Food and Drug Administration Safety and Landmark Advancements Act – June 12, 2022

FDA SAFETY AND LANDMARK ADVANCEMENTS ACT	
TITLE I: FEES RELATING TO DRUGS	
Sec. 101. Short title; finding.	• Establishes a short title ("Prescription Drug User Fee Amendments of 2022") and provides that the title will go toward human prescription drug activities as set forth in the commitment letter submitted to the Congressional Record.
Sec. 102. Definitions.	• Incorporates allergenic extract products licensed after October 1, 2022 into the user fee program. • Clarifies the date by which a product shall be considered withdrawn from sale for purposes of assessing the prescription drug program fee.
Sec. 103. Authority to assess and use drug fees.	• Reauthorizes the authority to collect fees in the Prescription Drug User Fee Amendments (PDUFA) program. • Updates the base fee amount. In fiscal year (FY) 2022, the base amount was $878,590,000, and in FY 2023 the base amount will be $1,151,522,958.
Sec. 104. Reauthorization; reporting requirement.	• Maintains the existing reauthorization process and requirements. • Performance and financial reports continue to be due to Congress every year.
Sec. 105. Sunset dates.	• Sunsets the authority to collect fees on October 1, 2027, and the requirement to submit performance and financial reports after January 31, 2028.
Sec. 106. Effective date.	• Clarifies that the effective date is October 1, 2022, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all human drug applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.
Sec. 107. Savings clause.	• Clarifies that submissions accepted for filing prior to October 1, 2022, will continue to be reviewed and assessed fees based on the agreement for FY 2017-2022.
TITLE II: FEES RELATING TO DEVICES	
Sec. 201. Short title; finding.	• Establishes a short title ("Medical Device User Fee Amendments of 2022") and provides that the title will go toward medical device activities as set forth in the commitment letter submitted to the Congressional Record.
Sec. 202. Definitions.	• Updating the definition of 'process for the review of device applications' to include de novo classification requests
Sec. 203. Authority to assess and use medical device fees.	• Reauthorizes the authority to collect fees in the Medical Device User Fee Amendments (MDUFA) program. • Updates the target base fee amounts for each year. FY2023 base is $130,184,348, the FY2024 base is increased to $183,280,756, ending at $213,687,660 in FY2027.

	• Modifies the fee for a panel track supplement from a fee equal to 75 of the fee for a premarket application to a fee equal to 80 percent for a premarket application. • Modifies the fee for a premarket notification submission from a fee equal to 3.4 percent of the fee for a premarket application to 4.5 percent of the fee for a premarket application. • Updates the payment requirement to include de novo classification requests. • Updates the total revenue amounts and the fee amounts for premarket applications and establishment registration. • Provides for a performance improvement adjustment to increase the base establishment registration fee amounts to reflect changes in the resource needs of FDA in the event of improved review performance, for FY 2025-27. • Provides that such performance goals shall be based on data available as of March 31 following the end of each fiscal year. • Provides for a hiring adjustment for FY 2025-27, if the number of hires to support the process for the review of device applications falls below certain thresholds. • Provides for an operating reserve adjustment for FY 2023-27, that would decrease the base establishment registration fee amounts, if FDA has operating reserves of carryover user fees in excess of a designated amount. • Provides that fees may not be assessed for the fiscal year, and FDA is not expected to meet any performance goals, if the amount appropriated for the fiscal year is more than one percent less than $398,566,000, updated from $320,825,000. • Updates the authorization of appropriations to include in the revenue amount the performance improvement adjustment, if applicable, and in the amount of reductions the hiring and operating reserve adjustment amounts, if applicable.
Sec. 204. Reauthorization; reporting requirement.	• Maintains the existing reauthorization process and requirements. • Performance and financial reports continue to be due to Congress every year.
Sec. 205. Accreditation programs.	• Clarifies the accreditation scheme for the conformity assessment under which the FDA accredits testing laboratories that meet certain criteria to assess the conformance of devices to certain standards, and the process for secretarial review of such accredited laboratory results. • Reauthorizes the program for accreditation of persons for the purpose of reviewing reports submitted under section 510(k) and making recommendations to the FDA regarding the initial classification of devices under section 513(f)(1), until 2027.
Sec. 206. Sunset dates.	• Sunsets the authority to collect fees on October 1, 2027, and the requirement to submit performance and financial reports after January 31, 2028.

Sec. 207. Effective date.	• Clarifies that the effective date is October 1, 2022, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all human device applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.
Sec. 208. Savings clause.	• Clarifies that submissions accepted for filing prior to October 1, 2022, will continue to be reviewed and assessed fees based on the agreement for FY 2017-2022.
TITLE III: FEES RELATING TO GENERIC DRUGS	
Sec. 301. Short title; finding.	• Establishes a short title ("Generic Drug User Fee Amendments of 2022") and provides that the title will go toward human generic drug activities as set forth in the commitment letter submitted to the Congressional Record.
Sec. 302. Authority to assess and use human generic drug fees.	• Reauthorizes the authority to collect fees. • Updates the base fee amount. In fiscal year (FY) 2022, the base amount was $493,600,000, in FY 2023 the base amount is $582,500,000. • Establishes a capacity planning adjustment to reflect changes in the resource capacity needs of FDA for human generic drug activities. • Allows the Secretary to increase the fee revenue and fees under this section, in addition to the inflation and capacity planning adjustments, if an adjustment is necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than 8 weeks for FY 2024, 9 weeks for FY 2025, and 10 weeks for FY 2026 and 2027.
Sec. 303. Reauthorization; reporting requirements.	• Maintains the existing reauthorization process and requirements. • Performance and financial reports continue to be due to Congress every year.
Sec. 304. Sunset dates.	• Sunsets the authority to collect fees on October 1, 2027, and the requirement to submit performance and financial reports after January 31, 2028.
Sec. 305. Effective date.	• Clarifies that the effective date is October 1, 2022, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all abbreviated new drug applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.
Sec. 306. Savings clause.	• Clarifies that abbreviated new drug applications that were received, prior approval supplements that were submitted, and drug master files that were first referenced on or after October 1, 2017, but prior to October 1, 2022, will continue to be reviewed and assessed fees based on the agreement for FY 2017-2022.
TITLE IV: FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS	
Sec. 401. Short title; finding.	• Establishes a short title ("Biosimilar User Fee Amendments of 2022") and provides that the title will go toward biosimilar activities as set forth in the commitment letter submitted to the Congressional Record.

