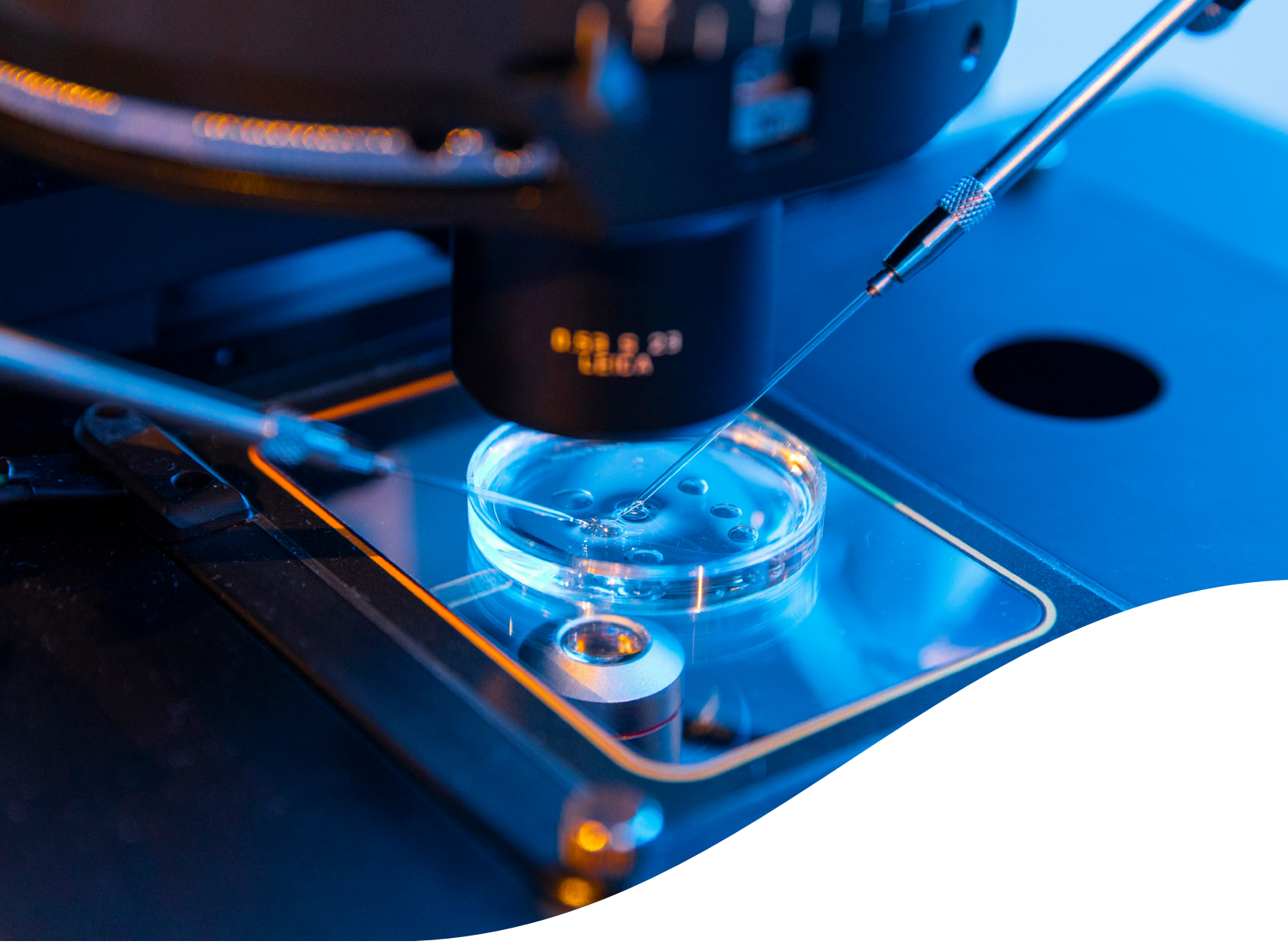

FDA in focus: 2025 in review and 2026 outlook

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Introduction

The United States Food and Drug Administration (FDA) has experienced unprecedented changes in leadership, policy, enforcement focus, and culture in 2025. These changes have contributed to meaningful shifts in established norms and practices within both the Agency and the industries it regulates. From the reduction in force (RIF) that reportedly reduced the Agency's full-time personnel by 20 percent to a heightened focus on revamping food regulation and policy, 2025 has been marked by regulatory uncertainty, shifting priorities, and change.

While FDA focused on pre-2025 priorities, such as addressing complexities in the global supply chain, artificial intelligence (AI), and innovation in product development, the Agency's approaches to these topics reflected shifts in prior interpretations and applications of law and policy. For example, where past efforts to secure the global supply chain focused on increasing FDA's presence and oversight of manufacturing and clinical activities outside of US and strengthening collaboration with foreign regulators, current initiatives focus on returning critical manufacturing and product development activities to the US.

FDA continued to encourage ethical AI practices for the development and use of AI-enabled medical products. It also piloted and deployed its own AI software, called Elsa, to support regulatory decision-making and other functions. Where prior FDA transparency initiatives focused on improving good guidance practices (GGPs) and increasing industry engagement with the Agency, current transparency policies focus on real-time public disclosure of Complete Response Letters (CRLs) reflecting non-approval decisions on drug applications.

The impact of these changes in driving regulatory efficiency and advancing the Agency's core public health mission remains to be seen and may define the legacy of the Agency and its current leadership for decades to come.

The Agency's Fiscal Year (FY) 2025 budget of $7.2 billion for total program funding remained unchanged from FY 2024. However, differences in the allocation of the budget from FY 2024 to FY 2025 provide insights regarding the Agency's 2025 priorities and potential areas of focus in 2026. A significant portion of the FY 2025 budget – about $146 million – was allocated to six areas:

- Food safety
- Employee compensation and related costs
- Modernization of cosmetics regulation
- Enterprise transformation, IT stabilization, and modernization
- Shortages and supply chain
- Foreign office expansion

Roughly $15 million in additional funds were specifically allocated to the human foods program, with comparatively less budget – about $5 million – allocated to medical products. This reflects a meaningful difference from the FY 2024 budget, which allocated roughly $98 million to medical product programs. While implementation of certain provisions of the Modernization of Cosmetics Regulation Act (MoCRA) was delayed in 2025, the FY 2025 budget allocated funds to the hiring of additional experts to manage elements of cosmetics safety assessments, including the use of per- and polyfluoroalkyl substances (PFAS) in cosmetics. If implemented, these financial measures could be reflected in increased cosmetic regulation and enforcement in 2026.

The FY 2026 budget provides $6.8 billion for total program funding – an overall decrease of about $271 million compared to FY 2025. Notably, the FY 2026 budget includes $234.6 million to support targeted Make America Healthy Again (MAHA) initiatives, as well as a net increase to the human foods program of more than $65.5 million compared to FY 2025. A significant portion of the 2026 food program budget is allocated to the regulation of additives, with the bulk of the budget focused on food safety. The overall FY 2026 budget also contemplates a total increase of $118.2 million for the medical device program to help ensure continuity and predictability of product review timelines and to sustain staffing levels.

On March 6, 2025, the Senate Health, Education, Labor, and Pensions Committee (HELP Committee) held a confirmation hearing on the nomination of Dr. Martin Makary to serve as FDA Commissioner. The confirmation of Dr. Makary was followed by an Agency-wide RIF in April 2025, which affected roughly 3,500 employees across all program areas. olicy and administrative personnel responsible for overseeing the creation and dissemination of Agency regulations, as well as those responsible for administering application review, were significantly affected.

The RIF resulted in delays in product reviews, with some companies experiencing significant changes in regulatory decisions on pending product applications midway through the product review process. Despite efforts to rehire critical personnel, by some counts, more than half of FDA's senior leadership had left the Agency by mid-year. As of December 2025, nearly 90 percent of the leaders of key offices, divisions, or programs (*e.g.*, Center directors and key program heads) that existed in 2024 have now departed. The level and pace of change within key leadership positions and programs have created uncertainty regarding the availability or effectiveness of established pathways for engagement, escalation of scientific disputes, and other discussions of key policy issues. The long-term impact of these staffing changes on promised efficiencies and safer products has yet to be determined.

While FDA increased efforts aimed at improving food safety, the Agency pursued deregulation in other areas. In May 2025, the Department of Health and Human Services (HHS) and FDA announced an initiative to identify and eliminate outdated regulations. Pursuant to the "10-to-1" deregulatory policy, for every new regulation proposed, at least ten existing regulatory actions will be rescinded. Citing efforts to reduce the cost of regulation and promoting a more "common sense" approach to regulation, the agencies issued a Request for Information (RFI) seeking ideas for regulations that should be rescinded. The 10-to-1 policy raises questions about how this proposed deregulatory initiative aligns with existing requirements under the Administrative Procedure Act (APA) and GGP, which are designed to ensure transparency and predictability when issuing new rules or guidance or rescinding existing ones.

In the spirit of deregulation, FDA and industry witnessed the dismantling of FDA's long-awaited and much-debated "Medical Device; Laboratory Developed Tests" (LDT) final rule. In September 2025, FDA rescinded the rule in response to a district court decision in American Clinical Laboratory Association v. FDA, which had vacated it. The LDT final rule created a regulatory framework of FDA premarket review and post-market oversight for laboratory tests, which were previously excluded from FDA regulation and subject to review primarily under the Clinical Laboratory Improvement Amendments (CLIA). The rule has been remanded to the Secretary of HHS for further consideration. With the implementation of 10-to-1 policy still on the table for 2026, significant questions remain regarding future of LDT regulation under FDA.

Although FDA's enforcement activities have remained static for the past decade, 2025 saw a predicted increase in FDA enforcement of advertising rules in response to new policies aimed at direct-to-consumer (DTC) drug advertising.

While First Amendment protections limit the extent and degree to which FDA can prohibit truthful and non-misleading speech, including in advertising, established precedent on Agency discretion, such as the US Supreme Court in Heckler v Cheney, gives FDA flexibility in how it deploys its enforcement authority to address statutory violations. As a result, FDA issued more than 100 cease-desist letters in 2025 focused on DTC drug advertising. This trend may continue in 2026.

As predicted, ongoing and evolving leadership and personnel changes, combined with the MAHA initiative and a series of Executive Orders (EOs), significantly impacted both FDA's rulemaking agenda and regulatory operations in 2025.

Below, DLA Piper's FDA Regulatory team highlights key guidance documents and developments from 2025, with insights and perspectives on what may come in 2026.

Make America Healthy Again

On May 22, 2020, the MAHA Commission released the 100-day *Make Our Children Healthy Again* report, as discussed here. This report was issued in response to a February 2025 EO, which established the President's Make America Healthy Again Commission to address chronic diseases in the US. The current report includes a description of childhood chronic diseases in the US (*e.g.*, obesity, diabetes, neurodevelopmental disorders, and mental health challenges among children), an assessment of potential contributing factors, an evaluation of the federal programs and funding intended to address childhood health issues, and an examination of the relevant data and potential industry influence on research. The report focuses on four key "root causes" of chronic disease:

- Diet
- Chemical exposure
- Technology impacts
- Medical treatments

For further analysis of the report, access DLA Piper's webinar here.

