

FDA FY 2027 Budget Proposes Broad New Authorities and Reforms Across Food, Drugs and Medical Devices

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The Food and Drug Administration (FDA)'s FY 2027 budget proposal, which is the first fully developed under Commissioner Marty Makary's tenure, includes a wide-ranging collection of legislative proposals that aim to expand the agency's authorities across nearly every major product area it regulates, including drugs, biologics, food and medical devices. While most of the budget requests funding to carry out programs within FDA's existing mandate, these proposals are requests for Congress to legislatively alter existing programs or create new authority in statute. In this alert, we provide a high-level overview of the new authorities FDA is seeking from Congress.

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Increased Enforcement Authorities Related to Advertising, Transparency, Records Retention and Drug Quality

- **Direct-to-Consumer Advertising.** FDA is seeking explicit authority to deem a drug misbranded if a direct-to-consumer (DTC) ad “lacks fair balance” or misleads an audience regarding a drug’s FDA approval, its approved indications, limitations of use, or the drug’s efficacy and benefits. These authorities would also apply to compounded drugs and would require advertisements for compounded drugs to prominently disclose that the FDA has not approved or evaluated these products for safety, effectiveness or quality. While FDA has sent numerous warning letters to pharmaceutical manufacturers and compounding pharmacies, the agency argues in its budget that these additional authorities would allow FDA to “more effectively” address advertising that it says lacks “fair balance.”
- **Complete Response Letter Disclosure.** While FDA has publicly released hundreds of complete response letters (CRLs) in recent months, including CRLs detailing why drug applications have not been approved, many letters are redacted, as the law prohibits FDA from releasing commercial confidential information (CCI) and trade secret information (TSI). This proposal would provide explicit authority for FDA to disclose certain information, and while the budget doesn’t detail exactly what

information FDA would like to release, it is possible the agency is seeking to release information that is currently considered CCI or TSI.

- **Addressing Fraudulent Data.** Arguing that the agency is “increasingly identifying instances of fraudulent or unreliable data” in drug and medical device applications, and in inspections for over-the-counter drugs and other medical products, often from firms based in China, FDA’s budget is proposing new or clarified authorities to act on these findings. However, the budget document does not provide clear details on what these new or clarified authorities would entail or explain why existing enforcement authorities are insufficient.
- **Disclosure of Information Related to Drug Impurities.** FDA is seeking new and clarified authorities to publicly disclose information from submissions to FDA related to impurities in drugs and share safety-related information with international regulators.
- **Postapproval Quality Updates.** This proposal would grant FDA authority to require drug sponsors to submit additional information on ongoing quality after the drug is approved. This is intended to supplement risk-based surveillance inspections, giving FDA greater insight into potential quality issues in products without conducting a postmarket inspection.
- **Civil Monetary Penalties for Failing to Report Ingredient Sources.** Current law requires drug applicants to disclose information about (active pharmaceutical ingredients) API, including the facilities where API is manufactured. However, there is a disconnect in what is known about how much API is used, and from what manufacturers, in final dosage forms, which limits FDA’s visibility into the supply chain, which may make it more difficult to anticipate drug shortages. FDA is now proposing to allow the agency to impose civil monetary penalties on finished dosage form manufacturers who fail to disclose how much API is used from each API manufacturer approved in the application.

Early-stage Development, Market Competition and Hatch-Waxman Reforms

- **New Alternative to Investigational New Drug Pathway.** Commissioner Makary has frequently discussed his concern with seeing early-stage drug development moving to China, where regulatory burdens and costs are lower. To reduce these burdens and compete with China, FDA is now proposing an alternative to the traditional investigational new drug (IND) pathway, which would exist alongside the existing IND pathway. The budget explains that this expedited IND would allow faster access to phase I clinical trials where existing data can satisfy the regulatory standard with validated new approach methodologies (NAMs), which are alternatives to animal testing. FDA recently released draft guidance on the validation of NAMs, and while relatively few NAMs have been validated to date, the current administration has made the expanded use of NAMs a priority.
- **Head Start for Domestic Generic Drug Manufacturers.** In what appears to be another effort to expand domestic drug manufacturing and development, FDA is

proposing to modify Hatch-Waxman filing rules to give certain U.S. generic drug manufacturers a head start in filing abbreviated new drug applications (ANDAs) with Paragraph IV patent challenges, offering them a better shot at getting coveted 180-day generic exclusivity. Under current law, generic manufacturers are all generally allowed to file on the same day, and first filers may be entitled to 180-day exclusivity for their generic drug. This proposal would allow domestic generic drug manufacturers that produce a drug in the U.S. or are making significant investments to expand U.S. manufacturing capacity to file one month earlier than other manufacturers.

