Volume 4, Number 3 May–June 2026

THE JOURNAL OF FEDERAL AGENCY ACTION

fastcase FULL COURT PRESS

The Journal of Federal Agency Action

Volume 4, No. 3 | May–June 2026

THE JOURNAL OF FEDERAL AGENCY ACTION (ISSN 2834-8818 (online)) at $495.00 annually is published six times per year by Full Court Press, a Fastcase, Inc., imprint.

For customer support, please contact Fastcase, Inc., 729 15th Street, NW, Suite 500, Washington, D.C. 20005, 202.999.4777 (phone), or email customer service at support@fastcase.com.

Publishing Staff
Publisher: David Nayer
Production Editor: Sharon D. Ray
Cover Art Design: Morgan Morrissette Wright and Sharon D. Ray

This journal's cover includes a photo of Washington D.C.'s Metro Center underground station. The Metro's distinctive coffered and vaulted ceilings were designed by Harry Weese in 1969. They are one of the United States' most iconic examples of the brutalist design style often associated with federal administrative buildings. The photographer is by XH_S on Unsplash, used with permission.

Cite this publication as:

The Journal of Federal Agency Action (Fastcase)

Editorial Office

729 15th Street, NW, Suite 500, Washington, D.C. 20005
https://www.fastcase.com/

POSTMASTER: Send address changes to THE JOURNAL OF FEDERAL AGENCY ACTION, 729 15th Street, NW, Suite 500, Washington, D.C. 20005.

Articles and Submissions

Direct editorial inquiries and send material for publication to:

Steven A. Meyerowitz, Editor-in-Chief, Meyerowitz Communications Inc., 26910 Grand Central Parkway, #18R, Floral Park, NY 11005, smeyerowitz@meyerowitzcommunications.com, 631.291.5541.

Material for publication is welcomed—articles, decisions, or other items of interest to attorneys and law firms, in-house counsel, corporate compliance officers, government agencies and their counsel, senior business executives, and anyone interested in federal agency actions.

QUESTIONS ABOUT THIS PUBLICATION?

For questions about the Editorial Content appearing in these volumes or reprint permission, please contact:

David Nayer, Publisher, Full Court Press at david.nayer@clio.com or at 202.999.4777

For questions or Sales and Customer Service:

Customer Service
Available 8 a.m.–8 p.m. Eastern Time
866.773.2782 (phone)
support@fastcase.com (email)

Sales
202.999.4777 (phone)
sales@fastcase.com (email)

ISSN 2834-8796 (print)
ISSN 2834-8818 (online)

Food and Drug Administration: The Major Items to Watch

Jordan K. Brossi, Michael J. Werner, Sara M. Klock, Rachel Gartner, and Parker M. Reynolds*

In this article, the authors explain that the Food and Drug Administration (FDA) has undergone extensive modifications as one component of President Donald Trump's efforts to reshape federal healthcare agencies. The authors provide an overview of the major items that the FDA is expected to focus on now and in the near future.

Under the leadership of U.S. Food and Drug Administration (FDA) Commissioner Martin Makary, the FDA has undergone significant change in the first 14 months of President Donald Trump's second term. As part of the changes announced by the U.S. Department of Health and Human Services (HHS), the FDA has consistently made its own announcements regarding policy changes—especially regarding drug review processes and the implementation of "radical transparency"—as well as actions in support of HHS-wide efforts such as implementing the Make America Healthy Again (MAHA) agenda and pursuing a deregulatory agenda.

Reauthorization of User Fee Agreements

The FDA must now contend with many consequential policies, beginning with the reauthorization of various user fee agreements (UFAs). Several UFAs—including those for prescription drugs, biologics, medical devices, biosimilars, and generic drugs—expire on September 30, 2027, and must be extended by statute. The statute provides legal authority for FDA to collect user fees from product applicants. It typically also contains reforms to FDA review processes.

UFAs take more than a year's worth of discussions between the FDA, regulated industries, and U.S. Congress to finalize. In addition to direct negotiations between the FDA and industry to establish and agree on user fee amounts and the FDA's corresponding review

The Journal of Federal Agency Action / May–June 2026, Vol. 4, No. 3, pp. 189–196.

ISSN 2834-8818 (online).

performance goals, other stakeholders will have the opportunity to provide input and participate in public meetings, as well as the rulemaking and public comment process. Congress will engage in this effort through the rest of this year and into next as it examines FDA actions and considers legislation.

Congressional leaders have begun the informal process of gathering public input by coordinating with the FDA and outside stakeholders to inform the UFA process. The ultimate, negotiated agreement between the FDA and regulated industries will ultimately be incorporated into legislation to be considered by the committees of jurisdiction—the U.S. House of Representatives Committee on Energy and Commerce and U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP)—and the committees' support is critical to inform the final product. Without congressional authorization, the FDA is unable to collect user fees, making each separate UFA "must pass" legislation and a critical moving vehicle for potential changes to any of the impacted industries. Consequently, this legislation becomes an opportunity to legislate on virtually any issue within the FDA's jurisdiction.

