision goal is met for FY 2023 and fee revenues are adjusted in support of performance improvements, the *De Novo* decision goal will be adjusted to 80 percent of files reaching MDUFA decision within 150 FDA Days for FY 2026 and 2027. *See id.* 11-12. Just like with PMAs and 510(k)s, if a decision has not been reached within the MDUFA goal, FDA will discuss with the applicant all outstanding issues with the submission preventing FDA from reaching a decision. *See id.* at 8.

Importantly, for PMAs, 510(k)s, and *De Novos*, FDA continue to aim to include "a statement of the basis for the deficiencies" (e.g., a specific reference to applicable section of a rule, final guidance, recognized standard unless the entire or most of document is applicable). *See id.* at 6, 7, 8, and 16. By January 1, 2023, FDA will update the 2017 Guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions." *See id.* at 16. FDA has set performance goals for inclusion of the statement of the basis for deficiencies in Original PMAs, Panel-Track Supplements, and *De Novos*, which ramps up each year as follows: 75 percent of deficiencies in FY 2023; 80 percent of deficiencies in FY 2024; 85 percent of deficiencies in FY 2025; 90 percent of deficiencies in

FY 2026; and 95 percent of deficiencies in FY 2026. *Id.* at 17. FDA will also audit a sampling of deficiency letters annually and report on the results of the audit to industry no later than the first quarterly meeting of the following fiscal year. *See id.*

With regard to Pre-Submissions, within 15 calendar days of receipt of a Pre-Submission, FDA will notify the sponsor regarding whether the Pre-Submission has been accepted for review and, if applicable, regarding scheduling of the meeting or teleconference. *See id.* at 3. This goal is unchanged from MDUFA IV. FDA will provide written feedback regarding the issues raised in the Pre-Submission meeting request within the 70 calendar days of receipt or 5 calendar days prior to a scheduled meeting, whichever is earlier for:

- In FY 2023, 90% of Pre-Submissions in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Submissions in the MDUFA Cohort if the MDUFA Cohort is 3585 or more, up to 4300 submissions;

- In FY 2024, 90% of Pre-Submissions in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Submissions in the MDUFA Cohort if the MDUFA Cohort is 4060 or more, up to 4300 submissions; and

- In FY 2025-2027, 90% of Pre-Submissions in the MDUFA Cohort up to 4300 submissions.

See id. If the process improvement fee adjustment is made and the FY 2023 goals are met, the MDUFA Cohort size will increase for FY 2025-2027 up to 4700 submissions. *See id*. at 12. If the process improvement fee adjustment is made and the FY 2024 goals are met, the MDUFA Cohort size will increase for FY 2026 and 2027 up to 4800 submissions. *See id*. If the process improvement fee adjustment is made and the FY 2025 goals are met, there will be no maximum limit on the number of submissions. *See id*. In all of these cases of the process improvement fee adjustment, the goal will remain to provide feedback within the specified timeframe on 90% of pre-submissions in FY 2025-2027. *See id*.

Based on these new goals, FDA will only be held to the goal for the specified number of pre-submissions in the MDUFA Cohort. After the MDUFA Cohort is filled, FDA will still provide timely feedback for pre-submissions relating to Breakthrough-designated devices and devices included in the Safer Technologies Program (STeP), and the Agency "to provide feedback for other Pre-Submissions as resources permit, but not to the detriment of meeting quantitative review timelines and statutory obligations." *Id*. at 4.

In addition, by March 31, 2024, FDA will issue a draft guidance updating its guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program." The updated draft will include "additional information to assist applicants and review staff in identifying the circumstances in which an applicant's question is most appropriate for informal communication instead of a Pre-Submission." *Id.* at 5.