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Sec. 402. Definitions.	• Removes applications for allergenic extract products from the list of applications excluded from the scope of the term biosimilar biological product applications.
Sec. 403. Authority to assess and use biosimilar biological product fees.	• Reauthorizes the authority to collect fees in the Biosimilars User Fee Amendments (BsUFA) program. • Requires that where ownership of a product is transferred, the licensee, assignee, or successor shall pay the annual biosimilar biological product development fee. • Makes changes regarding the removal of persons from the biosimilar product development program. • Updates the formula for calculating the total revenue amount for each fiscal year to include the strategic hiring and retention adjustment and the additional amounts of for $4,428,886 for FY 2023 and $320,569 for FY 2024. • Updates the annual base revenue to, for FY 2023 $43,376,922, and, for FY 2024-2027 the total revenue amount for the previous fiscal year, excluding any adjustments to the revenue amount under the operating reserve adjustment. • Requires FDA to use a capacity planning methodology in setting annual fees that FDA used in setting fees for FY 2021. • Establishes a minimum operating reserve of carryover user fees for the process for the review of biosimilar biological product applications, and to decrease the fees if FDA has carryover balances in excess of 33 weeks for FY 2023, 27 weeks for FY 2024, and 21 weeks for FY 2025. • Requires a written request to qualify for a waiver or return of fees.
Sec. 404. Reauthorization; reporting requirements.	• Maintains the existing reauthorization process and requirements. • Performance and financial reports continue to be due to Congress every year.
Sec. 405. Sunset dates.	• Sunsets the authority to collect fees on October 1, 2027, and the requirement to submit performance and financial reports after January 31, 2028.
Sec. 406. Effective date.	• Clarifies that the effective date is October 1, 2022, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all biosimilar biological product applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.
Sec. 407. Savings clause.	• Clarifies that biosimilar biological product applications and supplements that were accepted for filing on or after October 1, 2017, but prior to October 1, 2022, will continue to be reviewed and assessed fees based on the agreement for FY 2017-2022.
TITLE V: IMPROVING REGULATION OF DRUGS AND BIOLOGICAL PRODUCTS	
Sec. 501. Alternatives to animal testing.	• Clarifies that drug application sponsors can use alternative testing methods to animal testing in evaluating the safety and effectiveness of human drugs.

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	• Clarifies that sponsors of biosimilar applications can demonstrate biosimilarity to a reference product using alternative testing methods to animal studies.
Sec. 502. Safer disposal of opioids.	• Facilitates the disposal of opioids and other drugs with serious risks by allowing FDA to require these drugs be dispensed to patients with safe, in-home disposal systems. Clarifies that in-home disposal systems are eligible to be dispensed to patients
Sec. 503. Clarifications to exclusivity provisions for first interchangeable biosimilar biological products.	• Clarifies FDA's authority to tentatively approve a subsequent interchangeable biosimilar biological product while a first interchangeable product's period of exclusivity is pending • Clarifies that multiple interchangeable biosimilar biological products can share a period of first interchangeable exclusivity if they are approved on the same day and otherwise qualify for exclusivity.
Sec. 504. Improvements to the Purple Book.	• Aligns certain reporting requirements for biologics with the reporting requirements for drugs by: o Requiring holders of approved biologics license applications to report to FDA when withdrawing a product from the market; o Requiring holders of approved biologics license applications to submit a one-time report to confirm that their products listed in the Purple Book are still available for sale; and • Requires FDA to update the Purple Book for changes related to the status of biologics.
Sec. 505. Therapeutic equivalence evaluations.	• Requires FDA to make timely therapeutic equivalence evaluations for follow-on drugs approved through the 505(b)(2) pathway that have similar formulations as other approved products. • Facilitates the availability of lower-cost drugs available for automatic substitution at the pharmacy.
Sec.506. Modernizing accelerated approval.	• Clarifies that real world evidence that may be used to augment or support appropriate postapproval studies. • Requires FDA to publish on the FDA website why a study is not appropriate or necessary, if FDA does not require that a product approved under accelerated approval conduct a postapproval study. • Clarifies that the Secretary may specify the conditions for a postapproval study or study, which may include enrollment targets, study protocol, milestones, and target date for study completion. • Clarifies that the Secretary may require postapproval studies to be underway prior to approval. • Describes expedited procedures for withdrawal of an accelerated approval, including providing the sponsor with due notice and an explanation, opportunity for a meeting, opportunity for written appeal, opportunity for public comment, the publication of a summary of public comments received, and convening and consulting an advisory committee at the sponsor's request. • Requires that sponsors of drugs approved under accelerated approval submit to the Secretary a report of progress on required postapproval studies every 180 days. • Requires the Secretary to establish an intra-agency coordinating council within FDA to ensure the consistent and appropriate use of the accelerated approval pathway.