There are myriad issues that are likely to be debated during reauthorization, including those related to the FDA's review and approval processes, manufacturing policies, product development incentives for rare diseases and disorders, and expedited approval programs. It is also likely that the UFAs or coincidental legislation addresses policies announced by the FDA in 2025 and 2026, such as the Commissioner's National Priority Voucher (CNPV) pilot program, the new "plausible mechanism" approval pathway for rare disease products, and potentially tying FDA reviews to drug pricing.

Over-the-Counter Monograph User Fee Act Implementation

The appropriations bill that was signed into law on November 12, 2025, to reopen the federal government following the government shutdown included a reauthorization of the Over-the-Counter Monograph Drug User Fee Program (OMUFA) through September 2030. Congressional oversight activities are expected over the next several years to track OMUFA implementation.

Also contained in the OMUFA reauthorization was a provision to reform the approval processes for sunscreen ingredients. Within

a year, the FDA is tasked with issuing new guidance regarding how sponsors of active ingredients may use nonclinical testing alternatives to animal testing to meet safety and efficacy standards.

The FDA has moved quickly to advance efforts on a particular sunscreen active ingredient, announcing on December 11, 2025, that it had proposed[1] a new administrative order to add bemotrizinol as a new active ingredient to the over-the-counter sunscreen monograph. This is the first newly proposed active ingredient for decades. Bemotrizinol has been widely used in Europe, Australia, and Asia for decades and was approved by Health Canada in 2023. If finalized, this would be the first new sunscreen approved in the United States in decades and could lead the way for other approvals.

Next Steps for Accomplishing MAHA Goals

Priorities of the MAHA movement infused many of the FDA's efforts in 2025, and those efforts continue. It is likely the FDA will issue a proposed rule to change the generally recognized as safe (GRAS) standard, with a proposed rule being transmitted to and remaining at the Office of Management and Budget at the time of writing. Stakeholders are expected to have the opportunity to provide input on the proposed changes, which are likely to be significant and wide-ranging. The proposed rule—if and when finalized—is likely to require significant change from regulated industries, potentially mandating the reformulation of food and drink products and removal of ingredients from products entirely.

The FDA is expected to advance the MAHA directive by proposing a uniform federal definition of ultraprocessed foods (UPFs). The proposed definition follows the FDA's 2025 request for information and interagency coordination with the U.S. Department of Agriculture (USDA). This definition will serve as the foundation for future regulatory actions, including front-of-pack labeling requirements and enhanced ingredient transparency. Next steps likely include a draft rulemaking phase with public comment, integration of UPF status into additive safety reviews, and alignment with reforms to the GRAS notification process to close existing loopholes.

The end of this year is the deadline by which many major food companies voluntarily agreed to eliminate six synthetic dyes for the food supply, setting up a potential showdown should the FDA

seek to take more drastic action against companies that do not meet the agreed-upon timeline for removal. The FDA is anticipated to lean heavily on its enforcement authority against those who do not comply, such as the issuance of warning letters and potentially heightened inspections efforts.

Commissioner's National Priority Voucher Program

The FDA in June 2025 launched the CNPV program, designed to accelerate the review of products that align with national priorities by meeting four criteria as outlined by the FDA. To date, the FDA has awarded 18 vouchers, with the first nine recipients[2] announced on October 16, 2025, six additional awardees[3] announced on November 6, 2025, and others subsequently since. The sixteenth voucher was awarded on November 15, 2025, to the sponsor of a combination oncology product following "promising" Phase 3 clinical trials. Three awardees have since received FDA approval. It is anticipated that FDA leaders will continue to award these vouchers and review awardee products for approval.

However, as the number of awardees grows, concerns from stakeholders are becoming more evident, raising the possibility of litigation. CNPV remains the only Priority Review Voucher program to not be established by statute. Without specific authorizing legislation, the program operates without precedent and without being grounded in a specific portion of federal law, adding to litigation concerns. In addition, there are growing concerns regarding whether the CNPV program—which is resource-intensive to implement—is pulling reviewers away from other product reviews, whether the program is negatively impacting Prescription Drug User Fee Act (PDUFA)–required review deadlines and whether the program is allowing political interference in the FDA's decision processes.

The CNPV has also received scrutiny from Congress, with House Committee on Energy and Commerce Ranking Member Frank Pallone (D-NJ) and Senate HELP Committee Ranking Member Bernie Sanders (I-VT) sending a letter[4] to the FDA requesting additional details on the program. Congressional inquiries are likely to continue, particularly beyond 2026, should the Democrats take

over the House or Senate, as well as if there are potential efforts to place guardrails on the program through the next appropriations process or during consideration of PDUFA.