III. GENERIC DRUG USER FEE AMENDMENTS OF 2022

A. Significant Changes to GDUFA

Though it fully preserves GDUFA II's fee structure, *see* FUFRA § 3002(a) (allowing FDA to collect each of the fees authorized in GDUFA II and changing only the dates set forth in the statute), the Generic Drug User Fee Amendments of 2022 ("GDUFA III") make two significant changes to the program as a whole. ***First***, GDUFA III increases FDA's annual base revenue target for generic drug user fees from $493.6 million to $582.5 million in FY2023—a roughly 18 percent increase over GDUFA II's base revenue target. FUFRA § 3002(b). ***Second***, GDUFA III establishes a significant new mechanism for adjusting the Agency's targeted base revenue amounts in future fiscal years: Beyond the customary annual inflation adjustment, *see id*. § 3002(c)(1), GDUFA III permits FDA to make a so-called "capacity planning adjustment" that allows it to increase targeted fee collections based on FDA's internal projections of future "changes in the resource capacity needs." *Id*. § 3002(c)(2)(A). As a general matter, these annualized capacity planning adjustments may not exceed 3 percent per year; where certain additional criteria are satisfied (*e.g.*, more a certain number of ANDAs were submitted during particular periods or a significant percentage of those ANDAs were for complex generic products), FDA can increase fee collections by as much as 4 percent. *Id*. § 3002(c)(2)(C)(i)-(ii).

B. FDA's GDUFA III Performance Goals

ANDAs. Though FDA's GDUFA III Goals Letter[10] continues to represent that FDA generally will strive to act on 90 percent of standard original ANDAs within 10 months of submission and 8 months in the case of priority ANDAs, a new series of goal-date "adjustments" extends those timeframes in certain inspection-related circumstances.

- For priority ANDAs, FDA now can extend the 8-month review timeframe to 10 months not only where the applicant fails to submit a complete and accurate Pre-Submission Facility Correspondence ("PFC"), but also where the Agency determines "the information submitted in the ANDA differs significantly from what was submitted in the PFC" or otherwise decides that an inspection is needed "upon assessment of [the ANDA's] final bioequivalence study report." Goals Letter § I.A.2.b. Similar provisos apply to both major amendments, *See* GDUFA III Goals Letter § I.A.6.c-d, and prior approval supplements. *Id*. § I.B.2.c. Unfortunately, the commitment letter does not detail what circumstances might constitute a "significant difference" that is sufficient to trigger these provisos. And the fact that "adjustment"-triggering inspection decisions may not be made until late in the review process—up until FDA's review of the ANDA's bioequivalence is complete—is likely to introduce lasting uncertainty as to the traditional 8-month

[10] The GDUFA III Performance Goals and Program Enhancements are *available at* https://www.fda.gov/media/153631/download.

or 10-month timelines will stick in practice.

- Equally significant, the Goals Letter establishes a new 15-month deadline for both standard and original ANDAs where the applicant's initial submission to the Agency indicates that a facility is not currently ready for inspection. *Id*. § I.A.3. Though FDA has indicated that it at least will conduct a filing review for such ANDAs upon receipt, it makes clear that the Agency will not begin its substantive review of the ANDA until the applicant certifies that all relevant facilities are ready to be inspected. *Id*. Given the significance of this provision, ANDA applicants—and especially first filers, who must obtain tentative approval within 30 months to avoid a potential forfeiture of 180-day exclusivity—would be well-served to develop their most important applications at inspection-ready sites and otherwise ensure that all key facilities are suitable for inspection before ANDA submission.

The Goals Letter also makes two welcome changes to the treatment of Controlled Correspondence—especially in cases where applicants have been affected by FDA's issuance of new or modified product specific guidance ("PSG"). *Id*. § I.E.