	• Requires the Secretary to issue guidance on the use of novel endpoints and clinical trial designs in accelerated approval, and on the expedited withdrawal procedures.
Sec. 507. Rare disease pilot program.	• Requires FDA to establish a pilot program for increased interaction with sponsors of rare disease drug development programs for purposes of advancing the development of efficacy endpoints for drugs intended to treat rare diseases. The pilot program sunsets October 1, 2027. • Requires FDA to conduct up to three public workshops to discuss topics relevant to the development of endpoints for rare diseases. • Requires FDA to submit a report to Congress by September 30, 2026 describing the outcomes of the pilot program. • Requires FDA to issue guidance describing best practices and strategies for development of efficacy endpoints.
Sec. 508. Supporting review and development of drugs to treat rare diseases.	• Requires a GAO report assessing FDA policies, practices, and programs with respect to the review of applications for drugs and biological products intended to treat rare diseases and conditions. • Requires FDA to submit to Congress a report on FDA's activities with respect to the review of applications for drugs and biological products intended to treat rare diseases and conditions. • Requires FDA to finalize guidance on common issues in drug development for rare diseases.
Sec. 509. Generic drug labeling changes.	• Allows FDA to approve a generic drug even if its approved labeling differs from that of the reference listed drug, if the differences are limited to FDA-approved changes made to the labeling of the reference listed drug within 90 days of when the generic application is otherwise eligible for approval. • Provides that such differences in labeling cannot be in the "Warnings" section of the approved labeling, and that the generic drug applicant must submit revised labeling no later than 60 days after approval.
TITLE VI: OTHER REAUTHORIZATIONS	
Section 601. Reauthorization of the critical path public-private partnership.	• Reauthorizes the critical path public-private partnership at current authorization levels until 2027.
Section 602. Reauthorization of the best pharmaceuticals for children program.	• Reauthorizes funding that provides resources to conduct certain pediatric trials at current authorization funding levels until 2027.
Section 603. Reauthorization of the humanitarian device exemption.	• Reauthorizes FDA authorities regarding the development of devices for rare conditions until 2027.

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Section 604. Reauthorization of the pediatric device consortia program	• Reauthorizes FDA authority to issue grants to consortia for the development of devices for pediatric populations at current funding levels until 2027.
Section 605. Reauthorization of the exclusivity of drugs containing single enantiomers.	• Reauthorizes section 505(u) of the Federal Food, Drug, and Cosmetic Act, which authorizes FDA to grant exclusivity for drugs containing single enantiomers until 2027. • Clarifies the types of studies a sponsor of a drug containing a single enantiomer must complete to be eligible for exclusivity.
Section 606. Reauthorization of orphan drug grants.	• Reauthorizes FDA authority regarding grants to support the development of orphan drugs until 2027.
Sec. 607. Reauthorization of certain device inspections.	• Reauthorizes FDA authority regarding accreditation of third party inspections of certain devices.
TITLE VII: ENHANCING FDA HIRING AUTHORITIES	
Sec. 701. Enhancing FDA hiring authority for scientific, technical, and professional personnel.	• Enhances existing flexibilities and authorities for FDA to simplify and expedite the process for hiring individuals to scientific, technical, and professional positions, including personnel who work on the regulation of food, in addition to personnel who work on medical products, to enable the Agency to recruit and retain outstanding, highly qualified individuals for these positions.
Sec. 702. Strategic workforce plan and report.	• Requires the Secretary of HHS to develop and implement a strategic workforce plan that includes strategic goals and priorities for recruiting, hiring, training, developing, and retaining a qualified workforce, and establishes metrics and milestones for measuring progress in achieving those goals and priorities. • The Secretary shall publish this plan by September 30, 2023, and at least every 4 years thereafter. Each FDA center shall develop and update their own strategic plans informed by the agency-wide FDA plan.
TITLE VIII: ADVANCING REGULATION OF COSMETICS, DIETARY SUPPLEMENTS, AND IN VITRO CLINICAL TESTS	
Subtitle A. Cosmetics.	
Sec. 801. Short title.	• Establishes a short title “Modernization of Cosmetics Regulation Act of 2022.”
Sec. 802. Amendments to cosmetic requirements.	• Amends Chapter VI of the Federal Food, Drug, and Cosmetic Act to include new provisions for cosmetic products.
Sec. 604. Definitions.	• Provides definitions for the terms adverse event, cosmetic product, facility, responsible person, and serious adverse event.
Sec. 605. Adverse Events.	• Requires responsible persons to submit reports of serious adverse events to FDA no later than 15 days after receiving the report. • Requires responsible persons to maintain records related to each report of an adverse event for a period of 6 years, and authorizes FDA to have access to such records during an inspection.

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	• Provides that FDA may request a list of ingredients in specific fragrances or flavors in a cosmetic product, if FDA has reasonable grounds to believe that an ingredient or combination of ingredients has caused a serious adverse event.
Sec. 606. Good Manufacturing Practice.	• Requires FDA to establish good manufacturing practice regulations. Such regulations shall be, to the extent practicable and appropriate, consistent with national and international standards, and may allow FDA to inspect records necessary to demonstrate compliance with good manufacturing practice regulations during an inspection. • Requires FDA, in establishing good manufacturing practice regulations, to take into account the size and scope of businesses engaged in the manufacture of cosmetics, the public health risks of such cosmetics, and provide sufficient flexibility to be practicable for all sizes and types of manufacturing facilities subject to the regulations. • Requires FDA to issue proposed regulations on good manufacturing practices no later than 2 years after enactment and issue final regulations no later than 3 years after enactment.
Sec. 607. Registration and Product Listing.	• Requires persons that own or operate a manufacturing facility for cosmetic products to register each facility. • Requires registrants to renew registrations biennially, and otherwise notify FDA within 60 days of any changes to information registrants are required to submit as part of registration. • Requires FDA to provide for an abbreviated registration renewal process for persons that own or operate facilities that have not been required to submit any changes since the time of last registration. • Imposes requirements for the format and contents of registration. • Requires responsible persons to submit a product listing for each cosmetic product. • Requires responsible persons to submit product listings not later than 1 year after the date of enactment or, for a product first marketed after the date of enactment, within 120 days of marketing the product. • Provides for an abbreviated renewal process for product listings for which there have been no change since the previous listing. • Imposes requirements for the contents of listing, including the manufacturing facility registration number, a list of ingredients in the cosmetic product, and the product listing number.