The report also includes details of the Make Our Children Healthy Again Strategy, which contains recommendations in four "key pathways":

- Advancing Critical Research to Drive Innovation
- Realigning Incentives and Systems to Drive Health Outcomes Research to Drive Innovation
- Increasing Public Awareness and Knowledge
- Fostering Private Sector Collaboration

The recommendations span across all FDA-regulated product areas and will guide policymaking in the Trump Administration.

Drugs and biologics

2025

Regulatory flexibility for drugs for rare diseases

FDA continues to incentivize the development of drugs to address rare disease. Federal regulations at 21 CFR § 312.80 state that, in determining the approvability of a new therapy for a rare, life-threatening disease for which no treatment exists, FDA should "exercise the broadest flexibility" because "patients are generally willing to accept greater risks or side effects from products that treat life-threatening and severely-debilitating illnesses," and "the benefits of the drug need to be evaluated in light of the severity of the disease being treated."

Applying this rationale, in 2025, FDA issued several approvals of treatments for rare debilitating diseases with unmet need. A key example was the September approval of Stealth BioTherapeutics' Forzinity (elamipretide) injection as the first treatment for Barth syndrome, a rare inherited pediatric disease with no approved treatment. Stealth's NDA had previously received a Refusal to File (RTF) and then a CRL on the basis that the application did not contain a single adequate and well-controlled trial to establish efficacy, despite a 10–6 split decision in favor of approval by an advisory committee. Stealth resubmitted for accelerated approval using a different intermediate endpoint, and FDA granted accelerated approval with a required post-approval clinical trial. Among other rare disease products, this initial denial, and later approval, was seen as emblematic of the fluidity surrounding how regulatory flexibility actually works with respect to clinical trial design and approval standards for rare disease.

A month later, FDA appeared to take regulatory flexibility for rare diseases a step in the direction of increased certainty when Dr. Makary announced a "plausible mechanism" pathway for approving personalized therapies, stating, "And, so, we're going to be rolling out a new pathway for drugs, which is a pathway based on a plausible mechanism. If there's a rare condition or a condition that's incurable that affects a small number of people, we may be approving drugs based on a plausible mechanism on sort of a conditional basis." This pathway would be reserved for products "where a randomized trial is not feasible" and would prioritize rare diseases that are fatal or can cause severe disabilities in children. This pronouncement suggests a significant trend by senior Agency leadership toward regulatory flexibility for rare deadly diseases with unmet need. However, to date, FDA has not issued guidance on the "plausible mechanism" pathway. Some stakeholders have lauded FDA for this apparent trend, but others have called for more specifics and consistency.

"America-First" initiatives and the National Priority Voucher Program

FDA has followed the Trump Administration's "America-First" approach through several key programs. Dr. Makary stated, "Our gradual overreliance on foreign drug manufacturing has created national security risks." In response, the new FDA PreCheck Program aims to strengthen the domestic pharmaceutical supply chain by "increasing regulatory predictability and facilitating the construction of manufacturing sites in the United States." FDA PreCheck was developed in response to EO 14293, "Regulatory Relief to Promote Domestic Production of Critical Medicines," which directs FDA to streamline review of domestic pharmaceutical manufacturing and eliminate unnecessary regulatory requirements while maximizing review timeliness and predictability.

The PreCheck program introduces a two-phase approach to facilitate new US drug manufacturing facilities. First, the Facility Readiness Phase provides manufacturers with more frequent FDA communication at critical development stages and encourages companies to provide comprehensive facility-specific information through a Type V Drug Master File (DMF). Second, the Application Submission Phase streamlines development of the Chemistry, Manufacturing, and Controls section of the application through pre-application meetings and early feedback.

During a public meeting, Dr. Makary stated that "More than half of pharmaceuticals distributed in the U.S. are manufactured overseas," and "the U.S. is reliant on overseas sources for active pharmaceutical ingredients (APIs)." According to Dr. George Tidmarsh, Director of FDA's Center for Drug Evaluation and Research, the current situation is "weakening the U.S.'s pharmaceutical research and development infrastructure." The ANDA Prioritization Plan seeks to address this problem by facilitating faster reviews for generic companies that test and manufacture their products in the US.

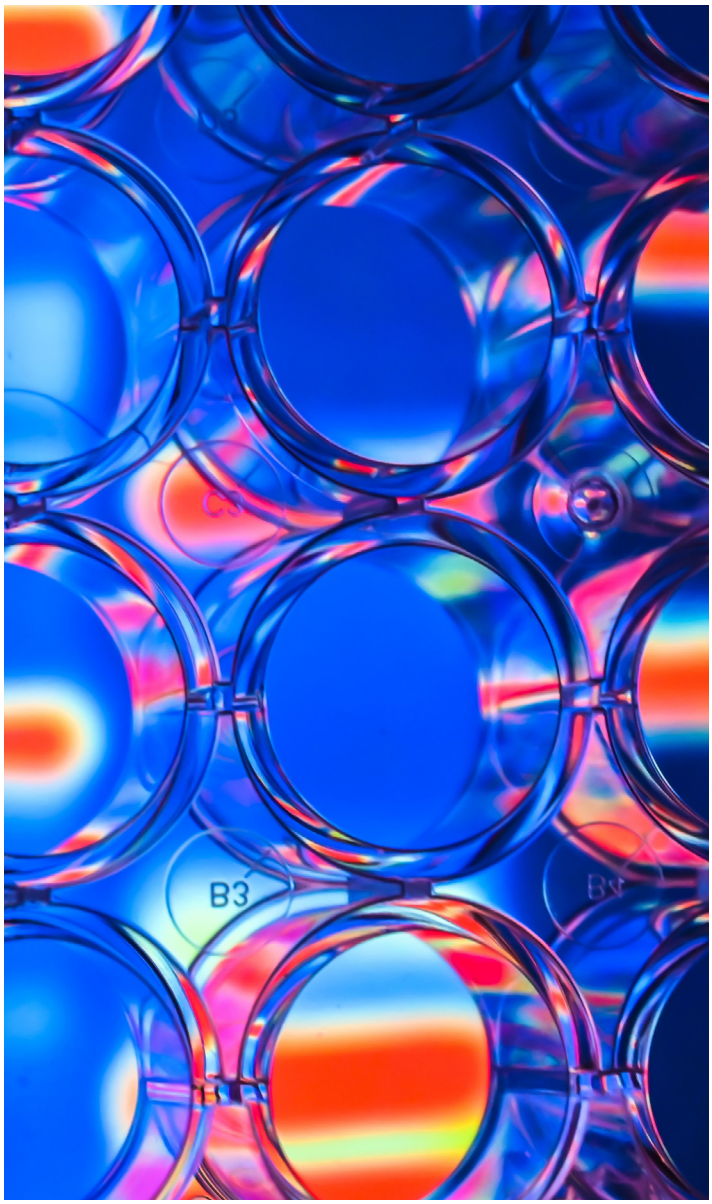
Perhaps the most widely reported program in this regard is the new Commissioner's National Priority Voucher (CNPV) Pilot Program, which FDA states "reflects FDA's commitment to create more efficient approval processes and modernize regulatory frameworks for greater agility to meet emerging public health needs." Through the program, a drug developer may redeem a voucher to participate in a novel FDA priority program that shortens the Agency's review time for selected drug applications from approximately ten to 12 months to one to two months. The new CNPV process convenes experts from FDA offices for a team-based review rather than using the standard review system, in which a drug application is sent to numerous FDA offices. Clinical information will be reviewed by a multidisciplinary team of physicians and scientists who will pre-review the submitted information and convene for a one-day "tumor board style" meeting. FDA has stated it will use specific criteria to make the vouchers available to companies that are "aligned with the national health priorities" of:

- Addressing a health crisis in the US
- Delivering more innovative cures for the American people
- Addressing unmet public health needs
- Increasing domestic drug manufacturing as a national security issue

Vouchers can be directed by FDA toward a specific investigational new drug of a company or be granted to a company as an undesignated voucher, allowing a company to use the voucher for a new drug at the company's discretion and consistent with the program's objectives. The program aims to accelerate the drug review process for companies aligned with US national priorities while maintaining FDA's rigorous standards for safety, efficacy, and quality.

At the time of the June 2025 announcement, FDA stated that, although selection does not guarantee approval and reviews could take longer than two months, the chosen applications will likely progress far more speedily. Since then, FDA has thus far issued vouchers for 18 products and announced its first review decision in December 2025 for the antibiotic Augmentin XR, which occurred within the two-month CNPV review window. FDA stated that the product "demonstrated clear alignment with the CNPV program's national health priorities by strengthening the U.S. drug supply chain through enhanced domestic manufacturing capacity at a U.S. facility" and thus will "help address antibiotic shortages in the U.S. that have plagued the healthcare system over the past two decades."

Industry stakeholders have raised questions related to whether such a shortened review is possible, whether the few anticipated vouchers will make a meaningful difference, and whether the Agency can handle another expedited approval program. These concerns may be addressed as more information about the program becomes available.



"Radical transparency" for complete response letters

In a move touted as "radical transparency," in July 2025, FDA publicly released more than 200 CRLs from drug and biologic reviews. A CRL is FDA's formal response letter explaining why a new drug application (NDA) or biologics license application (BLA) could not be approved in its current form. Federal regulations require FDA to maintain confidentiality of proprietary commercial information and trade secrets related to drug and biologics applications. This new policy of publication marks a sharp departure from past practice. CRLs have traditionally been kept confidential, with redacted excerpts appearing in some approval packages "on a case-by-case basis" due to commercial sensitivity. Explaining this unprecedented shift in policy, FDA has stated, "sponsors often misrepresent the rationale behind FDA's decision to their stakeholders and the public." The Agency also cited a 2015 analysis showing that "sponsors avoided mentioning 85% of FDA's concerns about safety and efficacy when announcing publicly that their application was not approved."

The initial batch released in July 2025 spans applications submitted between 2020 and 2024 that were later approved. FDA then announced in September that it had released 89 previously unpublished CRLs issued from 2024 to the present associated with pending or withdrawn applications and, going forward, that it intends to release CRLs in "real time" for applications that are currently pending before the Agency. Stakeholders have characterized this action as a step likely to face "steep obstacles" due to trade secret limitations imposed by law. For life sciences companies and their investors, this development raises complex questions about the balance between transparency and confidentiality. Executives must now navigate a landscape in which protecting trade secrets and managing regulatory disclosures becomes more challenging, even as greater transparency offers new insights (and pitfalls) for research and development strategy and investor communications.

FDA's "radical transparency" experiment could ultimately build greater trust in the Agency's decisions and lead to stronger drug applications. However, it also raises the stakes for how companies manage proprietary information, public disclosures, and the potential for information contained in such disclosures to be misinterpreted or misunderstood. Implications of FDA's new policy are discussed in further detail here.

Investigational drugs and clinical trials

FDA issued a number of draft and final guidances that will continue to shape the regulatory framework surrounding investigational drugs and clinical trials.

For example, in January 2025, FDA issued draft guidance "Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway," which provides key insight into one of the Agency's expedited review pathways.

Accelerated Approval is a regulatory pathway by which certain drugs intended to treat serious or life-threatening conditions with unmet medical needs may be reviewed and approved more quickly than with traditional approvals. For drugs granted accelerated approval, sponsors have been required to conduct confirmatory studies using surrogate or intermediate endpoints following product approval to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In the Consolidated Appropriations Act, 2023, Congress amended the Federal Food, Drug, and Cosmetic Act (FDCA) to provide additional authorities to help ensure timely completion of such trials. This draft guidance describes FDA's interpretation of when a study is considered "underway" and policies for implementing this requirement, including factors FDA intends to consider prior to an accelerated approval action.