- ***First***, it explains that "correspondence seeking regulatory and/or scientific advice after issuance of a Complete Response Letter ("CRL") or tentative approval, or after ANDA approval" can now be submitted as a Controlled Correspondence rather than as General Correspondence. Far more important, it goes on to provide that such submissions can be made ***during the ANDA assessment cycle***, so long the "applicant seeks further feedback from FDA after a product-specific guidance (PSG) Teleconference, as described in section III(C)(5)(c), below, or to seek a Covered Product Authorization." *Id*. In turn, the new PSG Teleconference provisions referenced in this proviso allow applicants who have already begun *in vivo* bioequivalence studies meet with and obtain FDA feedback concerning how a newly issued or revised PSG might impact their ongoing development activities. *Id*. § III.C.5. Together, these Controlled Correspondences and PSG Teleconferences are likely to provide applicants with an important opportunity to understand how PSG-related developments are likely to affect their ANDAs—and, if necessary, to seek Agency acceptance "for an approach other than the approach recommended in the PSG to ensure that the approach complies with the relevant statutes and regulations." *Id*. § III.C.5.c.

- ***Second***, the Goals Letter makes clear that whenever FDA issues or modifies a PSG, it "will ensure that at least division-level program leadership is aware of the potential impact on the pending ANDAs for drug products with related new or revised PSGs." *Id*. § III.C.6. Though we doubt these provisions will materially reduce the disruption occasioned by the issuance of mid-cycle PSGs, the need for lower level staff to address these issues with program leadership may raise the bar—at least on the margins—for making such changes after the first ANDAs have been submitted.

The Goals Letter also makes several enhancements to the process for issuing and acting on Information Requests ("IRs") and Discipline Review Letters ("DRLs").

- While the GDUFA II Goals Letter indicated that FDA would issue IRs and DRLs "as soon as the discipline has completed its review, with the first IR(s) and/or DRL(s) at about the mid-point of the review," GDUFA II Goals Letter § II.B.1, the GDUFA III Goal Letter commits FDA to act: "FDA ***will*** issue the appropriate IR(s) and/or DRL(s) from each assessment discipline ***by the mid-point of the assessment***." GDUFA III Goals Letter at II.B.1.b (emphasis added).

- The Goals Letter also strives to ensure that FDA will continue to issue IRs and DRLs after the mid-point of the first assessment and throughout subsequent review cycles in cases where resolution of the identified issues could lead to a tentative or final approval. *Id*. § II.B.1.c.

- Perhaps most important, the Goals Letter seeks to accelerate FDA's resolution of issues relating to "an applicant's request to 'carve out' language in the proposed labeling protected by patents or exclusivities" and "labeling deficiencies that result from changes to the labeling of the reference listed drug (RLD) or a new exclusivity or patent listing." *Id*. § II.B.2.a.i-ii. Under these provisions, FDA will "strive to issue any DRL at approximately months 6-7 of the assessment for those ANDAs with a 10-month goal date, or months 5-6 of the assessment for those ANDAs with an 8-month goal date." *Id*. § II.B.2.a.ii. Given how frequently these issues can complicate the approval pending ANDAs late in the review cycle, the Agency's decision to prioritize the resolution of these issues early in the review process may be among the most important changes to FDA's GDUFA commitments.

- Finally, the Goals Letter includes a series of provisions that are designed to promote greater transparency and facilitate dialogue between sponsors and project managers regarding important developments, including requirements that FDA notify applicants whenever they become aware of a forthcoming major deficiency or learn that the Agency is likely to miss a goal date (including identification of the reason for FDA's delay, the discipline at issue, and estimated time for action). *Id*. § II.B.6.b-c.

Beyond these generally applicable ANDA provisions, the GDUFA III Goals Letter provides new opportunities for applicants to obtain "targeted, robust advice" that is "tailored to enhance the development of Complex Generic Products." *Id*. § IV.A. Though FDA's GDUFA II Goals Letter indicated that FDA might be willing to discuss issues with sponsors of such products at the mid-cycle point, *see* GDUFA II Goals Letter § III.F, the new Goal Letter establishes a robust process for Complex Generic Product applicants to request and receive substantive feedback from the Agency regarding identified deficiencies. GDUFA III

Goals Letter § IV.B.1-3. Of special note, these new provisions provide an opportunity for applicants to obtain either an "Enhanced Mid-Cycle Review Meeting" or "Post-CRL Scientific Meeting" during which applicants can discuss pathways for resolving outstanding deficiencies—though the Goal Letter cautions that FDA will provide substantive feedback only in the latter circumstances, after the Agency has issued a CRL. *Compare id*. § IV.B.3 (providing that "FDA will discuss the data and information but will not provide substantive assessment of data or information provided by the applicant at [an Enhanced Mid-Cycle Review] meeting) *with id*. § IV.C.1 ("The purpose of [a Post-CRL] meeting is to provide an applicant scientific advice on possible approaches to address deficiencies identified in a CRL.").

