Provisions	Current Law (FFDCA Section 506(c))	Food and Drug Act 2022 (House User Fee Bill)	FDASLA (Senate User Fee Bill)	Omnibus
Scope of Products	Drug or biologic product for a serious or life-threatening disease or condition	Unchanged	Unchanged	Unchanged
Approval Standard	The drug or biologic product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.	Unchanged	Unchanged	Unchanged
Evidence	The evidence to support that an endpoint is reasonably likely to predict clinical benefit may include epidemiological, pathophysiological, therapeutic, pharmacologic, or other evidence developed using biomarkers, for	Unchanged	Unchanged	Unchanged

	example, or other scientific methods or tools.			
Development Plan	Not included	Codifies the Rare Disease Endpoint Advancement Pilot from the PDUFA VII commitment letter.	Codifies the Rare Disease Endpoint Advancement Pilot from the PDUFA VII commitment letter.	Codifies the Rare Disease Endpoint Advancement Pilot from the PDUFA VII commitment letter.
Limitations of Approval	Approval of an AA product *may* be subject to 1 or both of the following requirements: • That the sponsor conduct appropriate postapproval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit. • That the sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such period thereafter as FDA determines to be appropriate, at least 30 days prior to dissemination of the materials.	Maintains the "may" Specifics that studies "may be augmented or supported by real world evidence" Requires FDA to post a rationale on the website if a post market study is not required Adds that FDA may require such studies to be underway prior to approval; and refuse to approve a product under accelerated approval until such studies are underway.	Maintains the "may" Specifics that studies "may be augmented or supported by real world evidence" Requires FDA to post a rationale on the website if a post market study is not required Adds that FDA may require such studies to be underway prior to approval; and refuse to approve a product under accelerated approval until such studies are underway.	Maintains the "may" No mention of RWE Requires FDA to post a rationale on the website if a post market study is not required Adds that FDA may require, ***as appropriate***, such studies to be underway prior to approval; and refuse to approve a product under accelerated approval until such studies are underway

Post-Market Study Protocols	Not included	Adds that no later than the date of approval, FDA shall specify conditions for the post-approval study required, which may include enrollment targets, study protocol, milestones, and target completion date	Adds that no later than the date of approval, FDA shall specify conditions for the post-approval study required, which may include enrollment targets, study protocol, milestones, and target completion date	Adds that no later than the date of approval, FDA shall specify conditions for the post-approval study required, which may include enrollment targets, study protocol, milestones, and target completion date
Guidance	N/A	FDA shall issue guidance describing: • How sponsor questions related to endpoints may be addressed in early development meetings • The use of novel clinical trial designs conduct post-marketing studies • The new expedited withdrawal The draft guidances shall be issued not later than 18 months after the date of enactment of this Act; FDA will issue final guidances not later than 1 year after the close of the public comment period on such draft guidance.	FDA shall issue guidance describing: • How sponsor questions related to endpoints may be addressed in early development meetings • The use of novel clinical trial designs conduct post-marketing studies • The new expedited withdrawal • Considerations related to the use of surrogate or intermediate clinical endpoints that may support the accelerated approval The draft guidances shall be issued not later than 18 months after the date of enactment of this Act; FDA will issue final guidances	FDA shall issue guidance describing: • How sponsor questions related to endpoints may be addressed in early development meetings • The use of novel clinical trial designs conduct post-marketing studies • The new expedited withdrawal • Considerations related to the use of surrogate or intermediate clinical endpoints that may support the accelerated approval The draft guidances shall be issued not later than 18 months after the date of enactment of this Act; FDA will issue final guidances

			not later than 1 year after the close of the public comment period on such draft guidance.	not later than 1 year after the close of the public comment period on such draft guidance.
Withdrawal Procedures	FDA may withdraw approval of an AA product (with an informal hearing) if— • the sponsor fails to conduct any required postapproval studies with due diligence; • a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit; • other evidence demonstrates that the product is not safe or effective under the conditions of use; or • the sponsor disseminates false or misleading promotional materials with respect to the product.	Clarifies that failing to conduct the study includes with respect to the new post-market study plan agreements. Adds specific procedures for expedited withdrawal: • providing the sponsor due notice, an explanation for the withdraw, and a meeting with the Commissioner of Food and Drugs; and • an opportunity for written appeal to the Commissioner of Food and Drugs; • an opportunity for public comment on the notice proposing to withdraw approval; • publication of the comments received and the FDAs response to such comments	Clarifies that failing to conduct the study includes with respect to the new post-market study plan agreements. Adds specific procedures for expedited withdrawal: • providing the sponsor due notice, an explanation for the withdraw, and a meeting with the Commissioner of Food and Drugs; and • an opportunity for written appeal to the Commissioner of Food and Drugs; • an opportunity for public comment on the notice proposing to withdraw approval; • publication of the comments received and the FDAs response to such comments	Clarifies that failing to conduct the study includes with respect to the new post-market study plan agreements. Adds specific procedures for expedited withdrawal: • providing the sponsor due notice, an explanation for the withdraw, and a meeting with the Commissioner of Food and Drugs; and • an opportunity for written appeal to the Commissioner of Food and Drugs; • an opportunity for public comment on the notice proposing to withdraw approval; • publication of the comments received and the FDAs response to such comments