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	• Provides that a single listing submission for a cosmetic product may include multiple cosmetic products with identical formulations or formulations that differ only with respect to colors, fragrances, flavors, or quantity of contents. • Requires responsible persons to submit any updates to a product listing annually. • Requires FDA to issue facility registration and product listing numbers at the time of initial registration or listing, and clarifies that facility registration numbers shall be considered confidential commercial information. • Provides that FDA may suspend the registration of a facility if FDA determines that a cosmetic product manufactured by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans and FDA has a reasonable belief that other products manufactured by the facility may be similarly affected. ○ The suspension of cosmetics facilities is similar to the current process for food facilities, and contains certain guardrails and limitations.
Sec. 608. Safety Substantiation.	• Requires responsible persons to ensure, and maintain records supporting, that there is adequate substantiation of safety for cosmetic products. • Provides that, for purposes of determining whether a product is safe, FDA may consider, as appropriate and available, the cumulative or other relevant exposure to the cosmetic product or any ingredient in the product. • Exempts coal-tar hair dye from the safety substantiation requirements, and instead relies on the current provisions in Section 601 of the Federal Food, Drug, and Cosmetic Act for such products. Responsible persons for coal-tar hair dyes must maintain records related to the safety of such products.
Sec. 609. Labeling.	• Requires cosmetic product labels to include contact information through which the responsible person can receive adverse event reports. • Requires responsible persons to identify on the label of a cosmetic product each fragrance allergen in such product. • Requires FDA to determine by regulation the substances that are fragrance allergens, with a proposed regulation to be issued not later than one year after enactment, and a final rule issued not later than 180 days after the close of the public comment period for the proposed regulation, that takes into consideration international, state, and local requirements for allergen disclosure, including requirements in the European Union.

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	• Requires certain labeling for cosmetic product that are intended to be used only by licensed professionals to bear a label that the product shall be administered or used only by licensed professionals and includes the same information on its label that is required of cosmetics products intended for consumers.
Sec. 610. Records.	• Authorizes FDA to access and copy certain records related to a cosmetic product, including safety substantiation records, if FDA has a reasonable belief that a cosmetic product, including an ingredient in such cosmetic product, is likely to be adulterated such that the use or exposure to the product presents a threat of serious adverse health consequences or death to humans. • Provides appropriate protections for trade secret or confidential information as part of the access to such records.
Sec. 611. Mandatory Recall.	• Provides FDA the authority to order a recall of a cosmetic product if FDA determines that there is a reasonable probability that a cosmetic is adulterated or misbranded and the use or exposure to the cosmetic will cause serious adverse health consequences or death.
Sec. 612. Small Businesses.	• Provides certain exemptions for small businesses with average gross annual sales for the previous three-year period is less than $1,000,000.
Sec. 613. Exemption for Certain Products and Facilities.	• Exempts products and facilities that are also subject to the drug and device chapters of the Federal Food, Drug, and Cosmetic Act, such as over-the-counter drugs and devices, from requirements under the Modernization of Cosmetics Regulation Act of 2022, except for certain labeling requirements.
Sec. 614. Preemption.	• Provides that no state or political subdivision of a state may establish or continue in effect any requirement for cosmetics that is different from or in addition to any requirement in Chapter VI of the Federal Food, Drug, and Cosmetic Act with respect to registration and product listing, good manufacturing practice, recordkeeping, recalls, adverse event report, or safety substantiation. • Clarifies that the Modernization of Cosmetics Regulation Act of 2022 does not preempt any state laws other than those laws that are expressly preempted. • Clarifies that the language in the Modernization of Cosmetics Regulation Act of 2022 does not preempt any state from prohibiting the use or limiting the amount of an ingredient in a cosmetic product, and does not preempt any current requirement for reporting certain cosmetic ingredients to states.