DMFs. There are two significant developments regarding DMFs. ***First***, the Goals Letter establishes a new process for DMF holders to request FDA assessment six months before the planned submission of: (1) an original ANDA; (2) a post-CRL ANDA amendment; (3) a request to convert tentative approval to final approval. *Id*. § VI.E. To qualify for such a pre-submission assessment, the DMF holder must establish at least ***one*** of the following criteria:

- All relevant patents and exclusivities will expire within 12 months of the planned submission date;
- There are no blocking exclusivities or patents for the RLD; the planned ANDA submission does not contain a section viii carve out; and there are fewer than four approved therapeutically equivalent products in the Orange Book;
- The drug at issue could help address a drug shortage or public health emergency; or
- The submission is a for (1) a drug whose RLD has been discontinued and which does not have any unexpired patents or exclusivities, and (2) the only approved version of the drug is an ANDA that was not approved under a suitability provision.

Id. § VI.E.1.a-e. Pre-approval assessments also are available for prior approval supplements ("PAS") seeking to add a new API source, but only where the foregoing drug shortage/public health emergency standard is met. *Id*. § VI.E.2a-b.

Second, the Goals Letter makes clear that FDA will review solicited DMF amendments that relate to an ANDA or PAS even if the underlying ANDA or PAS is not currently under review. *Id*. § VI.F.1. In doing so, FDA intends to prioritize amendments that relate to ANDAs which could receive approval if DMF-related issues are successfully resolved. *Id*. § VI.F.2.

Facilities/Inspections. Finally, the Goals Letter creates two new opportunities for applicants who are adversely affected by facility-related issues. ***First***, it establishes facilities that have received a warning letter to seek and obtain a Post-Warning Letter Meeting "to

obtain preliminary feedback from FDA on the adequacy and completeness of the facility's corrective action plans ["CAPAs"]." *Id*. § VII.D.1-2. To qualify for such a meeting, the facility's CGMP status must be official action indicated ("OAI"); the identified violations or deviations from FD&C Act § 501 related only to drugs or drug-device combination products; the facility must have paid its GDUFA fees; and the facility must have submitted a thorough and complete CAPA. *Id*. § VII.D.3.a-c; *id*. § VII.D.4. Even so, FDA can decline a meeting request from an otherwise-qualified facility if it determines that insufficient progress toward remediation has been made, *id*. § VII.D.6, or defer such a meeting in lieu of re-inspecting the facility. *Id*. § VII.D.8.

Second, the Goals Letter provides that generic drug facilities that meet the same criteria listed above can request timely re-inspection of an OAI facility so long as the requesting facility establishes that it "has appropriately completed CAPAs that sufficiently address all of the deficiencies in a warning letter, with the exception of ongoing monitoring." *Id*. § VII.E.3. FDA will grant or deny such requests within 30 days of receipt, and has committed to conduct annually specified percentages of such inspections within 4 months of granting a request for a U.S. facility and 8 months of granting a request for a foreign facility (in both cases, the targets begin at 60 percent in FY 2024 and rise to 80 percent by FY 2026).

IV. BIOSIMILAR USER FEE ACT OF 2022

The Biosimilar User Fee Amendments of 2022 ("BsUFA III"), the third iteration of BsUFA, reauthorizes the collection of biosimilar user fees through 2027 in an effort to expedite biosimilar development activities. Like the other user fee programs, this provision provides FDA with the authority to assess and use the user fees collected to supplement congressional funding.

