

## FY27 Budget and Past: FDA Legislative Proposals

Drawing on prior FDA budget submissions, the following tables track FDA's legislative proposals from FY21 (the final budget request of the first Trump administration), FY24 and FY25 (years three and four of the Biden administration, respectively), FY26 (the first year of the second Trump administration), and now [the current proposed budget](#). This table focuses on the proposals most likely to be relevant to regulated industry, and does not include every proposal from each budget.

"Y" means that this policy was included in that budget proposal. "N" means that the policy was not included.

### Faster Review Times and Expediting/Incentivizing Development

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<p><b>Create a new clinical trial notification pathway to serve as an alternative to the burdensome existing investigational new drug pathway to accelerate drug development timeline to Make America Healthy Again.</b></p> <ul style="list-style-type: none"> <li>• Create an optional, risk-based Expedited IND pathway for certain Phase 1 clinical trials.</li> </ul>	Y	N	N	N	N
<p><b>Create an additional abbreviated licensure pathway for biological products.</b></p> <ul style="list-style-type: none"> <li>• Create an abbreviated licensure pathway for biological products similar to the pathway for follow-on drug products in section 505(b)(2) of the FD&amp;C Act.</li> </ul>	Y	N	N	N	N
<p><b>Permanently authorize the rare pediatric disease priority review voucher program and related user fees.</b></p>	Y	N	N	N	N

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<ul style="list-style-type: none"> <li>Permanently reauthorize the Rare Pediatric Disease Priority Review Voucher (PRV) program.</li> </ul>					

### Transparency and Review Process

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<p><b>Allow disclosure of certain information in complete response letters.</b></p> <ul style="list-style-type: none"> <li>Provide explicit authority to disclose certain information related to FDA's issuance of CRLs.</li> </ul>	Y	N	N	N	N
<p><b>Increase agency flexibility regarding the convening of advisory committees and the composition of such committees.</b></p> <ul style="list-style-type: none"> <li>Increase flexibility to appoint representatives of consumer interests and the drug manufacturing industry to Scientific Advisory Panels only where appropriate, rather than as a requirement.</li> </ul>	Y	N	N	N	N
<p><b>Align the FD&amp;C Act with longstanding timelines and procedures governing application reviews and streamline appeals when an application is not approvable.</b></p>	Y	N	N	N	N

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<ul style="list-style-type: none"> <li>Remove the 180-day timeframe to either approve an application or give the applicant notice of an opportunity for a hearing on whether the application is approvable.</li> </ul>					

### Biosimilars and Generics

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<p><b>Clarify when patent information must be submitted for a 30-month stay to be available.</b></p> <ul style="list-style-type: none"> <li>Clarify that a 30-month stay of approval of an ANDA, 505(b)(2) NDA, or ANADA is available only in connection with patents that are submitted by the holder of the brand drug application before the ANDA, 505(b)(2) NDA, or ANADA is submitted.</li> </ul>	Y	N	N	N	N
<p><b>Allow companies manufacturing generic medications domestically to file Paragraph IV certifications earlier, giving exclusivity rights to US manufacturers.</b></p> <ul style="list-style-type: none"> <li>Allow companies based in the US that currently manufacture a generic drug in the US or are making investments in new domestic manufacturing facilities to substantially increase manufacturing capacity of a generic drug in the US.</li> </ul>	Y	N	N	N	N

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<p><b>Eliminate the statutory distinction between the approval standard for biosimilar and interchangeable biosimilar products.</b></p> <ul style="list-style-type: none"> <li>Remove the separate statutory standard for interchangeability to streamline biosimilar approvals and promote competition.</li> </ul>	Y	Y	Y	N	N
<p><b>Explicitly address generic drug-device combination products.</b></p> <ul style="list-style-type: none"> <li>Clarify FDA's authority and approval requirements for generic drug-device combination products to ensure generics can rely on appropriate regulatory pathways even when reference products include device constituent parts.</li> </ul>	Y	N	Y	Y	N
<p><b>Amend three-year new clinical investigation exclusivity.</b></p> <ul style="list-style-type: none"> <li>Amend three-year exclusivity to where the applicant seeks such exclusivity and where the data supporting the exclusivity demonstrates the hypothesized effect of the drug, and to prevent information on new safety risks from blocking competition.</li> </ul>	N	N	Y	N	N
<p><b>Create a safe harbor for "skinny labeling."</b></p> <ul style="list-style-type: none"> <li>Establish a statutory safe harbor clarifying that generic applicants may omit protected indications or patented</li> </ul>	N	N	Y	Y	N