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	• Provides that the Modernization of Cosmetics Regulation Act of 2022, nor any other requirement shall be construed to modify, preempt, or displace any actions for damages or the liability of any person under the law of any state, whether statutory or based in common law. • Clarifies that the preemption and savings language in the Modernization of Cosmetics Regulation Act of 2022 do not affect the provisions under section 752 of the Federal Food, Drug, and Cosmetic Act (preemption for labeling or packaging of cosmetics).
Sec. 803. Enforcement and conforming amendments.	• New enforcement provisions become effective one year after enactment of the Modernization of Cosmetics Regulation Act of 2022. • Provides that failure to register or submit listing information, refusal or failure to follow a recall order, and failure to comply with adverse event reporting requirements are prohibited acts under the Federal Food, Drug, and Cosmetic Act. • Provides that cosmetic products are adulterated if they are manufactured under conditions that do not meet good manufacturing practice regulations or do not have adequate substantiation for safety. • Provides that cosmetic products are misbranded if they are not in compliance with labeling requirements contained in the Modernization of Cosmetics Regulation Act of 2022.
Sec. 804. Records inspection.	• Makes conforming edits to Section 704 of the Federal Food, Drug, and Cosmetic Act to provide that FDA inspections shall extend to records and information, such as safety substantiation information, when the applicable standard is met.
Sec. 805. Talc-containing cosmetics.	• Requires FDA to promulgate proposed regulations to establish testing methods for detecting and identifying asbestos in talc-containing cosmetic products not later than one year after the date of enactment of the Modernization of Cosmetics Regulation Act of 2022, and to issue final regulations not later than 180 days after the date on which the public comment period on the proposed regulations closes.
Sec. 806. PFAS in cosmetics.	• Requires FDA to assess the use of perfluoroalkyl and polyfluoralkyl substances (PFAS) in cosmetic products and the scientific evidence regarding the safety of their use in cosmetics products, including any risks associated with their use. • Provides that FDA can, as appropriate, consult with the National Center for Toxicological Research, in conducting the assessment. • Requires FDA to publish on the FDA website a report summarizing the assessment not later than 2 years after enactment of the FDA Safety and Landmark Advancements Act.
Sec. 807. Sense of the Senate on animal testing.	• Provides a sense of the Senate that animal testing should not be used for the purposes of safety testing on cosmetic products and should be phased out with the exception of appropriate allowances.

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Sec. 808. Funding.	• Provides for an authorization of appropriations for purposes of conducting the activities under this section and hiring personnel required to carry out this section.
Subtitle B. Dietary supplements.	
Sec. 811. Regulation of Dietary Supplements.	• Amends chapter IV of the FDCA to include a new provisions related to dietary supplements.
Sec. 403D. Dietary Supplement Listing Requirement.	• Requires responsible persons to list with FDA the dietary supplements they manufacture, pack, or distribute. • Requires each listing to contain certain information, primarily information that is required to appear on dietary supplement labels. • Allows for a single listing submission for a dietary supplement to include multiple dietary supplements with identical formulations that differ only with respect to color, additives, or flavorings, regardless of package size. • Requires the listing submission of a dietary supplement at the time of introduction into interstate commerce. • Requires responsible persons to notify FDA within one year of discontinuance of a dietary supplement. • Requires responsible persons to submit changes to listing information at the time the dietary supplement is introduced into interstate commerce. • Requires FDA to provide a listing number for each dietary supplement and a process for reserving such listing numbers. • Requires FDA to establish and maintain a publicly available, electronic database for some listing information. • Provides for an authorization of appropriations for purposes of conducting the activities under this section and hiring personnel required to carry out this section. Authorizes FDA to obtain, upon request, from responsible persons the name and address of dietary ingredient suppliers. • Requires FDA to publish final guidance on new dietary ingredient notifications no later than 18 months after the date of enactment of this Act. • Requires FDA to direct resources to inspections of facilities, suppliers, and dietary supplement types that present a high risk to public health. • Renders misbranded dietary supplements for which a responsible person has failed to comply with the listing requirements under this section.

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	• Makes the introduction into interstate commerce of any product marketed as a dietary supplement that does not meet the definition of a dietary supplement under the Federal Food, Drug, and Cosmetic Act a new prohibited act. • Makes the introduction into interstate commerce of a dietary supplement that has been manufactured by or for a person who has been debarred a new prohibited act.
Subtitle C. In vitro clinical tests.	
Section 821. Short Title and Table of Contents.	• Title of the bill is the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2022.
Section 822. Definitions.	• Provides definitions of relevant terms, including for an in vitro clinical test (IVCT). Clarifies that IVCT components - including blood, blood components, or human cells or tissues, laboratory equipment and personal protective equipment - are excluded from the definition of IVCT.
Section 823. Regulation of In Vitro Clinical Tests.	• Amends the FDCA to include a new subchapter J for in vitro clinical tests.
Section 587. Definitions.	• Defines relevant terms used throughout the remainder of the Act, including the definitions for analytical and clinical validity of an IVCT, instruments, developer, technology, mitigating measures, high-risk, moderate-risk, and low-risk tests, and first-of-a-kind tests.
Section 587A. Regulation of In Vitro. Clinical Tests.	• Clarifies that an IVCT shall be subject to the new regulatory requirements of Subchapter J, as added by this Act to be offered in interstate commerce. • Specifies that IVCT developers can transfer or sell an IVCT with premarket approval or technology certification. • Authorizes FDA to issue regulations to implement the Subchapter J.
Section 587B. Premarket Review.	• Provides details for the premarket, abbreviated premarket, and supplemental application review and approval process. • Outlines the information required in premarket, abbreviated premarket, and supplemental applications for an IVCT in order to ensure the test meets the applicable analytical and clinical validity standard required. • Provides the pathway to market for test instruments and instrument families. • Includes details related to an application for abbreviated premarket approval for eligible IVCTs, including moderate-risk IVCTs, test instruments, and specimen receptacles.
Section 587C. Exemptions.	• Establishes conditions for certain IVCTs to qualify for an exemption from the IVCT premarket review process and certain other requirements under VALID. • IVCTs that may qualify for such exemptions include low-risk IVCTs, humanitarian use IVCTs, custom and low volume IVCTs, modified IVCTs, and manual IVCTs.