A. Significant Changes to BsUFA

As in 2017 at the adoption of BsUFA II, BsUFA makes only modest changes to the existing fee structure. The most significant change comes in the form of consequences for failure to pay annual biosimilar biological product development fees for two or more consecutive years; in such a case, FDA may "administratively remove" the biosimilar licensee from the biological product development program after providing written notice. *See* FUFRA § 4003(a)(5). Like any discontinued participant in the biosimilar biological product development program, an entity that has been administratively removed from the program may reactivate by paying all annual development fees previously assessed that product and still owed. *See* FUFRA § 4003(a)(4)(D).

The biosimilar annual development fee, however, continues to apply for all those that are not removed from the program except when the product is "transferred to a licensee, assignee, or successor of such person" and written notice provided to FDA; that licensee, assignee, or successor instead is responsible for the annual biosimilar biological product development fee. *See* FUFRA § 4003(a)(3). Biosimilar user product development fees are

required except where a marketing application for the biological product has been accepted for filing; the sponsor has discontinued participation in the development program; or the sponsor has been administratively removed from the biosimilar biological development program. *See id.*

BsUFA also appears to remove the "biosimilar biological *product fee*" clause, which requires each sponsor "named as the applicant in a biosimilar biological product application" to pay an annual fee "for each such biosimilar biological product." *See* FUFRA § 4003(a)(8). Nevertheless, the annual biosimilar biological *product program fee* remains in place for all applicants for each biosimilar product identified in the biosimilar biological product application approved as of October 1 of that fiscal year and which may be dispensed only under a prescription. *See* FUFRA § 4003(a)(7)(A).

Finally, BsUFA adds a provision related to the movement of a product to the list of discontinued biosimilar biological products. If FDA receives a written request to move a product to that list and the request identifies the date that product will be withdrawn from sale, FDA, for purposes of assessing the biosimilar biological product program fee, will consider the product to be on the discontinued list the later of the date the request was received or the date the product withdrawn. *See* FUFRA § 4003(a)(7)(B). Products will be considered withdrawn from sale once the applicant has ceased distribution of the product except when a routine, temporary interruption in supply occurs. Congress has added a "special rule for product removed from the discontinued list": Any product that appears on the discontinued list as of October 1 of the fiscal year but is subsequently removed from the list during that fiscal year will be assessed the annual biosimilar biological product program fee for that fiscal year. That fee will be assessed only once for each product for each fiscal year. *See id.*

For Fiscal year 2023, BsUFA III increases the annual base revenue for biosimilar products to $43,376,922. Additionally, allergenic extracts are removed from the list of applications that are excluded from the definition of "biosimilar biological product application."

B. FDA's BsUFA Performance Goals

In the BsUFA III Commitment Letter,[11] FDA sets forth its goals for performance and procedures, as negotiated with industry, for FYs 2023-2027 to facilitate "timely access to safe and effective biosimilar medicines for patients." BsUFA III Commitment Letter at 3. Like in BsUFA II, FDA commits in BsUFA III to reviewing and acting on 90% of biosimilar biological product application submissions within 10 months of the 60-day filing date and within 6 months of the receipt date for resubmitted applications. *Id*. at 4. In this iteration, however, FDA has significantly revised its approach to supplements.

[11] The BsUFA III Performance Goals letter is *available at* https://www.fda.gov/media/152279/download.

Supplements are divided into four categories—A, B and C, D, and E and F—each with its own goal date. *Id*. at 4-5. Ultimately, FDA aims to receive and act on 90% of supplements within the allotted time frame but will phase-in that target such that FDA will aim for 70% in FY 2023, 80% in FY 2024, and 90% after FY 2025. *Id*. at 6. Category A will be reviewed and acted on within 3 months of receipt and includes supplements seeking to update labeling for a licensed biosimilar or interchangeable application to reflect additional safety information updated in the reference product labeling. *Id*. at 4. Category B is for supplements seeking licensure for an additional indication for a licensed biosimilar or interchangeable product, as long as the submission does not include new data sets; does not seek licensure for a new route of administration, dosage form, dosage strength, formulation, or presentation; and includes an up-to-date agreed-upon initial pediatric study plan as necessary. *Id*. Category C is for supplements seeking to remove an approved indication for a licensed biosimilar or interchangeable product. *Id*. Both Category B and Category C will be reviewed and acted on within 4 months of receipt. *Id*.