		• an AdCom if one had been previously held with regards to the withdrawal.	an AdCom if one had been previously held with regards to the withdrawal	• an AdCom if one had been previously held with regards to the withdrawal
Automatic Withdrawal	Not included	Not included	Not included	No included
Labeling	Not included	Requires labeling for products approved under the pathway: • a statement indicating that the product was approved under accelerated approval • a statement indicating that continued approval of the product is subject to postmarketing studies to verify clinical benefit; • identification of the clinical endpoint that is under study and any known limitations of that surrogate or intermediate endpoint in determining clinical benefit; • a succinct description of the product and any uncertainty about anticipated clinical	Not included	Not included

		benefit and a discussion of available evidence with respect to such clinical benefit; and any other information required by the Secretary in the order approving the product.		
Sponsor Reporting	(506D of FDCA "Reports of Postmarket Studies") A sponsor of a drug that has entered into an agreement with FDA to conduct a postmarketing study of a drug shall submit within 1 year after the approval of such drug and annually thereafter until the study is completed or terminated, a report of the progress of the study or the reasons for the failure of the sponsor to conduct the study. The report shall be submitted in such form as is prescribed by regulations. Any information pertaining to a report shall be considered to be public information to the extent that the information is necessary.	Adds additional provision to 506B: For AA products, the sponsor shall submit a report of the progress of any postapproval study, including progress toward any agreed upon enrollment targets, milestones, and other information as required, not later than 180 days after the approval of such drug and not less frequently than every 180 days thereafter, until the study is completed or terminated	Adds additional provision to 506B: For AA products, the sponsor shall submit a report of the progress of any postapproval study, including progress toward any agreed upon enrollment targets, milestones, and other information as required, not later than 180 days after the approval of such drug and not less frequently than every 180 days thereafter, until the study is completed or terminated	Adds additional provision to 506B: For AA products, the sponsor shall submit a report of the progress of any postapproval study, including progress toward any agreed upon enrollment targets, milestones, and other information as required, not later than 180 days after the approval of such drug and not less frequently than every 180 days thereafter, until the study is completed or terminated

FDA Reporting	Not Included	Adds a provision to 506(c): Not later than September 30, 2025, FDA shall submit to Congress a report describing— • the circumstances in which FDA considered RWE submitted to support post approval studies completed after the date of enactment.	Not Included	Not Included
Prohibited Acts	Sec. 301 of the FDCA outlines a list of acts and the causing thereof that are prohibited. There are 57 listed prohibitions.	Not included	Adds to Sec. 301 of the FDCA. "Prohibited Acts" a 58th prohibition: The failure of a sponsor of a product approved under accelerated approval pursuant to section 506(c) to conduct with due diligence any post-approval study required under section 506(c) with respect to such product; or to submit timely reports with respect to such product in accordance with section 506B(a)(2).	Adds to Sec. 301 of the FDCA. "Prohibited Acts" a 58th prohibition: The failure of a sponsor of a product approved under accelerated approval pursuant to section 506(c) to conduct with due diligence any post-approval study required under section 506(c) with respect to such product; to submit timely reports with respect to such product in accordance with section 506B(a)(2).

Council	Not Included	Not Included	Creates an Accelerated Approval council comprised of the Directors of CDER, CBER, OCE, OND, Office of Orphan Products, OTAT, Office of Medical policy, a review division within the Office of Neuroscience, and two other drug review divisions. Council will convene three times per year with the goal of discussing cross-disciplinary approached to product review and develop policy to ensure the consistent and appropriate use of accelerated approval across the agency. Annual report.	Creates an Accelerated Approval council comprised of the Directors of CDER, CBER, OCE, OND, Office of Orphan Products, OTAT, Office of Medical policy, a review division within the Office of Neuroscience, and two other drug review divisions. Council will convene three times per year with the goal of discussing cross-disciplinary approached to product review and develop policy to ensure the consistent and appropriate use of accelerated approval across the agency. Annual report.
Application			The changes under this section do not apply to drugs approved prior to the date of enactment.	The changes under this section do not affect ongoing withdrawal proceedings for products for which a notice of proposed withdrawal has been published in the

				Federal Register prior to the date of enactment of this Act. Such proceedings may continue under procedures in effect prior to the date of enactment of this Act.