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	• Clarifies the types of modifications to IVCTs with premarket approval that can be made without additional FDA review (*e.g.*, changes that do not affect the analytical or clinical validity of the IVCT).
Section 587D. Technology Certification.	• Establishes a technology certification pathway for a developer of moderate-risk IVCTs to be certified to offer multiple tests, using the same technology, and does not require FDA to review each test individually. • A technology certification provides that IVCT developers can continue innovating and offering certain IVCT within the scope of a technology certification order issued by FDA, as long as IVCTs remain within the scope of the order. • Requires an IVCT developer to submit a representative IVCT for FDA to review to help determine the scope of the technology certification order. • Outlines the parameters and eligibility requirements for a technology certification application. • Requires FDA to issue regulations on the technology certification pathway, which shall be subject to public comment for a minimum of 60 days. • Requires FDA to submit annual reports to Congress for a five-year period to provide updates on the status of the technology certification pathway.
Section 587E. Mitigating Measures.	• Permits FDA to establish mitigating measures for IVCTs with the same intended use. • Mitigating measures can be established to reduce or control the risk of a test, and may be applied to down class the risk of an IVCT. • Clarifies that mitigating measures required for IVCTs regulated as special controls for devices before the enactment of this Act will remain in effect unless FDA changes or withdraws them.

Section 587F. Regulatory Pathway Designation.	• Establishes a voluntary process to provide clarity to developers regarding the risk classification of their IVCTs.
	  ○ The process may be initiated by the developer or FDA.
	  ○ FDA may determine whether mitigating measures are sufficient to support a proposed risk classification through the process.
	  ○ FDA may redesignate certain IVCTs in response to new information that requires or allows for a change to the risk classification an IVCT.
	• Establishes a process for developers to request and receive informal feedback from FDA before submitting an application which may include feedback regarding the submission process, the appropriate regulatory pathway for an IVCT, and investigational plans for an IVCT.
	• Establishes a process for FDA to change the regulatory designation of an IVCT or IVCTs with the same indication for use in response to new information (such as new mitigating measures) or revoke any regulatory exemption for certain tests if there is a safety issue.

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Section 587G. Grandfathered In Vitro Clinical Tests.	• Specifies that an IVCT that was developed by a laboratory with an existing high complexity certificate under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and available for clinical use before the date of enactment of this legislation may continue to be offered in interstate commerce. • IVCTs that meet the criteria to be grandfathered are exempt from premarket review, labeling, test design, and quality requirements. • Provides a process for FDA to request and review information from IVCT developers about grandfathered IVCTs to ensure that such IVCTs continue to be accurate and safe for patients. • If FDA determines that an IVCT is no longer eligible for this exemption, an IVCT developer would be required to submit a premarket, abbreviated premarket, or technology certification application for review of such IVCT in accordance with the risks classification of the IVCT.
Section 587H. Advisory Committees.	• Allows FDA to establish advisory committees or use previously established committees to solicit scientific recommendations.
Section 587I. Breakthrough In Vitro Clinical Tests.	• Directs FDA to establish a program that promotes efficiency and flexibility in order to expedite the development and priority review of IVCTs that are deemed as breakthrough technology. • Defines a breakthrough IVCT as a technology that does not have an alternative on the market or the availability of which is in the best interest of patients or public health.
Section 587J. Registration and Listing.	• Requires IVCT developers to register and to list their IVCTs with FDA. • Requires that IVCT developers provide FDA with listing information related to their IVCTs and submit relevant information to a publicly available on the FDA website.
Section 587K. Test Design and Quality Requirements.	• Requires all persons required to register under Section 587J to maintain quality requirements based on the type of test offered and where it is developed. • Clarifies that FDA-regulated quality requirements apply only to the design and manufacturing of IVCTs and that the Centers for Medicare and Medicaid Services (CMS) will continue to regulate laboratory operations under CLIA.
Section 587L. Labeling Requirements.	• Specifies which types of IVCTs should meet applicable labeling requirements and outlines the information that must be contained in an IVCT's labeling, such as instructions for reporting adverse events, intended use of the IVCT, and warnings and limitations of the IVCT. • Specifies which labeling requirements do not apply to certain IVCTs including test instruments, analyte-specific reagents, and IVCTs for research or investigational use.
Section 587M: Adverse Event Reporting.	• Establishes a process for reporting adverse events associated with the use of IVCTs.

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Section 587N. Corrections and Removals.	• Requires that when IVCT developers report to FDA when they voluntarily undertake a correction or removal of an IVCT from the market in order to reduce a risk to health or remedy a violation that may present a risk to health.
Section 587O. Restricted In Vitro Clinical Tests.	• Describes the circumstances under which FDA may add certain conditions on the approval of an IVCT to minimize patient risk and ensure analytical and clinical validity of the IVCT.
Section 587P. Appeals.	• Directs FDA to provide a substantive summary of the scientific and regulatory reasoning for any significant decision made by FDA regarding the submission, review, or exemption of an IVCT. • Outlines the process by which any person may request a supervisory review of any significant decision made by FDA related to an IVCT by the next supervisory level or higher above that person.
Section 587Q. Accredited Persons.	• Provides the authority for FDA to accredit qualified entities to review and make recommendations on IVCT applications for both premarket approval and technology certification, and to conduct inspections of IVCT developers.
Section 587R. Recognized Standards.	• Authorizes FDA recognize national and international standards for IVCTs to meet the requirements under Subchapter J. Previously recognized device standards shall be considered recognized standards.
Section 587S. Investigational Use.	• Directs FDA to establish a process for applying for exemptions from Subchapter J for IVCTs used for research purposes (investigational use). • Requires IVCT developers to maintain records documenting the use of investigational IVCTs and provide to FDA research plans for the development of such IVCTs.
Section 587T. Comprehensive Test Information System.	• Directs FDA to create and maintain a website to provide information about IVCTs on the market, making certain information available to providers and consumers. • The website will also serve as a secure portal for the submission of premarket applications and technology certification applications, registration and listing, and adverse event reports.
Section 587U. Preemption.	• Prohibits State, Tribal, or local governments from establishing or continuing any IVCT regulations that are different from those established by the VALID Act. • Allows state laws that were in existence prior to Jan 1, 2022, to remain in effect as long as they do not impose requirements that differ from any requirement of VALID. • Clarifies that nothing in the act shall be construed to modify any action for damages or the liability of any person under the law of any State, or shift liability to health care practitioners or other users.
Section 587V. Adulteration.	• Lists circumstances in which an IVCT would be deemed to be adulterated.
Section 587W. Misbranding.	• Lists circumstances in which an IVCT would be deemed to be misbranded.