Supplements that seek licensure for an additional indication for a licensed biosimilar or interchangeable product and contain new data sets other than efficacy data or do not contain an up-to-date agreed-upon initial pediatric study plan are assigned to Category D and reviewed and acted upon within 6 months of receipt. *Id*. at 4-5. Finally, Categories E and F will be reviewed acted upon within 10 months of receipt for original submissions and 6 months for resubmissions. *Id*. at 5. Category E consists of supplements seeking licensure for an additional indication for a licensed biosimilar or interchangeable product containing efficacy data sets, and Category F is for supplements seeking an initial determination of interchangeability. *Id*. FDA will issue a filing letter within 74 calendar days of receipt for 90% of Category E and F supplements. *Id*.

Manufacturing supplements are not included in any of these categories. Instead, FDA aims to review and act on 90% of Prior Approval Supplements for manufacturing within 4 months of receipt. FDA aims to review 90% of all other manufacturing supplements within 6 months of receipt. *Id*. at 7.

Major amendments may extend review goal dates by 3 months. *Id*. at 7. Such amendments include major new clinical study reports; major re-analysis of previously submitted studies; submission of a risk evaluation and mitigation strategy with elements to assure safe use not included in the original application; or significant amendments to such a risk evaluation and mitigation strategy. *Id*. Major amendments to manufacturing supplements may extend the goal by 2 months. *Id*.

As part of the BsUFA Commitment Letter, FDA also introduces a "Program for Enhanced Review Transparency and Communication of Original 351(k) BLAs" to promote the efficiency and effectiveness of the first cycle review process and minimize the number of review cycles necessary for approval. *Id*. at 8. As part of the Program, FDA encourages applicants to discuss the planned content of a 351(k) application at a Pre-submission meeting. *Id*. at 9. Formal meetings during biological product development are categorized based on

issues with specific timelines for each meeting request, meeting schedules, and preliminary responses. *Id*. at 17-23. Any submitted applications should reflect discussions and agreements at these meetings, and, in response to any filed applications, FDA commits to providing a Day 74 Letter to notify applicants of the timeline for review. *Id*. at 11. FDA agrees to hold Mid-Cycle Review Meetings, Late-Cycle Review Meetings, and Advisory Committee Meetings as necessary. *Id*. at 11-14.

FDA also agrees to proprietary name review goals during the biosimilar biological product development phase, which includes review of 90% of proprietary name submissions within 180 days of receipt. *Id*. at 14. FDA intends to review 90% of proprietary name submissions filed during application review will be reviewed within 90 days of receipt. *Id*. at 15. FDA also agrees to Major Dispute Resolution procedures with a response to 90% of submitted written appeals within 30 calendar days. *Id*.

To facilitate the timely development of biosimilar and interchangeable biological products and their availability to patients, FDA will focus on enhancing communications during application review, including inspection communications, and advancing the development of combination and interchangeable products. *Id*. at 25. FDA will also pilot a regulatory science program focused on enhancing regulatory decision-making and facilitating science-based recommendations in areas foundational to biosimilar and interchangeable biological development. *Id*. The pilot program will focus on two demonstration projects: (1) advancing the development of interchangeable products, and (2) improving the efficiency of biosimilar product development. *Id*. at 30.

V. REAUTHORIZATION OF OTHER PROVISIONS

As its title states, FUFRA Title VI reauthorizes several important laws that were set to expire, many which are typically reauthorized on the same five-year reauthorization cycle as the user fee programs. These provisions cover the regulation of, incentives for, and funding for programs to facilitate development of drugs, biologics, and medical devices.