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conditions of use from their labeling (i.e., "skinny labeling") without incurring liability.					
<b>Amend the 180-day forfeiture provision addressing failure to market.</b> <ul style="list-style-type: none"> <li>Revise the statutory forfeiture framework for 180-day generic exclusivity to prevent first applicants from delaying commercial marketing in ways that block subsequent generics from entering the market.</li> </ul>	N	N	Y	Y	N
<b>Require full ingredient disclosure for drugs to promote generic competition.</b> <ul style="list-style-type: none"> <li>Require brand drug manufacturers to provide FDA with complete qualitative and quantitative formulation information, including inactive ingredients and other necessary details, to facilitate efficient review of ANDAs and reduce barriers to generic entry.</li> </ul>	N/A (became law)	N	Y	Y	N

### Postmarket Medical Product Authorities

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<b>Holding firms accountable for using misleading advertising to drive profits at the expense of consumers.</b>	Y	N	N	N	N

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<ul style="list-style-type: none"> <li>Deem a drug misbranded as a DTC drug in advertisement creates a misleading impression regarding FDA approval, including by making or suggesting overstated representations that are not supported.</li> </ul>					
<b>Postapproval quality updates.</b> <ul style="list-style-type: none"> <li>Grant FDA express authority to require drug applicants to submit a postapproval quality update to provide additional information on ongoing quality.</li> </ul>	Y	N	N	N	Y
<b>Modernizing the requirements in BPCA and PREA for agency review of pediatric postmarket safety reporting.</b> <ul style="list-style-type: none"> <li>Remove the time-based requirement for postmarket safety reviews, allowing FDA to dedicate resources to real-time, risk-based surveillance activities.</li> </ul>	Y	N	N	N	N
<b>Mutual recognition authority for bioresearch monitoring inspection.</b> <ul style="list-style-type: none"> <li>Give FDA authority to recognize GCP or GLP inspection reports from foreign regulatory counterparts that the agency finds capable of conducting such inspections.</li> </ul>	Y	N	N	N	N
<b>Give FDA significant enforcement authorities, including civil monetary penalties and the authority to pull products off the market if active pharmaceutical ingredient source data is not reported.</b>	Y	N	N	N	N

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<ul style="list-style-type: none"> <li>Impose civil monetary penalties on finished dosage form manufacturers who fail to disclose how much API is used from each API manufacturer.</li> </ul>					
<p><b>Clarify FDA's enforcement authority regarding manufacturing changes to approved drugs and biological products.</b></p> <ul style="list-style-type: none"> <li>Clarify FDA's ability to enforce requirements related to manufacturing changes for drugs and biologics.</li> </ul>	Y	N	N	N	N
<p><b>Require retention of data and records supporting marketed medical products and marketed medical product applications and act upon submissions containing fraudulent or unreliable data.</b></p> <ul style="list-style-type: none"> <li>Require sponsors and manufacturers to retain underlying data supporting both application and non-application medical products for the lifetime of the product and explicitly strengthen FDA's authority to suspend, withdraw, or otherwise act upon applications supported by fraudulent or unreliable data.</li> </ul>	Y	Y	Y	Y	N
<p><b>Expand FDA's ability to disclose and use certain information related to impurities in drugs that pose a risk to the public health.</b></p> <ul style="list-style-type: none"> <li>Broaden FDA's authority to disclose and internally use information related to drug impurities that may present</li> </ul>	Y	N	Y	N	N

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public health risks, including sharing with other stakeholders when necessary to mitigate harm.					
<p><b>Require destruction of imported products that pose a significant public health risk.</b></p> <ul style="list-style-type: none"> <li>Authorize FDA to require destruction, rather than re-export, of certain imported products that present significant public health risks, improving border enforcement efficiency.</li> </ul>	Y	Y	Y	Y	N
<p><b>Require site master files for drug manufacturing facilities.</b></p> <ul style="list-style-type: none"> <li>Require drug manufacturing establishments to submit standardized site master files describing facilities, operations, and quality systems to enhance FDA's inspectional planning and oversight capabilities.</li> </ul>	N	N	Y	Y	N
<p><b>Expansion of FDA tools to provide oversight of FDA-regulated products.</b></p> <ul style="list-style-type: none"> <li>Provide FDA with additional administrative and enforcement authorities to address noncompliance across regulated product categories, strengthening its ability to protect public health.</li> </ul>	N	N	Y	Y	N
<p><b>Expanding information disclosure authorities with states.</b></p>	N	N	Y	Y	N