- **Changes to the Hatch-Waxman 30-Month Stay.** This proposal would clarify that an automatic 30-month stay of FDA approval is available only for patents that are listed in the Orange Book (or Green Book, in the case of generic animal drugs) before a generic or 505(b)(2) application is filed. FDA's budget proposal notes that current law is ambiguous about whether patents listed after a generic application is submitted can still trigger a 30-month stay, particularly when patent information was provided to FDA as part of the brand application but not formally listed until later. FDA's proposal would establish a bright-line rule that would require generic drug and 505(b)(2) applicants to address late-listed patents, but they cannot delay approval through an automatic stay.
- **Biosimilar Interchangeability.** As it has done for several years, FDA is proposing to deem all biosimilars interchangeable with reference products, which would allow substitution by pharmacists. The proposal would also codify FDA's draft guidance which says the agency generally will not require comparative efficacy studies for biosimilar applications and would concentrate all biosimilar reviews in a single division.
- **Abbreviated Licensure Pathway for Some Biologics.** FDA is proposing a new approval pathway for biologics under which a sponsor of a new biological product may be able to rely on prior FDA determinations of safety, purity and potency. This pathway, which would be conceptually similar to the 505(b)(2) pathway for small molecule drugs, would simplify the biologic approval process, in an effort to spur additional competition and innovation.
- **Clarity in Regulation of Generic Drug-Device Combination Products.** Current law does not explicitly address how FDA should evaluate generic drug applications for drug-device combination products and generic drugs that are used with a device, such as autoinjectors and inhalers. FDA says this can make it difficult for companies to develop generic versions of these products and delay market entry. FDA is proposing changes to the law that would allow the agency to explicitly request and review specific information about the products. Additionally, FDA would allow for certain differences between device constituent parts of the generic and branded versions, with corresponding differences in the labels of the products.
- **Modernizing Pediatric Adverse Event Report Reporting.** Under current law, the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) require FDA to refer all adverse event reports to the FDA's Office of Pediatric Therapeutics and for those reports to be reviewed by the Pediatric Advisory Committee 18 months after a pediatric-related labeling change, regardless of when

those adverse events actually occurred within that 18-month period. FDA argues this process is out of date, duplicative and resource-intensive, as FDA has ongoing adverse event reporting and postmarket safety surveillance systems in place, and safety signals are often identified much earlier than 18 months after a labeling change, if they are made at all. FDA is proposing to reduce agency burden by removing this requirement from the law.

- **Permanent Reauthorization of the Rare Pediatric Disease Priority Review Voucher.** FDA is asking Congress to permanently reauthorize the rare pediatric disease priority review voucher (PRV), which awards a transferrable voucher to qualifying sponsors of drugs indicated for pediatric rare diseases that shorten review timelines from 10 months to six months. Congress recently reauthorized this program through Sept. 30, 2029, in the Consolidated Appropriations Act.

Manufacturing, Supply Chain, Inspections and Importation Reforms

- **Increased Administrative Destruction Authority.** Under current law, if FDA refuses the import of a shipment, importers generally may export the product, even if FDA believes the shipment contains adulterated, misbranded or counterfeit food, drugs and devices. According to FDA, this can lead to importers attempting to re-import these products at different ports of entry. FDA has some authority to administratively destroy small shipments of illicit drugs and devices valued at \$2,500 or less. This proposal would expand that authority significantly, allowing FDA to destroy refused products—including foods, cosmetics and other FDA-regulated products—if the products present “a serious public health concern.”
- **Expand Mutual Recognition Agreement (MRA) Authority to Bioresearch Monitoring Inspections.** Under current law, FDA may enter into agreements with foreign governments to recognize the foreign government’s inspection of a drug manufacturing establishment, reducing duplicative inspections and saving FDA resources. FDA is proposing to expand this authority to allow for mutual recognition of inspection reports under the bioresearch monitoring (BIMO) program, which regulates biomedical research, including clinical trials.
- **Medical Device Importation Restrictions.** In recent years, FDA has observed quality concerns on some medical devices imported from China and other countries that they claim put patients and health care providers at risk of harm. Notably, in 2023 and 2024, FDA issued safety communications recommending that U.S. suppliers, consumers and health care organizations transition away from using plastic syringes manufactured in China, noting widespread distribution of devices that had not been cleared or approved by FDA, with leaks, breakage and other issues. FDA is now seeking additional authorities to require foreign firms to provide assurances that devices are compliant with U.S. quality system requirements.
- **Manufacturing Changes.** FDA is proposing statutory changes to clarify its authority to enforce requirements to notify FDA of manufacturing changes before they happen, such as a change in manufacturing processes and sites, a change to API suppliers, and other manufacturing changes that have substantial potential to affect safety and efficacy of a drug. While federal regulations have established a notification

framework, some have argued FDA's authority to enforce the regulations is ambiguous. FDA is seeking clearer enforcement authorities.