In October 2025, FDA issued final Q&A guidance, "Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers." This document clarifies pathways for providing investigational drugs to patients with serious or immediately lifethreatening diseases who lack satisfactory alternatives. In the guidance, FDA touches on the various types of access, submission categorization, emergency use, the role of institutional review boards (IRBs) and informed consent, safety reporting, charging patients, and the respective responsibilities of sponsors and treating physicians. Sponsors should maintain clear policies and procedures for triage of requests, recordkeeping and reporting, safety monitoring, drug supply chain controls, and compliance with charging provisions.

That same month, FDA issued the third of a four-guidance series entitled, "Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments," which provides a framework for selecting or developing fitforpurpose clinical outcome assessments (COAs) (patient-reported, clinician-reported, observer-reported, and performance-based outcomes) for drugs, biologics, and devices, including patient-focused outcome measurement and how to develop evidence to support COA in a particular context of use. In addition to these general principles, the guidance also covers considerations for selecting COA tools. Once the fourth document in this series is finalized, this set of guidance documents will replace the 2009 patient-reported outcome (PRO) measures labeling guidance.

In June 2025, FDA announced the availability of draft guidance entitled, "Q1 Stability Testing of Drug Substances and Drug Products," which aligns with the International Conference on Harmonisation (ICH) Q1 series on stability study design, testing frequency, stress testing, and extrapolation to establish retest periods and shelf life of drug substances and drug products to support drug product marketing. This draft guidance is a consolidated revision of multiple ICH series of stability guidances published between 1996 and 2004. The document also provides stability related guidance for product categories not previously covered under the existing stability guidances, such as advanced therapy medicinal products, vaccines, and other complex biological products, including combination products. The draft guidance is also intended to provide an internationally harmonized approach to providing alternative, scientifically justified approaches that may be encountered due to scientific considerations and characteristics of data being evaluated.

In further efforts to harmonize US frameworks with international practices, FDA announced the availability of revised draft technical specification guidance entitled, "M11 Technical Specification: Clinical Electronic Structured Harmonised Protocol."

The guidance, prepared by the ICH, provides recommendations on the use of an open, non-proprietary standard to enable electronic exchange of clinical protocol information, as well as a template, offering an international standard for the content and exchange of information to facilitate review and assessment. This specification and template revise and replace their draft versions issued in December 2022.

In January 2025, FDA published draft guidance entitled, "Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products," which lays out expectations when sponsors use artificial intelligence (AI) or machine learning (ML) tools to generate, process, or analyze data relied upon in regulatory submissions (regarding safety, effectiveness, or quality for drugs).

Specifically, this guidance provides a seven-step risk-based credibility assessment framework for establishing and evaluating the credibility of an AI model for a particular context of use (COU):

1. Define the question of interest
2. Define the COU for the AI model
3. Assess AI model risk
4. Develop plan to establish AI model credibility within COU
5. Execute the plan
6. Document results of plan and discuss deviations
7. Determine adequacy of AI model for COU

In addition to describing each step, the guidance also touches on life cycle maintenance of credibility of AI model outputs. This guidance document is discussed in further detail here.

The Drug Supply Chain Security Act (DSCSA), originally enacted in November 2013, established a ten-year, phased implementation to establish a program for a package-level electronic track-and-trace system for prescription drugs. Early phases required trading partners to exchange transaction information and implement serialization by affixing unique product identifiers to drug packages. The final phase, which took effect on November 27, 2023, mandated interoperable electronic tracing of products at the package level, but was followed by a one-year extended stabilization period. In response to ongoing implementation challenges, FDA issued temporary, phased exemptions for trading partners that have initiated interoperable systems, setting compliance dates of May, August, and November 2025 for manufacturers or repackagers, wholesale distributors, and dispensers, respectively, while small dispensers (fewer than or equal to 25 employees) are exempt from certain requirements until November 27, 2026. Eligible entities need not apply to rely on these exemptions, but those not covered may seek waivers or exceptions, and all stakeholders are encouraged to monitor FDA policies and engage early with the Agency to navigate evolving obligations and enforcement. The DSCSA guidelines are discussed further here.

Consistent with MAHA's initiatives to phase out common petroleum-based synthetic food dyes, discussed in detail in the *Food, beverage, and dietary supplements* section of this report, the Agency also issued a draft guidance, "Replacing Color Additives in Approved or Marketed Drug Products," to provide recommendations for replacing color additives in approved or marketed drug products – either because FDA deems the additive to be unsafe and repeals the color additive regulation, or because a business decides to voluntarily remove the additive. The guidance includes information on how to conduct studies to assess the change in color additives; how to update the composition statement, drug specifications, and labeling; and how to document the change. FDA states that replacing a color additive with one that conforms to the Agency's regulations would be considered a moderate change, and a changes being effected in 30 days (CBE-30) supplement would be appropriate unless there are other changes (*e.g.*, changes in levels of inactive ingredients that exceed five percent of the target unit dose weight; major changes that would require a prior approval supplement, or PAS). Also notable is that the removal of a color additive – rather than replacement – constitutes a minor change that applicants must report in an annual report, but no CBE or PAS would be required.

FDA also addressed the requirements of section 505(o)(4) of the FDCA, which authorizes FDA to require certain drug and biological product application holders to make safety-related labeling changes based on new safety information that becomes available after approval of the drug or biological product. In September 2025, FDA issued an updated guidance, "Safety Labeling Changes--Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry," to incorporate additional authorities from the 2018 Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act to require manufacturers to inform users about postmarket safety information. Specifically, the SUPPORT Act amended the definition of "adverse drug experience" to clarify that "any failure of expected pharmacological action of the drug" would also potentially "include reduced effectiveness under the conditions of use prescribed in the labeling." In short, the SUPPORT Act clarified that reduced effectiveness of a drug over time, such as is the case with opioids, can form the basis for regulatory action under 505(o)(4) to alter or implement requirements for post-market studies or labeling changes to include this additional type of effectiveness information.

In response to statutory requirements of the SUPPORT Act, which directs FDA to issue or update existing guidance to help address challenges to developing non-opioid medical products to treat pain, FDA published draft guidance entitled, "Development of Non-Opioid Analgesics for Chronic Pain, Draft Guidance for Industry" in September 2025.

This guidance, which garnered 120 comments from industry, trade associations, and consumers, provides FDA's current thinking on clinical development programs for nonopioid analgesics intended for chronic pain. Specifically, the document discusses establishing indications; considerations related to trial design, effectiveness (choice of populations and endpoints), and safety data collection; and leveraging FDA's expedited review programs.

Over-the-counter drugs

FDA's final rule, "Nonprescription Drug Product With an Additional Condition for Nonprescription Use" (ACNU), which issued in late 2024, was set to take effect in January 2025; however, the effective date was delayed twice until finally taking effect in May. This rule, which lays out the structure of the ACNU pathway, expands access to drugs by allowing certain products to be marketed over the counter (OTC) if an "additional condition" reliably ensures appropriate selfselection, use, or monitoring beyond labeling alone. The rule describes what an ACNU can be (*e.g.*, questionnaires, digital applications, inpharmacy processes), evidentiary expectations to demonstrate that the ACNU works as intended, humanfactors or usability and realworld validation considerations, labeling integration, and lifecycle and postmarketing considerations (including maintenance of the ACNU, change control, and pharmacovigilance). The final rule is discussed in detail here.

In December, FDA issued a Request for Information on Increasing Access to Nonprescription Drugs. The RFI focuses on the NDA process and evidence required to support an NDA for OTC drugs. The FDCA provides two pathways to market non-prescription drugs in the US: (1) compliance with an established OTC drug monograph, which does not require premarket review or approval by FDA, or (2) an NDA, which is often used where there is no established monograph or where the drug does not meet the criteria for prescription-only dispensing.

Under section 505 of FDCA, an applicant seeking to market a non-prescription drug under an NDA must submit data to demonstrate, among other things, that the drug can be used safely and effectively in a non-prescription setting. In addition to substantial evidence of safety and effectiveness, non-prescription drug NDAs often label comprehension studies, self-selection studies, actual use studies, human factors studies, and other types of consumer studies may be required to evaluate proposed non-prescription drug product labeling and to demonstrate that the drug is safe and effective for use in self-medication, as directed in proposed labeling as required under 21 CFR § 310.200(b). The less that is known about the use of a medication without the intervention of a healthcare practitioner, the more data that typically will be required.

To optimize the NDA review process for non-prescription drugs, the Agency seeks feedback on the following questions or topics by February 2, 2026:

1. What are challenges faced in the development of drugs for non-prescription use?
2. What are the biggest opportunities to improve access to non-prescription drugs?
3. How could interested parties – including, but not limited to, drug developers, healthcare providers, patients, consumers, and retailers – work together to increase access to safe and effective non-prescription drugs?
4. Looking ahead to a 2026 public meeting, what specific topics or questions would you like to see on the agenda for public discussion?
5. Scientific considerations
6. What scientific barriers most limit progress in increasing access to non-prescription drugs?
7. What additional scientific tools, technologies, or data sources could support access to non-prescription drugs?
8. Are there specific diseases or conditions that have not, traditionally, been treated with non-prescription drugs for which non-prescription drugs could be safely and effectively used without the supervision of a licensed healthcare practitioner? If so, what information would support such use under the applicable statutory and regulatory requirements for non-prescription drugs?

In December, FDA proposed amending OTC monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use to include bemotrizinol as an active ingredient in sunscreen up to six percent. The proposal is in response to an OTC monograph order request (OMOR) to FDA seeking an administrative order finding that a sunscreen drug product containing bemotrizinol as an active ingredient is generally recognized as safe and effective (GRASE) under the conditions described in OTC Monograph M020.

If finalized, the change would be significant, as this would be the first new active ingredient for sunscreen allowed in the US since 1999.

Bemotrizinol provides broad-spectrum protection against ultraviolet A and B rays, and it has been approved for use in sunscreen around the world for around two decades. The proposal is an outgrowth of the CARES Act of 2020, which streamlined and restructured the OTC monograph framework, and the 2026 Appropriations Bill, which allows for non-clinical testing alternatives to animal testing for the consideration of sunscreen active ingredients.

Compounding

In September 2025, FDA issued Warning Letters to several telemedicine providers for offering various compounded drug products, including semaglutide and tirzepatide. Specifically, FDA cited the companies for claiming their compounded drug products were the same as FDA-approved versions of various glucagon-like peptide-1 (GLP-1) receptor agonist drugs. FDA also reinforced that neither the salt forms of semaglutide sodium and semaglutide acetate nor retatrutide and cagrilintide lawfully can be used in compounding.

Generic drugs

In June 2025, FDA finalized two guidance documents related to generic drugs, "Post-Warning Letter Meetings Under GDUFA" and "ANDAs: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions." First, the post-warning letter discusses the implementation of the Post-Warning Letter Meeting process for certain drug manufacturing facilities, a program enhancement agreed upon by FDA and industry as part of the Generic Drug User Fee Amendments (GDUFA) negotiations. Specifically, this guidance explains FDA's process for assessing, granting, and conducting Post-Warning Letter Meetings with facilities that have received drug current good manufacturing practice (cGMP) warning letters to discuss corrective actions and remediation plans. The document also covers how to prepare and submit a complete meeting package and a discussion on how FDA intends to conduct these meetings.