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<ul style="list-style-type: none"> <li>Expand FDA's ability to share certain nonpublic information with state officials to support coordinated enforcement, oversight, and public health responses.</li> </ul>					
<p><b>Evaluation of non-application drug manufacturers before marketing.</b></p> <ul style="list-style-type: none"> <li>Require certain manufacturers that are not subject to premarket application requirements (e.g., certain over-the-counter or compounded products) to undergo evaluation prior to marketing to ensure compliance with applicable standards.</li> </ul>	N	N	Y	Y	N
<p><b>Streamlining the collection process for FSMA reinspection and recall fees.</b></p> <ul style="list-style-type: none"> <li>Improve FDA's authority and mechanisms to assess and collect Food Safety Modernization Act (FSMA) reinspection and recall fees from responsible parties.</li> </ul>	N	N	Y	N	N
<p><b>Require public health data reporting authority to utilize postmarket health information.</b></p> <ul style="list-style-type: none"> <li>Require specified entities to provide postmarket health data to FDA to enhance real-world safety surveillance and inform regulatory decision-making.</li> </ul>	N	N	Y	N	N

## Drug Shortages and Preparedness

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<p><b>Enhanced drug manufacturing amount reporting information.</b></p> <ul style="list-style-type: none"> <li>Require manufacturers to submit more detailed production volume and capacity information, including related to reliance on specific suppliers, to improve FDA's ability to anticipate and mitigate shortages.</li> </ul>	Y (similar to a proposal noted above)	Y	Y	Y	N
<p><b>Lengthen expiration dates to mitigate critical drug shortages.</b></p> <ul style="list-style-type: none"> <li>Clarify FDA's authority to extend expiration dates of certain drugs, when supported by appropriate scientific data, to help alleviate critical shortages.</li> </ul>	N	N	Y	Y	Y
<p><b>Expand FDA's mandatory recall authority to cover all human and animal drugs.</b></p> <ul style="list-style-type: none"> <li>Extend FDA's mandatory recall authority to all human and animal drugs, enabling the agency to require recalls when voluntary action is not sufficient to protect public health.</li> </ul>	N	N	Y	Y	N
<p><b>Require drug manufacturers to notify FDA of an increase in demand.</b></p> <ul style="list-style-type: none"> <li>Require manufacturers to notify FDA of significant increases in demand that could impact supply and contribute to shortages.</li> </ul>	N	N	Y	Y	N

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<p><b>Require labeling to include the original manufacturer and supply chain information.</b></p> <ul style="list-style-type: none"> <li>Require certain drugs to identify the original manufacturer and relevant supply chain information on labeling to enhance transparency and traceability.</li> </ul>	N	Y	Y	Y	N

### Medical Devices

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<p><b>Remove the temporal limitation on FDA's medical device shortages authorities and require manufacturers to maintain and share risk management plans.</b></p> <ul style="list-style-type: none"> <li>Make permanent FDA's medical device shortage authorities and require manufacturers to develop, maintain, and share risk management plans to better prevent and mitigate supply disruptions.</li> </ul>	N	N	Y	Y	Y
<p><b>Disrupt the flow of problematic imported medical devices.</b></p> <ul style="list-style-type: none"> <li>Provide additional authorities that would give FDA greater assurances that foreign firms are manufacturing devices intended for import into the United States in compliance with quality systems requirements.</li> </ul>	Y	Y	N	N	N

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<p><b>Establishing a regulatory framework for digital health medical devices.</b></p> <ul style="list-style-type: none"> <li>Establish a framework that would allow FDA to tailor and apply the appropriate requirements for the reasonable assurance of safety and effectiveness for a software as a medical device product.</li> </ul>	N	N	N	N	Y

**Food and Dietary Supplements**

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<p><b>Strengthen oversight of critical foods and other foods to better protect infants and children.</b></p> <ul style="list-style-type: none"> <li>For infant formula, require industry to report all positive results for certain pathogen testing and expand environmental monitoring requirements.</li> <li>Establish authority for FDA to establish binding limits for contaminants in food, require final testing of products for contaminants, and address mandatory recall authority for foods with contaminants above established levels.</li> </ul>	Y	N	Y	Y	N
<p><b>Ensure FDA access to industry data to strengthen food chemical safety.</b></p>	Y	N	N	N	N