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Section 587X. Postmarket Surveillance.	• Allows FDA to require, by order, IVCT developers to conduct postmarket surveillance of their IVCTs.
Section 587Y. Electronic Format for Submissions.	• Requires all IVCT submissions completed under Subchapter J to be made electronically.
Section 587Z. Postmarket Remedies.	• Allows FDA to order an IVCT developer to submit a plan to notify individuals subject to risk, repair, replace, or provide a refund for a premarket-approved IVCT that is found to present an unreasonable risk of substantial harm to public health and no more practicable means is available under the FD&C Act, after affording the developer opportunity for an informal hearing. • Allows FDA to direct the IVCT developer to immediately cease distribution of the IVCT and notify entities or individuals that use the test if a premarket-approved IVCT is found to cause serious adverse health consequences or death.
Section 587AA. Applicability.	• Specifies that FDA shall avoid issuing or enforcing regulations or guidance that are duplicative of regulations or guidance issued under CLIA. • Stipulates that provisions under Subchapter J will not restrict a provider's ability to administer or prescribe an approved IVCT, or otherwise limit the practice of medicine.
Section 587BB. Judicial Review.	• Specifies that any person adversely affected by an order issued under 587B or 587D may file a petition with a relevant court to seek judicial review of such order within 30 days of such order.
Section 824. Enforcement and Other Provisions.	• Details the circumstances under which IVCTs would be in violation of the Federal Food, Drug, and Cosmetic Act (FDCA) and subject to existing relevant penalties of the FDCA.
Section 825. Transition.	• Sets the effective date of the VALID Act to October 1, 2027, subject to some exceptions. • Allows for the establishment of mitigating measures in advance of the effective date of the VALID Act to ease the transition for developers. • Requires FDA to hold all public meetings listed under the VALID Act within 1 year of enactment and issue certain regulations and guidance within 3 years of enactment. • Determines that IVCTs introduced into the market after the enactment of the VALID Act, but before its effective date will be deemed "transitional tests." • IVCTs that are undergoing FDA review on the effective date of this Act will be regulated according to the pathway through which they were submitted. • IVCTs that were medical devices with existing approval, licensure, clearance, humanitarian use exemption, investigational use exemption, and breakthrough designation at the effective date of the VALID Act shall be deemed IVCTs with approval, humanitarian use exemption, investigational use exemption, and breakthrough designation under Subchapter J.

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	• Risk classifications of such devices shall also transition to the applicable risk classification under Subchapter J.
Section 826. Emergency Use Authorization.	• Amends the FDCA to add IVCTs as a product eligible for emergency use authorization during a public health emergency.
Section 827. Antimicrobial Susceptibility Tests.	• Amends a section of the FDCA addressing breakpoints for antimicrobial resistance tests to adequately address issues pertaining to IVCTs that are developed to help direct the treatment of infectious diseases and maintain the policies established under the 21st Century Cures Act.
Section 828. Combination Products.	• Amends a section of the FDCA addressing combination product regulation to clarify the combination product process for products that include an IVCT.
Section 829. Resources.	• Provides requirements for the collection of user fees to review IVCT submissions. • Authorizes FDA to collect user fees under certain conditions.
Section. 830. Authorization of appropriations.	• Provides for an authorization of appropriations for purposes of funding implementation of this subchapter, to be available until expended through 2027.
Sec.831.Guidance on Diagnostic Innovation.	• Requires FDA to issue guidance to assist developers of in vitro clinical tests intended to identify or diagnose rare diseases and in vitro clinical tests intended to address an unmet medical need. • Provides that such guidance shall include considerations for addressing barriers to developing sufficient data to demonstrate clinical validity for such tests, such as challenges associated with data collection and obstacles to the timely generation of evidence.
TITLE IX: OTHER PROVISIONS	
Sec. 901. Facilities management.	• Preserves Section 905 of the FDA Reauthorization Act (FDARA) by clarifying that FDA use of budget authority for costs excluded under Section 905 (e.g., for furniture and fixtures) can count towards meeting the spending trigger amount for user fees for the PDUFA, GDUFA, MDUFA, and BsUFA programs. This provision starts in FY 2024.
Sec. 902. User fee program transparency and accountability.	• Strengthens the reporting requirements for the user fee programs to ensure greater accountability and transparency with respect to the FDA's commitments. • Requires FDA, with regulated industry, to provide regular updates to Congress regarding user fee negotiations, and to publish the minutes from user fee negotiations within 30 days.
Sec. 903. OTC hearing aids final rule.	• Requires FDA to publish a final rule to establish a category of over-the-counter hearing aids not later than 30 days after the enactment of the Food and Drug Administration Safety and Landmark Advancements Act.