Second, the Pre-Submission guidance describes the Pre-Submission Facility Correspondence (PFC) mechanism for priority ANDAs, detailing when and how sponsors should submit a PFC, how FDA will use this information to set a review goal for a priority ANDA and plan for preapproval inspections, and clarifying that manufacturing sites must be inspection-ready at the time of PFC submission, while bioequivalence study sites do not. The guidance covers required content, timing relative to ANDA filing, what constitutes a "significant change," how FDA uses the PFC to determine whether priority review timelines can be met, and possible outcomes of a PFC assessment. Having received a number of comments from industry and trade associations related to potentially problematic language, this final guidance represents a fourth iteration following its 2017 draft and revisions in 2017 and 2022.

In December 2025, FDA issued a second revision of its final guidance, "ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs: Guidance for Industry," providing clarifying revisions to its recommendations on preparing and submitting amendments to tentatively approved ANDAs, including timing and content of requests for final approval on the earliest date on which the ANDA may lawfully be approved based on patent and/or exclusivity protections. A notable change compared to prior versions of this guidance clarifies that amendments requesting final approval should be designated clearly in a cover letter as "FINAL APPROVAL REQUESTED" and should provide the legal or regulatory basis for the request, including "a copy of a court decision, settlement or licensing agreement, or other information described in 21 CFR [§] 314.107, as appropriate."

Formal meetings and interchangeable biosimilars study requirements

On July 18, 2025, FDA issued final guidance entitled, "Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products Guidance for Industry," which provides the Agency's recommendations on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar or interchangeable biological products. Notably, FDA states that the maximum number of questions – including sub-questions – that should be included in any Biosimilar User Fee Amendments (BsUFA) meeting request is "no more than 10 questions listed consecutively regardless of discipline" (or fewer, if the questions are more complex). In addition to providing other best practices for meeting requests, the guidance aligns the available meeting types with those in the BsUFA III commitment letter and clarifies the "face-to-face" meeting formats to be requested based on core attendee presence.

In October 2025, FDA issued new draft guidance, "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies," which could make the development of biosimilars faster and less costly.

Unlike small-molecule drugs which are regulated under the FDCA, biologics and biosimilars are regulated under the Public Health Service Act (PHSA). The approval pathway for biosimilars was established by Congress in 2010 through the Biologics Price Competition and Innovation Act (BPCIA) to promote competition in markets dominated by high-cost biologics. The PHSA provides that a product is "biosimilar" if it is highly similar to the reference product notwithstanding minor differences in clinically inactive components, and if there are no clinically meaningful differences in terms of the safety, purity, and potency. Further, a biosimilar is "interchangeable" if it can be expected to produce the same clinical result as the reference product and if administered more than once to an individual the risk of switching the products is not greater than the risk of using the reference product without switching. At the time, the prevailing view was that the interchangeable category was superfluous because technology did not exist to determine that a biologic was the "same" as another. The ensuing years have whittled away at that premise. According to the Purple Book, as of December 31, 2025, FDA had approved 79 biosimilars and 13 interchangeable biosimilars, nine of which have included switching studies.

The new draft guidance changes FDA's policy on when a comparative efficacy study would be required to demonstrate biosimilarity. Stakeholders have asserted that a comparative analytical assessment is sufficiently sensitive to characterize biosimilars and makes clinical studies unnecessary, especially for proteins. Essentially, FDA has now accepted the argument that technology now permits in vitro testing that can demonstrate a biosimilar protein is identical to the reference product protein, and in that situation clinical studies should not be required.

Perhaps even more critically, FDA has indicated it will finalize guidance providing that switching studies are no longer needed to demonstrate interchangeability. This policy has increasingly been implemented, albeit somewhat quietly, over the past few years. Sponsors of biosimilar products would find, upon submission, that the Agency was open to designating them as interchangeable based on the evidence provided, even though they did not proffer switching studies and did not request the additional designation.

With FDA eliminating the need for switching studies, the Agency has removed the most significant barrier to interchangeability. Rather than conducting human clinical trials, sponsors may now use modeling to support interchangeability, drastically reducing the cost and time for producing an interchangeable biosimilar. Stakeholders have noted that this potentially makes all biosimilars, at least all protein biosimilars, effectively interchangeable. This is consistent with the Commissioner's stated position that all biosimilars should be considered interchangeable. Further, in its FY 2025 budget, FDA specially stated its proposal in this regard,

"FDA is seeking to amend section 351 of the PHSA to no longer include a separate statutory standard for a determination of interchangeability and to deem all approved biosimilars to be interchangeable with their respective reference products." Ultimately, it seems it will not be long until all biosimilars are interchangeable, thus effectively rendering them biological generics.

Uncertainties for cell and gene therapy

Several FDA developments in June 2025 garnered widespread attention from cell and gene therapy (CGT) developers as well as from patient advocates and other supporters of biomedical innovation.

FDA announced in June 2025 that it would halt new clinical trials that transfer genetic material to hostile countries, including China, due to concerns about informed consent based on "mounting evidence that some of these trials failed to inform participants about the international transfer and manipulation of their biological material." Such action is consistent with President Biden's EO 14117 and President Trump's EO 14292 directing the federal government to prevent the exploitation of Americans' sensitive personal data by foreign adversaries. The announcement sparked concerns about whether trials of investigational gene therapies that could require manufacturing contributions from any ex-US facility will continue to be authorized by the Agency.

Simultaneously, both Dr. Nicole Verdun and Dr. Rachael Anatol, the Director and Deputy Director, respectively, of the Office of Therapeutic Products, known as the "super office" that supervises review decisions for BLAs for gene therapy, cellular therapy, tumor vaccines, and plasma protein therapeutics, were placed on administrative leave.

On a subsequent podcast, Dr. Makary and Centers for Biologics Evaluation and Research (CBER) Director Vinay Prasad noted that certain Chimeric Antigen Receptor T-cell therapy (CAR-T) products are being manufactured in China for American patients, which both officials have stated they view as a national security threat.

Ultimately, uncertainties resulting from these actions and statements could risk a loss of confidence and consistency in the Agency's CGT policies, while a reduction in review staff could potentially delay or impede application reviews.

On the guidance front, CBER issued two draft guidance documents in September 2025: "Expedited Programs for Regenerative Medicine Therapies for Serious Conditions" and "Innovative Designs for Clinical Trials of Cellular and Gene Therapy Products in Small Populations."

In the Expedited Programs guidance, FDA provides sponsors engaged in the development of regenerative medicine therapies for serious or life-threatening diseases or conditions with recommendations on the expedited development and review of such therapies, including those designated as "regenerative medicine advanced therapy" (RMAT). RMAT was implemented under the 21st Century Cures Act and represents another significant potential avenue to facilitate faster review and approval of therapeutic products, in this case specific to regenerative products such as CGTs. The guidance, which closely mirrors a 2019 final guidance of a similar name, describes considerations for the clinical development of regenerative medicine therapies and opportunities for sponsors of such products to interact with CBER review staff. FDA also encourages sponsors to perform product characterization studies early and throughout development to prevent potential delays, and it clarifies the level and types of evidence needed to support RMAT, including comparability data.

In the Innovative Clinical Trial Design guidance, FDA provides recommendations to sponsors that are planning clinical trials of CGT products intended for use in rare diseases or conditions that affect small populations, including requirements and considerations for the use of clinical trial designs and endpoints to generate clinical evidence, which can support product licensure. This guidance, in alignment with principles presented in FDA's existing guidance documents related to this topic, provides more tailored recommendations for cell and gene therapy trials to facilitate FDA's evaluation of product safety and effectiveness when the standard two randomized controlled studies would prove challenging due to smaller affected population. Specifically, FDA explains the types of evidence and approaches the Agency would consider in these types of therapies, such as single-arm own-control trials, disease progression modeling, externally controlled studies, and adaptive clinical trials.

GxP

In January 2025, FDA issued draft guidance entitled, "Considerations for Complying with 21 CFR 211.110," which relates to cGMP for finished pharmaceutical products and manufacturing process controls. This guidance, once finalized, will provide considerations for complying with regulatory requirements to ensure batch uniformity and drug product integrity. This document also discusses related quality considerations for drug products that are manufactured using advanced manufacturing (*e.g.*, innovative manufacturing technologies or practices such as 3D printing) and provides recommendations on how manufacturers can incorporate process models into commercial manufacturing control strategies rather than requiring physical sampling and testing in-process materials.

Combination products

2025

In June 2025, FDA issued its "Unique Device Identifier Requirements for Combination Products: Draft Guidance for Industry" for combination products with device constituent parts. The draft guidance clarifies that some combination products are not subject to the unique device identifier (UDI) requirements. For example, if the device constituent part of a combination product is a Class I device exempted from good manufacturing requirements or an investigational device, it would be exempt from the UDI requirement. The guidance provides additional information depending on whether a combination product is a single-entity, co-packaged, or cross-labeled combination product.

In November 2025, FDA updated its "How to Prepare a Pre-Request for Designation (Pre-RFD): Guidance for Industry." FDA emphasizes that a Pre-RFD should focus on a single intended use and should not provide information related to the safety or effectiveness of the product or other information that does not relate to helping the Office of Combination Products (OCP) understand how the product works. In addition to providing more detailed information on what the sponsor should include in a Pre-RFD, FDA's update outlines two forms of Pre-RFD meetings that sponsors may request. The first, an informational meeting, is held prior to the submission of a Pre-RFD to provide the OCP with information about a product. The second, an explanatory meeting, would follow FDA's issuance of a Pre-RFD assessment, to discuss and address any questions the sponsor may have. FDA intends to hold informational meetings within six weeks after receipt of a complete meeting package, and it intends to hold explanatory meetings within two weeks after receipt of the meeting request. FDA's 60-calendar-day review goal for Pre-RFDs begins after the Agency sends the sponsor an acknowledgement of receipt.

In November 2025, FDA issued its "Cross-Center Master Files: Where to Submit: Guidance for Industry" draft guidance to provide recommendations on where to submit master files referenced in or intended to support more than one regulatory submission in which the lead center may vary or where the information therein may need to be reviewed by more than one FDA center. The center to which the master file will be submitted is known as the "hosting center," and FDA discourages submitting multiple copies of the master file to multiple centers in order to maintain appropriate control. Generally, the hosting center should be the lead center for review, but when there is a biological product constituent part or drug constituent part for a drug/device or biologic/device combination product, FDA recommends that the Center for Drug Evaluation and Research (CDER) or CBER be the hosting center. For non-combination products, typically, the center that will receive the first referencing submission should be the hosting center. However, when a master file will be used to support Center for Veterinary Medicine (CVM)-regulated animals as well as human medical products, the human medical product center should be the hosting center. However, sponsors generally should not submit a master file to a human medical product center if it will only be used to support animal drugs reviewed by CVM.

Medical devices

2025

Device shortages

In January 2025, FDA also issued its Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act: Guidance for Industry and Food and Drug Administration Staff, replacing its November 2023 version. The finalized guidance includes a "506J Device List," which Congress required FDA to establish under section 2513(c) of the FY 2023 Omnibus and contains device product codes for which manufacturers are required to notify FDA when there is a shortage. FDA will update the 506J Device List periodically.