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<ul style="list-style-type: none"> <li>Require industry to provide certain postmarket data, or conduct certain postmarket evaluations, of chemicals added to food.</li> </ul>					
<b>Collect foreign food facility registration fees.</b> <ul style="list-style-type: none"> <li>Establish a biennial registration fee for all foreign human and animal food facilities.</li> </ul>	Y	N	N	N	N
<b>Share food safety information with state, local, tribal, and territorial authorities.</b> <ul style="list-style-type: none"> <li>Authorize FDA to share certain food-related information with state, local, tribal, and US territorial authorities.</li> </ul>	Y	N	N	N	N
<b>Prevent food shortages, including critical foods.</b> <ul style="list-style-type: none"> <li>Strengthen FDA's authorities to identify, prevent, and respond to shortages of critical foods, including enhanced reporting and supply chain visibility tools.</li> </ul>	N	N	Y	Y	N
<b>Modernize the Dietary Supplement Health and Education Act (DSHEA).</b> <ul style="list-style-type: none"> <li>Update the dietary supplement regulatory framework to enhance transparency, strengthen FDA oversight authorities, and improve tools to address unsafe or unlawful products in the marketplace.</li> </ul>	N	N	Y	Y	Y

## Animal Drugs

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<p><b>Enhance availability of generic animal drugs.</b></p> <ul style="list-style-type: none"> <li>• Create an exception in labeling requirements for generic animal drugs from the requirement that a generic animal drug's labeling be the same as the labeling of a reference-listed new animal drug (RLNAD) where the RLNAD is approved in more than one "major species."</li> </ul>	N	N	Y	Y	Y
<p><b>Provide a structured and tiered risk-based framework for biologic products for animals subject to FDA regulation.</b></p> <ul style="list-style-type: none"> <li>• Establish a clearer, risk-based regulatory framework for certain animal biologics under FDA jurisdiction to improve predictability and efficiency, including a path to market for lower-risk products.</li> </ul>	N	N	Y	Y	N
<p><b>Regulate certain articles as zootechnical animal food substances.</b></p> <ul style="list-style-type: none"> <li>• Clarify FDA's authority to regulate certain zootechnical substances intended for use in animal food to ensure appropriate safety and oversight.</li> </ul>	N	N	Y	N	N
<p><b>Enhance postmarket safety of animal drugs.</b></p> <ul style="list-style-type: none"> <li>• Strengthen FDA's postmarket surveillance and enforcement authorities for animal drugs to better identify and address safety concerns.</li> </ul>	N	N	Y	Y	N

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<p><b>Prevent animal drug diversion and misuse.</b></p> <ul style="list-style-type: none"> <li>Enhance FDA's tools to prevent diversion and inappropriate use of approved animal drugs.</li> </ul>	N	N	Y	N	N
<p><b>Change in agency regulatory oversight responsibility for certain new animal drug products.</b></p> <ul style="list-style-type: none"> <li>Clarify or adjust regulatory oversight responsibility for certain products between FDA and the Environmental Protection Agency.</li> </ul>	N	N	Y	Y	Y

## Tobacco

<b>Legislative Proposals</b>	<b>FY27 Budget (Trump II-2)</b>	<b>FY26 Budget (Trump II-1)</b>	<b>FY25 Budget (Biden-4)_</b>	<b>FY24 Budget (Biden-3)</b>	<b>FY21 Budget (Trump I-4)</b>
<p><b>Strengthen enforcement against importation of unauthorized ENDS and other illegal tobacco products.</b></p> <ul style="list-style-type: none"> <li>Amend the statute to strengthen requirements related to importation, change the inspection approach for domestic establishments from biennial to risk-based, and narrow judicial review on decisions related to applications.</li> </ul>	Y	N	N	N	N
<p><b>Create parity between nicotine and nicotine analog in statute.</b></p>	Y	N	N		

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<ul style="list-style-type: none"> <li>Amend the definition of "tobacco product" to include nicotine analogs, and thus establish FDA jurisdiction over such products.</li> </ul>					
<p><b>Modernize the tobacco user fees framework to apply to all regulated tobacco products.</b></p> <ul style="list-style-type: none"> <li>Authorize FDA to assess and collect user fees from each manufacturer and importer of any products subject to Chapter 9 of the FD&amp;C Act; increase the current limitation on total tobacco user fee collections by \$114 million; and index all future collections to inflation.</li> </ul>	N	N	Y	Y	Y
<p><b>Request improved hiring authority for FDA's Center for Tobacco Products.</b></p> <ul style="list-style-type: none"> <li>Extend the agile hiring authorities and salary flexibility of the 21st Century Cures Act for CTP to improve its ability to recruit, hire, and retain personnel.</li> </ul>	N	N	Y	N	N