A. Sec. 5001. Reauthorization of the best pharmaceuticals for children program

Originally enacted as part of Food and Drug Administration Modernization Act ("FDAMA") in 1997, the Best Pharmaceuticals for Children Act ("BPCA") provided several incentives for research and development of treatments for pediatric diseases, including six months marketing exclusivity for conducting certain pediatric-specific clinical studied. Congress reauthorized the BPCA in 2002, Pub. L. No. 107-109, 115 Stat. 1408 (2002), and made BPCA permanent as part of the 2012 Food and Drug Administration Safety and Innovation Act ("FDASIA"). In addition to the pediatric marketing exclusivity incentive, the BPCA directs the National Institutes of Health ("NIH") to facilitate, fund, and prioritize clinical research into potential treatments for pediatric diseases. Funding for NIH grants is again reauthorized in FUFRA § 5001 (amending section 409I(d)(1) of the Public Health

Service Act), providing an additional $5,273,973 million in NIH awards for the period from October 1, 2022 through December 16, 2022.

B. Sec. 5002. Reauthorization of the Humanitarian Device Exemption Incentive

This provision of FUFRA extends the incentive for pediatric Humanitarian Device Exemption ("HDE") devices by allowing the sponsor to charge a sufficient amount to obtain a profit . The incentive expired on October 1, 2022, but is revived and extended to expire on December 17, 2022.

C. Sec. 5003. Reauthorization of the Pediatric Device Consortia Program

The pediatric device consortia program, a grant program for pediatric medical device advisors to help pediatric devices, is authorized with "$1,107,534 for the period beginning on October 1, 2022, and ending on December 16, 2022."

D. Sec. 5004. Reauthorization of Provision Pertaining to Drugs Containing Single Enantiomers

Provided certain conditions are met, the FDC Act permits the sponsor of an NDA for an enantiomer (that is contained in an approved racemic mixture) to "elect to have the single enantiomer not be considered the same active moiety as that contained in the approved racemic drug" so as to qualify for a period of five-year New Chemical Entity ("NCE") exclusivity. FDC Act § 505(u)(1). FDC Act § 505(u) was scheduled to sunset on September 30, 2022. FUFRA reauthorizes FDC Act § 505(u) for the period from October 1, 2022 through December 16, 2022.

E. Sec. 5005. Reauthorization of the Critical Path Public-Private Partnership

FUFRA § 5005 reauthorizes the Critical Path Public-Private Partnership, an FDA initiative to accelerate medical product development and close the translational gap between basic science and development of medical products. The reauthorization (through an amendment to FDC Act § 566(f)) provides funding in the amount of $6,000,000 for the period from October 1, 2022 through December 16, 2022.

F. Sec. 5006. Reauthorization of Orphan Drug Grants

FUFRA § 5006 reauthorizes the Orphan Grants Program, allowing FDA to provide grants to public and private entities and individuals to assist in defraying the costs of developing drugs, devices, and medical foods for rare conditions. The reauthorization (through an amendment to section 5(c) of the Orphan Drug Act) provides funding in the amount of $6,328,767 for the period from October 1, 2022 through December 16, 2022.

G. Sec. 5007. Reauthorization of Certain Device Inspections

This provision extends the third-party accreditation program for device inspections from October 1, 2022 to December 17, 2022.

H. Sec. 5008. Reauthorization of reporting requirements related to pending generic drug applications and priority review applications

FDARA § 807 required FDA to report quarterly on the number of pending and approved ANDAs subject to priority review under FDC Act § 505(j)(11) and expedited review under new FDC Act § 506H until October 1, 2022. FUFRA § 5008 extends this provision until December 16, 2022.

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The information in this memorandum is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein. For more information about this memorandum or about FUFRA, please contact Kurt R. Karst (kkarst@hpm.com), Michael D. Shumsky (mshumsky@hpm.com), Sara W. Koblitz (skoblitz@hpm.com), or James E. Valentine (jvalentine@hpm.com) for issues concerning drug or biological products, or Jeffrey K. Shapiro (jshapiro@hom.com) or Allyson B. Mullen (amullen@hpm.com) for issues concerning medical devices.