FDA also describes the critical medical device list (CMDL) developed in response to the January 2021 Executive Order 14001, A Sustainable Public Health Supply Chain, and in concert with the Centers for Medicare and Medicaid Services, Centers for Disease Control and Prevention, Administration for Strategic Preparedness and Response, and Department of Veterans Affairs as well as industry stakeholders. The CMDL is broader than the 506J device list, but it is intended for use by clinicians, hospital systems, group purchasing organizations, industry, and state and local governments.

Premarket review and marketing submissions

In January 2025, FDA issued an update to its November 2003 guidance, "Premarket Approval Application and Humanitarian Device Exemption Modular Review: Guidance for Industry and FDA Staff." FDA has permitted premarket applications (PMAs) to use a modular approach, allowing submitters to submit non-clinical data and manufacturing information (sections or "modules") while developing their clinical data in order to speed up FDA review and evaluation. The guidance expands this review approach to humanitarian device exemption (HDEs) in addition to PMA, but the Agency notes that the approach is more suitable for products in the early stages of their clinical development. It is not for devices that are nearly complete, where a product may undergo changes prior to submission for review, or PMA or HDE supplements. The guidance also includes a modular PMA or HDE flowchart to help sponsors determine whether a modular review is appropriate as well as a sample shell for modules.

In May 2025, FDA updated its "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program: - Final Guidance for Industry and Food and Drug Administration Staff" to align with its commitments under the Medical Device User Fee Amendments of 2022 (MDUFA V). FDA recommends that submitters carefully consider the number of topics and extent of feedback they request in a single Pre-Sub. Specifically, the Agency suggests that submitters include no more than three to four substantial topics, as more may be difficult for the Agency to address in one Pre-Sub. Additionally, given their evolving nature, FDA recommends that if more than a year has passed since the submitter received feedback on clinical practice, testing methods, or medical device technology-related questions, they consider contacting the review division to confirm FDA's previous advice is still applicable.

In June 2025, FDA issued its "Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers: Draft Guidance for Industry and Food and Drug Administration Staff." FDA formally provides guidance on how and when to report change of ownership through a purchase, sale, or other transfer of a 510(k) clearance, *i.e.*, via the FDA Unified Registration and Listing System / Device Registration and Listing Module (FURLS/DLRM) within 30 days after entering into an operation described in 21 C.F.R. § 807.20. New owners must also submit timely updates to the Global Unique Device Identification Database (GUDID).

In December 2025, FDA issued a revised final version of its "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices." One of the key differences between the revised final and the prior version published in December 2023 is the Agency's replacement of the concept of fitness for purpose with that of "relevance and reliability." Sponsors should assess the relevance and reliability of sources, study design, and analytic components as well as the strengths and limitations of generating evidence to address specific regulatory purposes. FDA recommends that sponsors submit a relevance and reliability assessment if including real-world evidence (RWE) in regulatory submissions.

The Agency also discusses the importance of finalizing a protocol and analysis plan before reviewing outcome data. Further, sponsors should not have access to outcome measure results while the protocol is under development, and in many cases, individuals also should not have access to outcomes in the dataset used for the study. Also, while the Agency has not historically addressed privacy beyond ensuring that subjects from whom data is gathered are appropriately consented under FDA's good clinical practice regulations, in the revised final guidance, FDA specifically states that any linkages performed within and across real-world data (RWD) sources should use a "predefined linkage methodology" that protects the privacy of individuals, *i.e.*, a privacy preserving record linkage (PPRL). The Agency does not elaborate on how these linkages may also comply with applicable privacy laws, such as the Health Insurance Portability and Accountability Act (HIPAA). Finally, FDA includes additional examples of where RWD or RWE was used in support of regulatory decision-making in Appendix B of the revised final guidance.

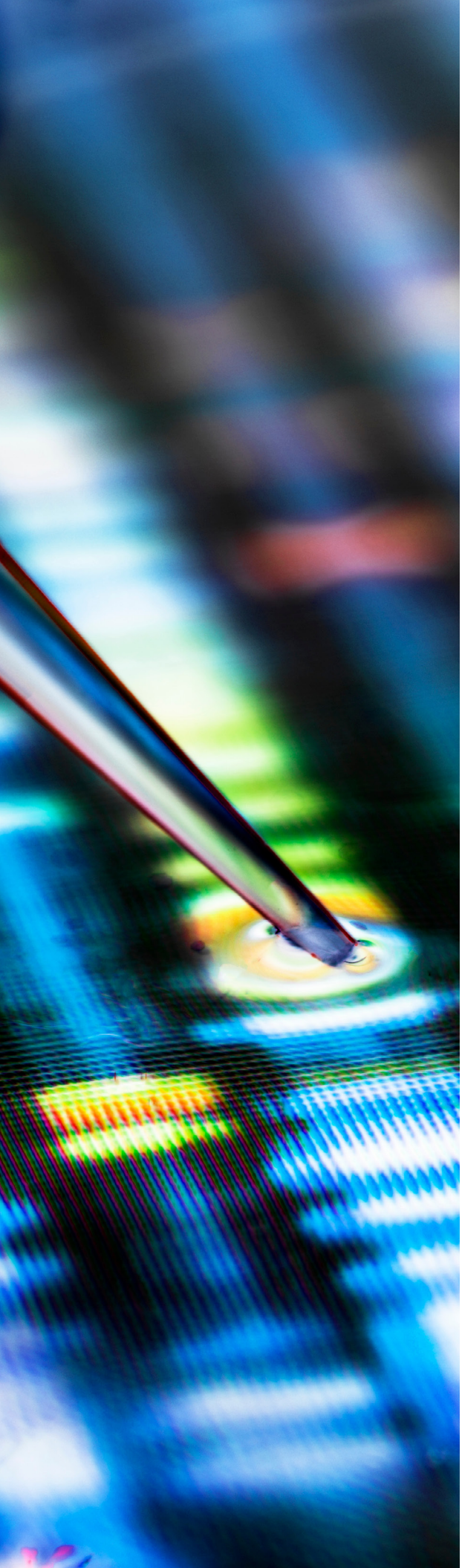
Laboratory developed tests

In September 2025, FDA rescinded its "Medical Devices; Laboratory Developed Tests" final rule (LDT Final Rule) in response to the March 31, 2025 final judgment from the United States District Court for the Eastern District of Texas in *American Clinical Laboratory Association v. FDA*, No. 4:24-CV-479-SDJ, 2025 U.S. Dist. LEXIS 59869 (E.D. Tex. Mar. 31, 2025), which vacated the LDT Final Rule and remanded the matter to the Secretary of Health and Human Services for further consideration.

Quality management systems

In September 2025, FDA issued its final "Computer Software Assurance for Production and Quality System Software: Guidance for Industry and Food and Drug Administration Staff." The guidance generally supplements but expressly replaces section 6 (Validation of Automated Process Equipment and Quality System Software) of the January 2002 "General Principles of Software Validation; Final Guidance for Industry and FDA Staff." It also maintains a risk-based approach to establish confidence in automations used for production or quality systems. FDA identifies high process risks, *i.e.*, medical device risks, as those where failure to perform as intended may result in a quality problem that foreseeably compromises safety. These may require more rigorous assurance activities. For software, this may mean the use of scripted testing. FDA declined to incorporate requests from commenters on the draft guidance to more closely align the guidance to principles and definitions in the "Q9(R1) Quality Risk Management" guidance.

In October 2025, FDA issued its "Quality Management System Information for Certain Premarket Submission Reviews: Draft Guidance for Industry and Food and Drug Administration Staff" to provide information about expectations related to Quality Management System Regulation (QMSR) requirements and quality management system (QMS) requirements in PMA and HDE applications. The draft guidance, which is intended to align with the newly implemented QMSR, which is intended to more closely align with the international consensus standard for device QMS, ISO 13485:2016, by amending 21 CFR Part 820 to incorporate by reference the QMS requirements of ISO 13485:2016. When finalized, it will supersede the February 2003 "Quality System Information for Certain Premarket Application Review; Guidance for Industry and FDA Staff." In the guidance, FDA describes the information for PMAs that would be sufficient for providing the "full description" of the methods used in, and the facilities and controls used for, the manufacturing, processing, packing, or installation of devices.



Digital health

2025

In January 2025, FDA issued its "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations: Draft Guidance for Industry and Food and Drug Administration Staff." The draft guidance, discussed in detail here, provides insights on how FDA plans to apply total product life cycle (TPLC) principles that have historically applied to traditional hardware medical devices and AI-enabled software device functions.

In June 2025, FDA issued its final "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff," which contains additional clarifications for cyber devices under amended section 524B of the FDCA (discussed in detail here) including tracking software bill of materials (SBOM) and managing firmware or software updates.

In July 2025, after a number of inquiries to and meetings with the company, FDA issued a Warning Letter to wearables manufacturer WHOOP, Inc. for marketing a blood pressure insights feature without FDA clearance or approval while marketing the product to deliver "medical-grade health & performance insights." WHOOP asserts that the feature, which provides systolic and diastolic blood pressure estimates, is intended to track blood pressure trends and help users understand how blood pressure affects their wellness. FDA also asserted that providing a blood pressure estimate is not a general wellness function, as it is not a low-risk function under FDA's "General Wellness: Policy for Low Risk Devices." The Agency reasoned that providing an erroneous reading can have significant consequences for users, which is a factor that could affect a general wellness designation under the guidance. After receiving the Warning Letter, the company publicly responded to FDA that it disagreed with the Agency's characterization of the blood pressure insights feature as a medical device because it is "designed to help you understand how your body responds to daily life, not to diagnose or treat any condition" and "[w]ellness features like this are common in wearable technology." The response highlights the ambiguous line between "wellness" products and "device" functions and FDA's sometimes inconsistent approach to these risk-based determinations. The Warning Letter also signals heightened scrutiny of making disease-related claims for wearable technologies. For example, FDA categorizes a class of "pulse oximeters intended for wellness use" as devices under enforcement discretion while regulating other oximeters as devices. The outcome of any subsequent enforcement or litigation may have a significant effect on how FDA regulates "general wellness" products.

In August 2025, FDA issued its revised final "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions: Guidance for Industry and Food and Drug Administration Staff," which contains recommendations on information to include a Predetermined Change Control Plan (PCCP) in a marketing submission for a medical device that includes AI-enabled device software functions (AI-DSFs).

The revision removes references to the 2022 Blueprint for an AI Bill of Rights that recommended manufacturers consider other characteristics, such as race, ethnicity, sex, religion, age, national origin, disability, veteran status, and genetic information, when considering whether the data used to train, tune, and test algorithms are complete and representative of the proposed intended use populations.

In December 2025, FDA announced its Technology-Enabled Meaningful Patient Outcomes for Digital Health Devices Pilot (TEMPO Pilot) in connection with the Centers for Medicare and Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI) Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model. The TEMPO Pilot was developed by FDA's Center for Devices and Radiological Health (CDRH) to encourage the development and use of digital health devices to improve health outcomes for people living with certain chronic diseases by providing a new, risk-based approach for using devices in care covered by the ACCESS model. The ACCESS model tests an outcome-aligned payment approach to expand access to technology-supported care options that may help patients improve their health or manage chronic disease. The program also promotes the collection and reporting of RWE to better understand how these technologies perform in real-world settings and their potential impact on health outcomes.