Expanded Food and Tobacco Authorities

- **Infant Formula and Critical Foods Oversight.** Expanding on its current regulatory authority over infant formula and other food, FDA is proposing to require infant formula manufacturers to conduct environmental monitoring in their facilities, retain all records and report all positive tests for contaminants to FDA. This proposal also includes a provision that would expressly allow FDA to set binding limits for contaminants in foods, with mandatory recall authority for foods that go above those levels. This proposal may have some bipartisan appeal, as FDA previously included it in the FY 2025 budget, proposed during the Biden administration, and Rep. Emilia Sykes (D-OH) has previously introduced H.R. 2472, which would enact several of these provisions.
- **Food Chemical Post-Market Oversight.** FDA is proposing new requirements for food additive and color additive manufacturers to provide post-market data to FDA and conduct post-market safety evaluations and reassessments of chemicals added to food and submit data to FDA. While light on details, this proposal would appear to strengthen FDA's hand in regulating food and color additives that are already on the market.
- **Require New Food Facility Registration Fees.** Under current law, FDA does not collect registration fees from food facilities. While the agency inspects food facilities, it must do so using funding appropriated from the federal government. Citing the burden to resources and its efforts to "Make America Healthy Again," FDA is asking Congress for new authority to collect registration fees from foreign food facilities to supplement its human and animal food program.
- **New Powers to Share Confidential Food Safety Information with State, Local, Tribal and Territorial Authorities.** FDA is seeking clear authority to share real-time information on foodborne illness surveillance data, laboratory sampling, food inspection information, consumer complaints and other information with state, local, tribal and territorial public health authorities while prohibiting the public disclosure by these authorities of trade secrets (TS) or confidential commercial information (CCI). When there are outbreaks of foodborne illness or other concerns with food safety, it often behooves FDA to share information with state and local public health authorities, who are in a position to help monitor and mitigate health challenges. However, due to state public disclosure or "sunshine" laws, there are often concerns that TS or CCI may be improperly disclosed as a result of these communications, which may lead to hesitation by FDA to share information, or a reluctance of state and local partners to receive information, if sunshine laws would require public disclosure of TS or CCI. This proposal would allow FDA to communicate information without concern that TS or CCI would be made public.
- **Tobacco Registration and Inspections.** FDA's budget includes a proposal to expand its oversight of tobacco products, citing challenges in its efforts to prevent the importation of unauthorized e-cigarettes. This proposal would require annual

registration and product listing for importers and wholesale distributors of tobacco products; shift inspections to a risk-based inspection schedule; consider making a false statement about the import of a tobacco product as a prohibited act; and only allow adversely affected applicants to bring litigation challenging FDA tobacco product decisions.

- **Definition of “Nicotine Analogue.”** FDA is proposing a new definition of “nicotine analogue,” which it says are synthetically manufactured substances chemically similar to nicotine, but which fall outside the definition of tobacco products. FDA would propose to regulate these products under the existing organizational structure for tobacco regulation.

Updated FDA Processes and Management

- **Aligning Application Review and Appeals Timelines and Procedures.** The Federal Food, Drug, and Cosmetic Act includes references to drug review timelines that do not reflect how the agency has operated for decades. For example, the statute says FDA must, within 180 days, approve a drug application or issue a notice of opportunity for a hearing if the application is not approvable. For years, FDA has used user-fee-driven review timelines negotiated between FDA and industry and authorized by Congress. Additionally, instead of hearing opportunities when a drug is not approvable, FDA issues complete response letters (CRLs) detailing why a drug cannot be approved and allowing drug applications to be resubmitted. FDA would like Congress to update the statute to reflect these practices. Additionally, FDA is proposing to update hearing procedures to mimic the expedited withdrawal appeal procedures Congress allows for accelerated approval drugs, specifically a written appeal process with the opportunity for a meeting with the commissioner or a designee.
- **Advisory Committee Flexibility and Composition.** Current law requires the FDA commissioner to appoint representatives of consumer interests and the drug manufacturing industry to many scientific advisory panels. FDA is now proposing to allow the commissioner to only appoint these representatives to advisory committees where he deems it appropriate. Additionally, FDA is seeking the authority to alter advisory committee charters to adjust the types and frequency of advisory committee meetings.
- **Medical Assistance and Evacuation Insurance for FDA Employees.** Current HHS authorities do not allow FDA to provide medical assistance and evacuation insurance for FDA employees on official government travel. Given the global nature of FDA’s work—personnel are often working all over the world conducting foreign inspections and other business—FDA is seeking the authority to purchase this insurance for its employees on official travel.

Next Steps

With FDA user fee reauthorization on the horizon, we expect some of these policies may be considered for inclusion in a legislative package. Brownstein will monitor developments and is prepared to assist stakeholders with legislative and regulatory policy strategies.

THIS DOCUMENT IS INTENDED TO PROVIDE YOU WITH GENERAL INFORMATION REGARDING ADJUSTED THE WHITE HOUSES FY 2027 FDA BUDGET REQUEST. THE CONTENTS OF THIS DOCUMENT ARE NOT INTENDED TO PROVIDE SPECIFIC LEGAL ADVICE. IF YOU HAVE ANY QUESTIONS ABOUT THE CONTENTS OF THIS DOCUMENT OR IF YOU NEED LEGAL ADVICE AS TO AN ISSUE, PLEASE CONTACT THE ATTORNEYS LISTED OR YOUR REGULAR BROWNSTEIN HYATT FARBER SCHRECK, LLP ATTORNEY. THIS COMMUNICATION MAY BE CONSIDERED ADVERTISING IN SOME JURISDICTIONS.