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Sec. 904. Enhancing coordination and transparency on inspections.	• Advances intra-agency coordination between field investigators and drug shortage staff at FDA. • Requires FDA to include additional information in an annual report with respect to FDA domestic and foreign inspections and FDA recognition of foreign government inspections. • Requires FDA to include additional information in an annual report with respect to the timing of inspections and regulatory and enforcement actions. • Harmonizes the timing of the FDA annual reporting requirement on inspections under Section 902 of the Food and Drug Administration Reauthorization Act to align with reporting requirements related to the PDUFA user fee program.
Sec. 905. Certificates to foreign governments.	• Clarifies that FDA can issue Certificates to Foreign Governments for devices that are manufactured by a device establishment located outside of the United States, if the establishment is registered, the device is listed, the device is lawfully marketed, and imported or offered for import into the United States.
Sec. 906. Importation of drugs.	• Codifies existing regulatory requirements promulgated under section 804(b) of the Food, Drug, and Cosmetic Act related to the importation of drugs from Canada, and includes additional protections to ensure commercial importation under section 804 poses no additional risk to health and safety. • Eliminates the requirement for FDA to grant waivers to permit personal importation of prescription drugs and revises section 804(j) of the Food, Drug, and Cosmetic Act to require FDA to promulgate regulations to facilitate importation of certain prescription drugs for personal use from Canada, if importation for personal use will not increase public's exposure to counterfeit prescription drug products or pose a risk of creating, exacerbating, or prolonging the opioid epidemic, and under such other conditions as the Secretary determines to be appropriate. • Streamlines FDA's ability to terminate importation programs authorized under section 804(b) or 804(j) of the Act.
Sec. 907. Improving information technology systems of the Food and Drug Administration.	• Requires FDA to develop and submit to Congress and post on the FDA website a coordinated information technology strategic plan to modernize the information technology systems of the FDA. • Requires GAO to assess the implementation of such plan.
Sec. 908. Regulation of certain products as drugs.	• Deems all contrast agents, radioactive drugs, and over-the-counter monograph drugs to be drugs and not medical devices. • Waives application fees for products that are currently medical devices that would be deemed to be drugs.

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Sec. 909, Report on the mailroom and Office of the Executive Secretariat of the Food and Drug Administration.	• Requires FDA to submit a report to Congress on policies, procedures, and activities of the mailroom and the Office of the Executive Secretariat of the FDA, the development and implementation of new or revised policies and procedures to monitor and ensure the effective receipt, tracking, managing, and prioritization of complaints, and the effective receipt of common carrier packages to FDA. • Requires quarterly reporting to Congress on information regarding FDA's handling of common carrier packages and correspondence. • Requires GAO to conduct a report assessing the policies and practices of the Division of Executive Operations in the Office of the Secretariat with respect to the receipt, tracking, managing, and prioritization of correspondence.
Sec. 910. Protecting infants and improving infant formula supply.	• Establishes the Office of Critical Foods in the Center for Food Safety and Applied Nutrition (CFSAN) at the FDA. • Provides flexibility to FDA to waive the 90 day premarket submission requirement for infant formula when there is a supply disruption and apply a 30 day premarket submission requirement, which will remain in effect for 90 days beginning on the date that FDA distributes manufacturer notifications of meaningful disruptions in the production of infant formula. • Not later than one year after enactment, requires FDA to submit a report to Congress on the timelines related to FDA's review of premarket submissions for infant formula. • Requires FDA to publish a list on the FDA website detailing which infant formula products may be appropriate substitutes for infant formula products in shortage that are relied on by individuals with amino-acid and metabolic conditions. • Requires FDA to participate in meetings with representatives from other countries to discuss harmonizing regulatory requirements for infant formula. • Requires a study by the National Academies of Sciences, Engineering, and Medicine to report on challenges in supply, market competition, and regulation of infant formula in the United States, and any differences from infant formula marketed in the European Union. • Requires FDA to submit an annual report to Congress on infant formula submissions and inspections. • Requires FDA to respond to a submission for infant formula not later than 65 days after receiving such submission and, in the case of a new infant formula manufacturer or a manufacturer of a new infant formula, 45 days. • Requires FDA to review the required nutrients in infant formula every four years. • Requires infant formula manufacturers to submit a report to FDA promptly after the initiation of a recall, including a plan of actions the manufacturer will take to address the recall. • Requires FDA to submit the manufacturer's report to Congress, along with information concerning the current domestic supply of infant formula and, if the recall impacts over 10 percent of the

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	domestic production of infant formula intended for sale in the United States, actions that FDA will take to work with the manufacturer or other manufacturers to increase production. • Requires FDA to ensure timely communication with manufacturers following an inspection and to reinspect facilities in a timely manner. • Requires FDA to conduct annual inspections of each manufacturer of infant formula in accordance with a risk-based approach and ensure coordination among the investigators and CFSAN. • Requires FDA, in consultation with the Secretary of Agriculture, to develop and issue within 90 days of enactment a national strategy on infant formula to increase the resiliency of the infant formula supply chain, protect against future contamination and other potential causes of shortages, and ensure parents and caregivers have access to formula and information they need. • Requires manufacturers of critical foods to notify FDA of a permanent discontinuance in the manufacture or an interruption of the manufacture of such food that is likely to lead to a meaningful disruption in the supply of such food in the United States, and the reason for such discontinuance or interruption, as soon as practicable, but no later than 5 business days after such discontinuance or such interruption. • Requires FDA to distribute information on such meaningful disruption to the Secretary of Agriculture and other appropriate entities. • Requires critical food manufacturers to develop, maintain, and implement, as appropriate, a redundancy risk management plan that identifies and evaluates risks to the supply of critical food for each establishment in which such food is manufactured. • Provides that if a person fails to submit a notification, FDA shall issue a letter to such person informing such person of such failure, and then no later than 45 days after issuance of the letter, FDA may post such letter (and, at the request of such person, any response to such letter) on the FDA website.