The Pilot program is intended to support premarket review of digital health devices that are intended for use in the following clinical or therapeutic areas: early cardio-kidney-metabolic (*e.g.*, hypertension, dyslipidemia, obesity, prediabetes), cardio-kidney metabolic (*e.g.*, diabetes, chronic kidney disease), musculoskeletal (*e.g.*, chronic musculoskeletal pain), and behavioral health (*e.g.*, depression or anxiety). FDA plans to select up to ten manufacturers in each of the stated clinical or therapeutic areas. One potential benefit of participation is that companies may request that FDA exercise enforcement discretion for certain medical device requirements that might otherwise be mandated for product clearance or commercialization. These requirements might include threshold requirements such as premarket authorization or certain clinical trial requirements. The notice does not specify what factors or criteria FDA will consider in deciding whether to extend enforcement discretion for certain requirements. These determinations might be made on a product-specific and risk-based basis, but the concept raises broader questions regarding the Agency's authority to override statutory requirements for medical devices as well as inevitable questions regarding the fairness and transparency of any such determinations to non-pilot program participants.

Participating manufacturers will have to collect, monitor, and provide real-world data (RWD) and RWE to FDA and CMS in order to better understand how these devices can improve care and outcomes for patients with chronic diseases.

Additionally, manufacturers may have to comply with special labeling requirements for their devices or maintain certain records, such as those typically required under the investigational device regulations for adverse events.

The Agency began collecting statements of interest for participation in the Pilot on January 2, 2026. Interested manufacturers may email FDA at FDA-TEMPOPilot@fda.hhs.gov with "Statement of Interest for Participation in the TEMPO Pilot" and include the following:

- Manufacturer's name
- Manufacturer's device (including current authorizations and prior FDA interactions and submission numbers)
- Proposed indications for use statement identifying intended use to improve patient outcomes in the relevant clinical use area

- A request that FDA give the manufacturer a statement that FDA does not intend to enforce certain legal requirements (*i.e.*, the manufacturer may make a specific request for enforcement discretion with respect to certain medical device requirements that might normally apply to the device)

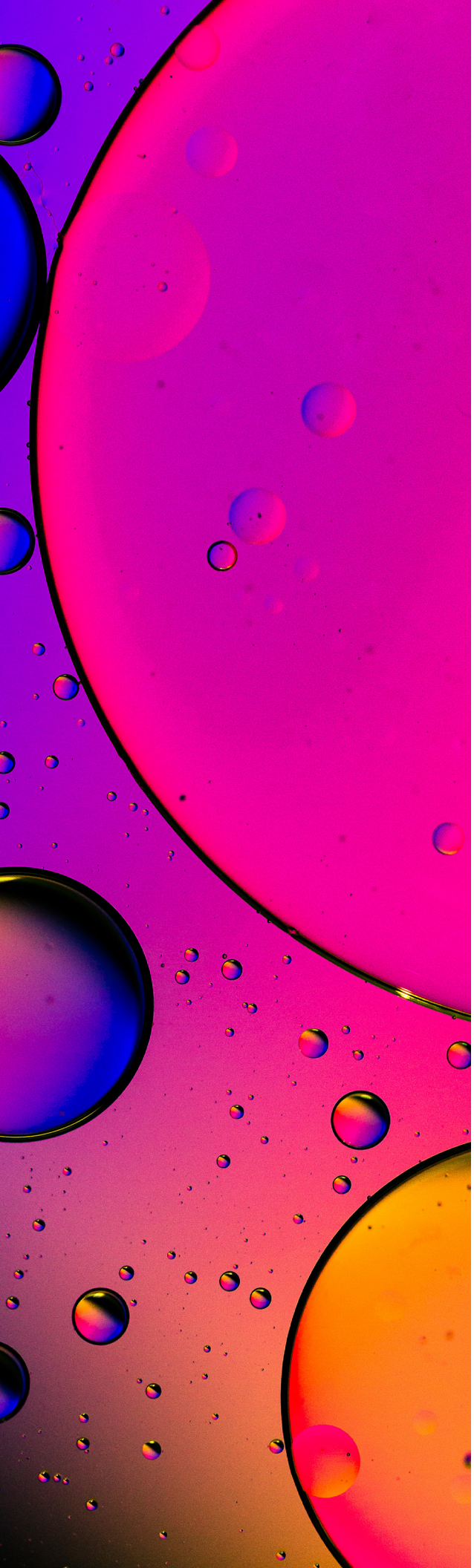
FDA will send follow-up requests to manufacturers who submitted a statement of interest in early March 2026. Upon receipt of a follow-up, FDA recommends that manufacturers be prepared to submit the following detailed information to the Agency:

- Device description, including proposed indications for use and proposed claims
- Data to demonstrate the device is adequately safe and can function as designed and to support a "reasonable expectation" that the device could provide a patient benefit
- Information about the quality management system
- A risk mitigation plan that sufficiently mitigates risks to patients and provides for collection, monitoring, analysis, and reporting of RWD and RWE
- Proposed performance goals and a statistical analysis plan for patient outcomes
- A proposed timeline for data collection and submission to FDA of a marketing submission, if applicable
- A proposed interim reporting plan (including frequency) to report adverse events, new risks, and progress with respect to other established timelines

FDA will evaluate the detailed follow-up information in determining whether a manufacturer will be accepted into the Pilot. Participation does not guarantee that a manufacturer will not need to further develop data to support a submission or that a device will receive FDA clearance or approval. However, it suggests that program participants may receive "sprint" discussions, interactive reviews, and greater levels of interaction and feedback from the Agency similar to the Breakthrough Device Designation program.

While the announcement of the program does not include comprehensive details regarding the program benefits, elements, timelines or process, the general description seems reminiscent of past pilot programs designed to promote greater coordination between FDA and CMS on premarket review and coverage decisions for medical devices that address certain policies or health outcomes. The announcement does not expressly state whether CMS will play a direct role in the review process as it has with past FDA pilot programs such as the Early Payor Feedback Program (EPFP) and Parallel Review of medical devices pilot program with CMS. The announcement also does not describe in detail how FDA and CMS plan to use RWE or RWD obtained from the TEMPO Pilot.

The TEMPO Pilot program is an extension of FDA's Home as Healthcare Hub program and similar pre-existing initiatives designed to address the growing shift in traditional healthcare delivery models from in-clinic settings to the home. The recognition that digitally enabled care has the potential to improve health outcomes and access to care aligns with FDA's regulatory priorities. As with other pilot programs, the success of the program will depend on the Agency's ability to strike the appropriate balance between efficiency and innovation, risk-based decision-making, and the statutory constraints in which it is required to operate.



Food, beverage, and dietary supplements

2025

Chemicals, additives, and contaminants

The MAHA Commission, launched in February 2025 by President Trump and chaired by HHS Secretary Robert F. Kennedy Jr., has driven a major federal push to combat diet-related chronic disease. The MAHA Commission's Make Our Children Healthy Again 100-day assessment focused on children, examining obesity, diabetes, neurodevelopmental disorders, mental health challenges, contributing factors, federal programs, and industry influence, as discussed here. The MAHA Commission's September 2025 Make Our Children Healthy Again Strategy Report (Strategy Report) outlined a roadmap to "end childhood chronic disease," prioritizing food safety reforms, stricter chemical oversight, and agency realignment. Key recommendations included phasing out petroleum-based food dyes, updating generally recognized as safe (GRAS) regulations, and enhancing post-market chemical reassessment, while addressing risks from contaminants like microplastics. FDA and the U.S. Department of Agriculture (USDA) are working toward a uniform definition of "ultra-processed foods" (UPFs). Together with HHS, FDA and USDA issued the Ultra-Processed Foods; Request for Information in July 2025, requesting data and information to assist in developing a uniform definition of UPFs. With the comment period closed, FDA will likely be working toward a proposed rule. Once finalized, it is expected that the Administration will use this definition in several different policy initiatives, including around labeling, nutrition advice, and federally subsidized nutrition programs like Supplemental Nutrition Assistance Program (SNAP) and school lunches.

In addition, in August 2025, Dr. David A. Kessler, who served as FDA Commissioner from 1990 to 1997, filed a petition to revoke GRAS status for refined carbohydrates, echoing MAHA's call to close the "GRAS loophole" that dominates UPFs. In March 2025, Secretary Kennedy held a closed-door meeting with food industry leaders, where he pressed for reductions in additives, particularly FD&C colors requiring batch certification. After the Strategy Report was issued, an additional closed-door meeting was reported to be held in mid-November 2025, bringing together stakeholders to discuss many of the recommendations in the Strategy Report.

In May 2025, FDA and National Institutes of Health (NIH) announced the Nutrition Regulatory Science Program, a joint research initiative created, according to an NIH press release, to address the diet-related chronic diseases crisis and "provide critical information to inform effective food and nutrition policy actions to help make Americans' food and diets healthier."

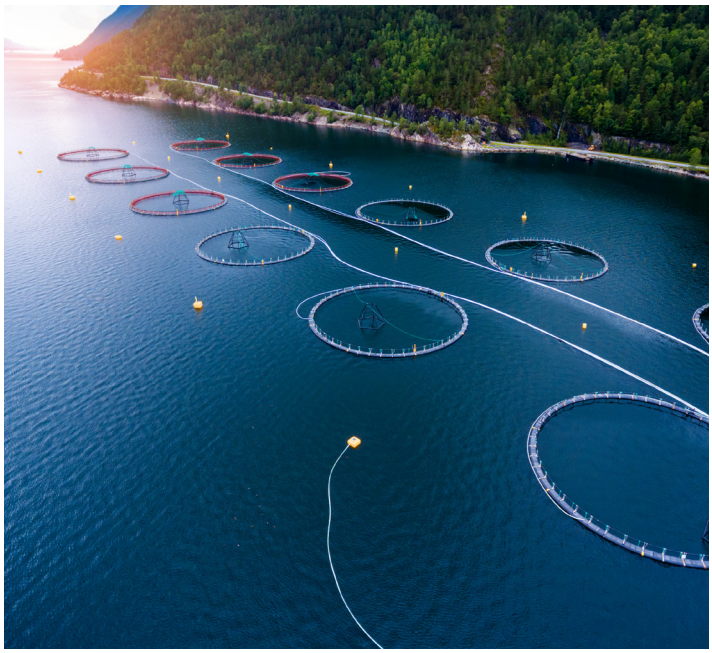
Together, these developments signal a sweeping effort to tighten chemical food safety standards, define UPFs, and accelerate the shift toward greater transparency in the food supply, driven by coordinated federal initiatives and growing state-level momentum.

Together, these actions mark an unprecedented shift in food safety and ingredient regulation at both federal and state levels. These efforts align with broader FDA initiatives under Secretary Kennedy.

One initiative that is gaining momentum is reform of the process for GRAS with the goal of providing greater transparency regarding ingredients in the food supply. Currently many companies introduce new ingredients using the "self-affirmation" GRAS pathway that does not required pre-market review by, or notification to, FDA. The Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs (OIRA) began reviewing FDA's proposed rule, "Substances Generally Recognized as Safe," in December 2025. Originally slated for publication in October 2025, the timeline was likely delayed by the government shutdown. If finalized, the rule would amend GRAS regulations in 21 CFR Parts 170 and 570 to require mandatory submission of GRAS notices for substances used in human and animal food, including direct ingredients, and indirect additives from packaging. FDA would maintain and update a public-facing GRAS notice inventory for all substances subject to mandatory notice and clarify the process for determining when a substance is not GRAS. Substances already listed or affirmed as GRAS by regulation, or those with an FDA "no questions" letter, would remain exempt. Self-affirmed GRAS substances would need FDA notification to continue use, or risk being deemed unapproved and any food containing them considered adulterated.