Reducing Animal Testing

The FDA in 2025 made changes to phase out the use of animal models and expand the use of real-world evidence, instituting a shift toward new approach methodologies and away from a requirement for identifiable individual data in certain drug and device application submissions. Both are efforts to accelerate product approvals and speed their ability to get to market. These efforts are anticipated to continue and hew closely to the FDA's Roadmap to Reducing Animal Testing in Preclinical Safety Studies[5] that was published in April 2025. Stakeholders will continue to have opportunities to inform the guidance development process, with the FDA's guidance on real-world evidence recently being published in the Federal Register.

Adoption of Artificial Intelligence

The FDA has moved swiftly to integrate artificial intelligence (AI) capabilities into FDA employee workflows, as well as add new AI-powered tools to its list of approved devices and qualify the first AI drug development tool, using authorities from the 21st Century Cures Act.

With digital health and AI-powered devices likely to continue as priorities, expect to see significant action by the FDA and Congress this year. The FDA's Center for Radiological Devices and Health includes several draft and final guidance topics[6] related to digital health and AI for FY2026.

Cannabis

On December 18, 2025, President Trump signed an executive order (EO) aimed at speeding research into marijuana and cannabidiol (CBD),[7] with a major goal being to reclassify marijuana from

Schedule I—the most highly controlled substance—to Schedule III of the Controlled Substances Act.

The EO directs the U.S. Department of Justice to take all necessary steps to complete the rulemaking process to reschedule marijuana under Schedule III. In addition, the EO directs the development of guidance on an upper limit on milligrams to tetrahydrocannabinol (THC), with consideration to per-container limits and CBD-to-THC ratio requirements. The EO further calls on leaders of the HHS, FDA, Centers for Medicare & Medicaid Services and National Institutes of Health to develop research methods and models using real-world evidence to improve access to certain products.

Notably, this policy has opponents in Congress who recently enacted legislation that restricts access to certain foods and supplements with cannabinoids derived from hemp. It is likely that the next steps in the rulemaking process and the issuance of guidance will occur this year, with ample opportunity for public comment.

Cell and Gene Therapy

The FDA was publicly aggressive in its support for cell and gene therapy in 2025. FDA leaders announced numerous initiatives designed to facilitate speedy product review, including FDA Chief Medical and Scientific Officer Vinay Prasad's announcement[8] of a new "plausible mechanism" pathway for rare disease products and issuance of several guidance points. In addition, several gene therapies received vouchers from the CNPV program.

Stakeholders are advised to watch if these initiatives lead to more product approvals. The Office of Therapeutic Products, which reviews cell and gene therapies, saw staff disruption over the past year. With an ever-increasing number of investigational new drug applications filed and thousands of mid- and late-stage clinical trials advancing, the FDA's ability to manage these applications and provide appropriate product review will be tested.

Other initiatives to watch include FDA enforcement activities related to certain stem cell treatments and the number of platform technology and advanced manufacturing technology designations issued by the FDA, as well as sponsors' use of the Regenerative Medicine Advanced Therapy and accelerated approval pathways.

Domestic Manufacturing

Over the past several years, Congress has considered multiple new incentives to increase the number of drug products and their active pharmaceutical ingredients manufactured in the United States but has yet to pass comprehensive legislation to do so, and there remains no dedicated programs in existence to support domestic manufacturing. To fill the gap, the FDA has pursued several programs to accelerate permitting processing for new manufacturing facilities in the United States, as well as launch a precleared list of products for import to the United States.

Conclusion

Any and all of the issues discussed above will be considered by the FDA and likely be debated by Congress. Stakeholders are advised to watch events at the agency level and on Capitol Hill closely, particularly as the next appropriations processes begin and midterm elections draw closer—a time that is notorious for slowed congressional activity as focus turns to competitive reelection races. Absent congressional activity, the FDA is anticipated to continue moving full steam ahead using the full extent of its regulatory capabilities to advance the priorities of the Trump administration.

Notes

* The authors, associated with Holland & Knight LLP, may be contacted at jordan.brossi@hklaw.com, michael.werner@hklaw.com, sara.klock@hklaw.com, rachel.gartner@hklaw.com, and parker.reynolds@hklaw.com, respectively.

1. https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm?event=OrderDetail&orderid=OTC000039.

2. https://www.fda.gov/news-events/press-announcements/fda-awards-first-ever-national-priority-vouchers-nine-sponsors.

3. https://www.fda.gov/news-events/press-announcements/fda-awards-second-batch-national-priority-vouchers.

4. https://democrats-energycommerce.house.gov/sites/evo-subsites/democrats-energycommerce.house.gov/files/evo-media-document/11.20.25-final-letter-to-fda-on-cnpv.pdf.

5. https://www.fda.gov/files/newsroom/published/roadmap_to_reducing_animal_testing_in_preclinical_safety_studies.pdf.

6. https://www.fda.gov/media/188993/download?attachment.

7. https://www.whitehouse.gov/presidential-actions/2025/12/increasing-medical-marijuana-and-cannabidiol-research/.

8. https://www.nejm.org/doi/full/10.1056/NEJMsb2512695.