Color additives remain a major focus. At the end of the Biden Administration, FDA announced in January 2025 that it will revoke its authorization for the use of FD&C Red No. 3 in all foods and ingested drugs under the Delaney Clause due to evidence of cancer in laboratory animals, despite FDA's conclusion that Red No. 3 did not pose a risk to humans. In April 2025, under the Trump Administration, Secretary Kennedy announced plans to work with the food industry to phase out all petroleum-based synthetic dyes by the end of 2026, including FD&C Green No. 3, FD&C Red No. 40, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Blue No. 1, and FD&C Blue No. 2, while revoking authorizations for Orange B and Citrus Red No. 2. FDA has updated its chemical review list, adding azodicarbonamide (ADA), Blue dye 1, Blue dye 2, butylated hydroxyanisole (BHA), Green dye 3, Red dye 40, Yellow dye 5, and Yellow dye 6 to the list. To support industry transition, FDA approved several natural alternatives for food effective June 26, 2025: Galdieria extract blue, calcium phosphate, and butterfly pea flower extract. In July 2025, FDA also approved a petition to use gardenia (genipin) blue in foods under GMPs.

Beyond federal agency action, Congress introduced three major bills targeting GRAS reform aimed at greater transparency. These bills include requiring FDA review of all GRAS ingredients, thereby eliminating the GRAS self-affirmation pathway.



In addition, more than 35 states have advanced legislation addressing food and color additives and UPFs. These state measures vary widely: some mandate warning labels or disclosures, others ban certain additives in public schools or restrict the purchase of certain foods under SNAP, and a few impose statewide ingredient bans. A number of these state bills have already passed into law (or received SNAP waivers from USDA), with compliance timelines ranging from the 2025-2026 school year through early 2028.

Class action litigation and aggressive plaintiff tactics have amplified scrutiny of claims like "100% Natural," "No Preservatives," "Healthy," and "No Artificial Ingredients."

States have been increasingly proactive in enforcement. For example, the Texas Attorney General issued civil investigative demands to major food companies over "healthy" claims tied to synthetic dyes, leading to voluntary compliance agreements with General Mills (June 2025) and WK Kellogg Co. (August 2025) to remove artificial colorings by 2026-2027.

Growing regulation of synthetic dyes and UPFs, combined with emerging science linking them to chronic health conditions, is fueling personal injury and mass tort exposure. The evolving regulatory landscape points to increased accountability and a potential wave of diet-related injury lawsuits.

HHS and FDA announced the rollout of the Chemical Contaminants Transparency Tool, a searchable database allowing users to find out about possible chemical contaminants in foods and other products.

In January 2025, FDA released its final guidance on Action Levels for Lead in Processed Food Intended for Babies and Young Children as part of its Closer to Zero initiative. We continue to watch for the release of draft guidance documents establishing action levels for cadmium and for inorganic arsenic in food intended for babies and young children.

These guidance documents were expected by year end but were delayed, possibly due to a combination of reduced staff and the lengthy government shutdown.

An FDA Constituent Update released in mid-April 2025 sets out the final results from the Agency's testing of domestic and imported bottled waters for PFAS. The Agency tested 197 samples of bottled waters sold at retail locations across the US in 2023 and 2024, looking for 18 types of PFAS, among them the six PFAS for which EPA has established maximum contaminant levels for drinking water. Of the 197 samples, only ten had detectable PFAS levels, the Update stated, "none of which had levels that would have exceeded the maximum contaminant levels."

FDA issued a Notice in the Federal Register announcing that, as of January 6, 2025, 35 food contact notifications (FCNs) related to the use of PFAS as a grease-proofing substance in paper or paperboard food packaging are no longer effective.

FDA continues to update its framework for chemical safety in the food supply. In June 2025, FDA requested public comment on a proposed Tool for the Prioritization of Food Chemicals for Post-Market Assessment, both those intentionally added (*e.g.*, food additives, GRAS substances) and unintentional contaminants. The proposed approach uses Multi-Criteria Decision Analysis (MCDA) to score chemicals through a pre-determined set of criteria that takes into account factors specific to exposure from food. In July 2025, FDA released its Expanded Decision Tree (EDT) chemical toxicity and risk screening tool, designed to evaluate chemicals based on their structural features to determine the safety of their use in foods.

The Agency stated that, in the months to come, it will introduce a modernized, evidence-based prioritization scheme for reviewing existing chemicals; finalize a systematic post-market review process; issue an updated list of post-market chemicals under review; and expedite its review of such chemicals.

In May 2025, FDA announced approvals for three new color additives from natural sources: butterfly pea flower extract (blue), galdieria extract (blue), and calcium phosphate (white). We continue to watch for the release of a draft guidance document regarding food colors derived from natural sources – specifically the use of fruit juice and vegetable juice as color additives in food. This guidance document was anticipated, but not published, by year end.

In September 2025, FDA published a final rule amending existing regulations to allow the use of hydrogen peroxide in food, including meat and poultry, as an antimicrobial agent, oxidizing and reducing agent, and bleaching agent, and to remove sulfur dioxide. Effective September 4, FDA has amended the food additive regulations to provide for safe use of vitamin D3 as a supplement in yogurt and other cultured dairy products fermented with *Lactobacillus delbrueckii*, subspecies *bulgaricus* and *Streptococcus thermophilus* at a higher level than previously allowed.

There were also several developments around microbiological contamination in 2025. In May 2025, FDA's Coordinated Outbreak Response & Evaluation (CORE) Network released its 2023 Annual Report. In 2023, the CORE Signals and Surveillance Team evaluated 69 incidents and initiated 25 outbreak responses. As a result of these investigations, FDA issued 10 public health advisories notifying the public of multistate outbreaks of foodborne illnesses or adverse events. The report provides more detail about enforcement actions and trends in foodborne outbreaks. It is reported that in 2025, FDA investigated more than 30 multi-state outbreaks.

In January 2025, FDA issued a draft Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event guidance addressing pathogens in low-moisture ready-to-eat foods aimed at helping industry prevent and respond to these contamination events, including expectations around sanitation programs, environmental monitoring and corrective actions. In April 2025, USDA's Food Safety Inspection Service (FSIS) announced a notice to withdraw its 2024 proposed overhaul of salmonella regulatory framework for poultry products. In December 2025, FSIS issued a notice to delay further (FSIS had already delayed this in a notice in April) the date it will begin sampling not ready-to-eat breaded, stuffed chicken products for salmonella due to inaccuracy of current available test methods resulting in false positives. No future date for testing was provided. This testing was to implement a 2024 final determination by FSIS that these products would be adulterated if they contain 1 colony forming units (CFU) or more of salmonella.

Dietary supplements

In 2025, six states have introduced legislation to restrict the sale of weight-loss and muscle-building dietary supplements to individuals under 18. As of now, New York remains the only state with an active law on this issue. The San Francisco City Attorney filed a lawsuit targeting leading food manufactures, alleging marketing and sales practices have contributed to chronic disease and significant public health costs for local governments and seeking restitution for public health costs, civil penalties and injunctive relief. This action marks the first time a government has initiated this type of lawsuit. To learn more about UPFs and how to minimize risk, watch DLA's Consumer Goods, Food, and Retail webinar.

We continue to watch for the release of a draft guidance document establishing identity and safety information about new dietary ingredient (NDI) notifications. This guidance document was expected by year end.

In December 2025, FDA issued a Letter to the Dietary Supplement Industry on the DSHEA Disclaimer. FDA indicated it has received several industry requests to amend the labeling regulation at 21 C.F.R. § 101.93(d), which governs the placement of the Dietary Supplement Health and Education Act of 1994 (DSHEA) disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." The Agency stated that it intends to exercise enforcement discretion over the requirement that the disclaimer appear on each panel of a product label where a dietary supplement claim, such as a structure or function claim (also known as a "403(r)(6)) claim") appears.

In 2025, FDA, FTC, and the National Advertising Division (NAD) increased scrutiny of dietary supplement marketing practices, particularly influencer-driven campaigns and labeling. Enforcement actions focused on companies making unsubstantiated disease claims, which caused products to be misbranded as unapproved new drugs under the FDCA. Regulators emphasized compliance with truth-in-advertising standards, proper influencer disclosures, and scientific substantiation for health-related claims, signaling a coordinated effort to curb deceptive practices in the supplement industry.

Labeling and disclosures

In January 2025, FDA published its Evaluating the Public Health Importance of Food Allergens Other Than The Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act guidance outlining how FDA evaluates the public health importance of food allergens not among the nine major allergens, aimed at FDA staff and stakeholders, including those preparing citizen petitions.

The guidance details the scientific factors and evidence FDA considers for labeling and production decisions and finalizes its evaluation framework.

Key updates clarify that non-Immunoglobulin E (IgE)-mediated reactions can serve as supplemental evidence, incorporate references to the recent United Nations Food and Agriculture Organization and World Health Organization expert report, and expand discussion of prevalence data when a food is not commonly consumed in the US.

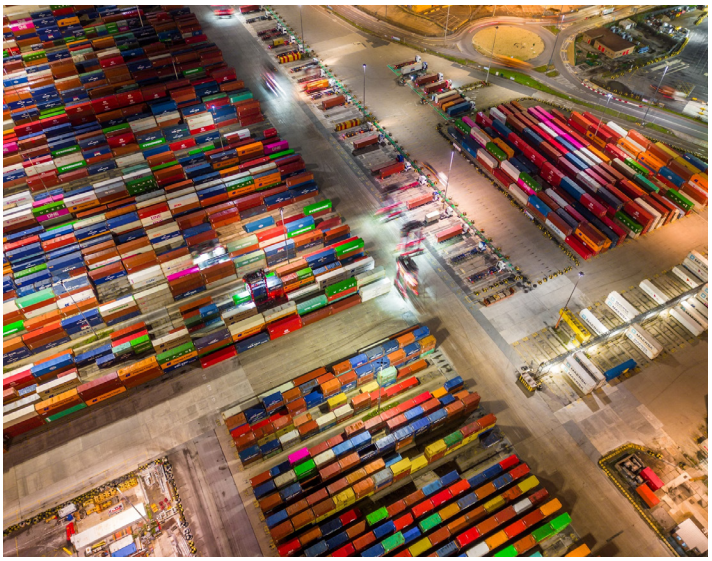
In March 2025, FDA issued the Guidance for Industry: Questions and Answers Regarding Food Allergen Labeling, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5), now in a searchable format. The guidance consolidates prior versions and clarifies labeling requirements for the nine major allergens, with updates such as expanded definitions for eggs and milk and removal of certain tree nuts, including coconut, from the major allergen list.

In February 2025, FDA announced it would postpone the effective date for its final rule defining the meaning of the term "healthy" until April 28, 2025. Under the 2025 Appropriations Bill, the compliance date for this rule is early 2028. During this compliance period, manufacturers may continue using the previous "healthy" definition or adopt the new one. Additionally, states are preempted from enforcing any labeling requirements for "healthy" that differ from either the old federal standard or the new rule until the compliance date.

FDA set January 1, 2028 as the uniform compliance date for all final food labeling rules issued between January 1, 2025 and December 31, 2026. This does not affect compliance dates for rules finalized before 2025. The uniform date is intended to reduce industry costs by aligning updates, allowing time to use existing labels and develop new ones, and FDA encourages earlier compliance where feasible.

A U.S. laboratory study of over 300 primary household shoppers evaluated 15 proposed front-of-package "Healthy" symbols using Best-Worst Scaling and identified two clear favorites. The top-ranked options were labels 8a and 12a, indicating strong consumer preference for those designs. The findings may inform FDA's selection of a preferred "healthy" label for packaged foods.

The comment period for FDA's Front-of-Package Nutrition Information proposed rule closed in July 2025 with nearly 12,000 public comments submitted. While industry expressed concerns about this proposal, the Administration views this rule as a tool that provides greater transparency for consumers, allowing them to make dietary choices that can help to reduce chronic dietary disease rates. As such, this rule, discussed in detail here, is identified as a priority in the MAHA Strategy Report released in September 2025.



Infant Formula

In January, FDA released its draft guidance on Establishing Sanitation Programs for Low-Moisture Ready-to-Eat (LMRTE) Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event to, in part, help infant formula manufacturers comply with cGMP requirements of 21 CFR Part 106.

In March 2025, FDA announced Operation Stork Speed, an initiative designed to enhance "the ongoing quality, safety nutritional adequacy, and resilience of the domestic infant formula supply." Under this initiative, the agency will review nutrient requirements for infant formula, expand testing for heavy metals and other contaminants in formula and children's foods, and extend the personal importation policy. It will also enhance transparency through regular stakeholder updates, explore clearer labeling, and collaborate with NIH and other scientific bodies to close research gaps on short- and long-term health outcomes of formula feeding.

In May 2025, FDA issued an RFI as it seeks to determine if the nutritional requirements for infant formula should be revised.

At FDA's June 2025 infant formula roundtable, Commissioner Martin Makary noted parents want more options without seed oils, added sugars, or corn syrup, and said FDA may use its regulatory authority to encourage better formulations. Thirteen scientific experts discussed improving formula composition, harmonizing U.S. standards with global norms, enhancing labeling transparency, and accelerating market access for improved products. Brenner concluded that FDA will work with HHS partners to advance these efforts. The Reagan-Udall Foundation released a report summarizing insights from September 2025 roundtables on infant formula safety. The discussions, involving public health experts, caregivers, researchers, and manufacturers, support FDA's efforts under Operation Stork Speed – a May 2025 initiative with HHS to strengthen formula safety and supply following the 2022 shortage.

In November 2025, ByHeart voluntarily recalled all batches of its infant formula due to risk of *Clostridium botulinum*. The recall was initiated in response to an investigation into a recent outbreak of infant botulism, which, as of the end of 2025, resulted in 51 hospitalizations across 19 states.

Alternatives to animal-derived foods

FDA issued a draft guidance,

> Labeling of Plant-Based Alternatives to Animal-Derived Foods in January 2025, outlining recommended naming and labeling practices for plant-based alternatives to animal-derived foods under its jurisdiction, such as egg, seafood, poultry, meat, and certain dairy substitutes. The guidance excludes plant-based milks and animal proteins produced by microflora, and it emphasizes that products must use a common or usual name—or a clear statement of identity – that specifies the plant source; "plant-based" alone is not sufficient. FDA allows use of familiar animal-food terms (*e.g.*, "burger" or "cheddar"), but they should clearly identify and qualify the plant source (*e.g.*, "Soy-Based Cheddar Cheese"), and the statement of identity must appear in bold on the principal display panel in a size reasonably related to the most prominent text.

In May 2025, FDA sent a "no questions" letter to San Francisco-based Wildtype concerning its cell-cultured salmon, making it the first company to complete the US pre-market scientific and safety consultation product for a seafood product. In July 2025, FDA issued a "no questions" letter, concluding Believer Meats' cultured chicken cell material is GRAS for use in human food – the fifth cell-cultured animal product to receive such a determination.

Supply Chain Safety, Imports, and Supplier Verification

FDA has issued a proposed rule to extend the compliance date of the Requirements for Additional Traceability Records for Certain Foods (Food Traceability Rule) by 30 months until July 20, 2028. While that proposed rule has not been finalized, the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (2026 Appropriations Bill) prohibits FDA from spending any appropriated funds to "administer or enforce" this rule in FY 2026. During this period, FDA must work closely with farms, restaurants, retailers, and warehouses to develop practical flexibilities for lot-level tracking without requiring case-level detail. Within 180 days, the Agency must issue recommendations to industry and provide guidance on handling food waste recovery, reclamation, transfers, and returns. FDA will also run data intake exercises to test its Product Tracing System and identify technical challenges before full implementation. These are all indicators that FDA may be making some changes to the final rule prior to the July 2028 effective date.

FDA continues to emphasize compliance with supplier verification. FDA issued 25 warning letters this year for various Foreign Supplier Verification Program (FSVP) violations.

The annual application window for FDA's Voluntary Qualified Importer Program (VQIP) portal for FY 2026 benefits closed on September 1. In July 2025, FDA announced FY 2026 user fee rates for the VQIP and Accredited Third-Party Certification Program (TPP).

In September 2025, FDA published a final rule amending its prior notice regulations for articles of food arriving by international mail. This rule requires that, starting October 1, 2026, prior notice must include the name of the mail service and a tracking number, enhancing FDA's ability to monitor, inspect, and coordinate shipments that may pose public-health risks.

In July 2025, FDA announced that due to a Customs and Border Protection (CBP) policy change, "all entries of FDA-regulated products must be reviewed for admissibility by FDA, regardless of their quantity or value." This ended the previous "de minimis" exemption for low-value shipments, potentially increasing the number of products held, denied admissibility, or put on import alert.

Inspections

In May 2025, FDA announced that it will expand the use of unannounced inspections at such foreign manufacturing facilities. Every year, FDA carries out an estimated 3,000 inspections, in more than 90 countries, of foreign manufacturing facilities that produce foods, medicines, and medical products for American consumers. This is in addition to the Agency's more than 12,000 annual inspections of domestic food and drug manufacturing sites. However, while inspections carried out in the US are often unannounced, foreign facilities are given advanced warning of a coming inspection, typically weeks ahead.

In June 2025, the HHS Office of Inspector General (OIG) published FDA Food Safety Inspections of Domestic Food Facilities, a report required under the Food Safety and Modernization Act (FSMA). The report, which reviews data on FDA inspections carried out between FY 2017 and 2023, finds that since the start of the COVID-19 pandemic, FDA has conducted fewer food safety inspections; that it often has failed to meet required timeframes and has used its resources inefficiently, most notably by seeking to inspect thousands of facilities that were no longer in operation; and that its "identification of significant violations has decreased steadily over time."

In June 2025, FDA announced a revision of its Compliance Program setting out the procedures and guidelines FDA inspectors follow when inspecting food facilities, both in the US and abroad. The update aligns inspection activities with current general food labeling requirements and clarifies expectations to ensure consistent enforcement across domestic and foreign operations – namely incorporating sesame as the ninth major food allergen, including guidance on gluten-free labeling requirements, and aligning with the 2016 updates to the Nutrition Facts label.

Standards of identity

FDA implemented three separate rulemakings in July 2025, announcing its intention to eliminate 52 standards of identity (SOIs) for food products that it considers obsolete or unnecessarily burdensome. FDA issued a direct final rule to rescind the SOIs for 11 foods no longer sold in the US, and two proposed rules, which would revoke an additional 41 SOIs. One proposed rule would eliminate 18 standards for dairy products such as milk, cream, cheeses, and frozen desserts (among them acidified milk, low sodium cheddar cheese, cream cheese with other foods, high-moisture jack cheese, and goat's milk ice cream). The other would remove 23 standards covering bakery products, macaroni and noodles, canned fruit juices, fish and shellfish, and certain food dressings and flavorings.

Other developments

FDA suspended the Food Emergency Response Network Proficiency Testing Program in April 2025 as a result of staff reductions at HHS. The Proficiency Testing Program is critical for ensuring that state and federal labs can accurately detect contaminants in food during emergencies. The suspension raises concerns about slower response times and reduced capacity to identify foodborne hazards during outbreaks.

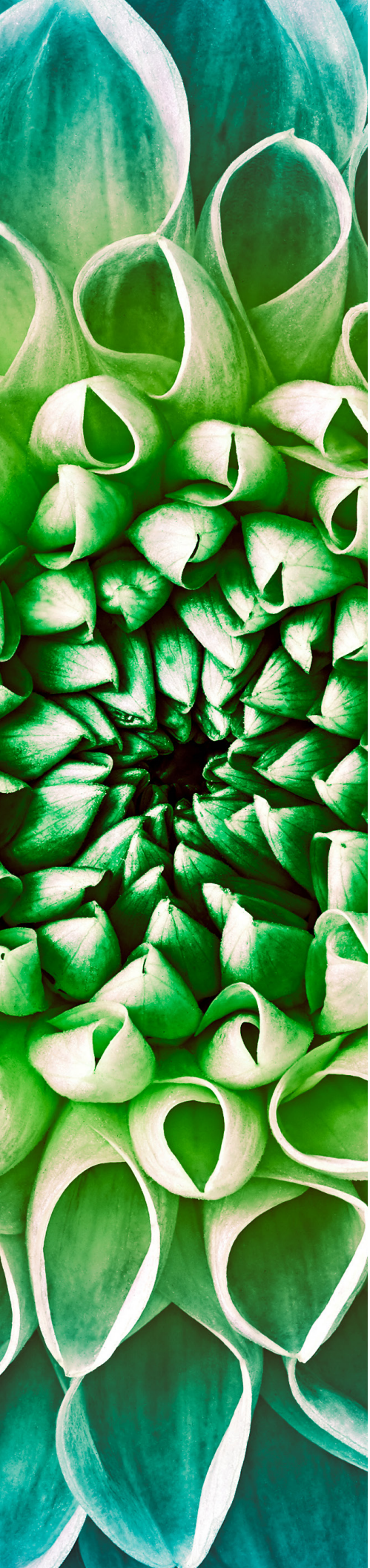
In May 2025, FDA and NIH announced the Nutrition Regulatory Science Program, a joint research initiative created, according to an NIH press release, to address the diet-related chronic diseases crisis and "provide critical information to inform effective food and nutrition policy actions to help make Americans' food and diets healthier."

HHS and the USDA, which jointly issue the Dietary Guidelines for Americans every five years, typically issue them in December. However, the Guidelines have been delayed and will not arrive until early 2026.

Both USDA and FDA are taking action to protect the US food supply from *Cochliomyia hominivorax*, commonly called New World Screwworm (NWS), a devastating parasite endemic in parts of South America and the Caribbean that in July 2025 was detected less than 400 miles south of the US-Mexico border.

Next year, we continue to watch for the release of a draft guidance document providing action levels of opiate alkaloids on poppy seeds. This guidance document was anticipated in 2025.

Next year, we await the release of chapter 12 entitled "Preventive Controls for Chemical Hazards" of its Hazard Analysis and Risk-Based Preventive Controls for Human Food. This guidance document was anticipated but not published by 2025 year end.



Cosmetics

2025

MoCRA was enacted in 2022 to provide FDA with increased authorities and oversight of the cosmetic industry. While the statute required FDA to issue several rules and take other actions within specified timeframes, the agency has fallen behind in implementation. Key updates include:

- GMPs: MoCRA required FDA to propose GMPs for cosmetic product facilities by December 29, 2024, and a final rule by December 29, 2025. To date, FDA has not proposed a GMP rule nor announced an expected publication date.
- Fragrance Allergen Disclosure: MoCRA mandated a proposed rule by June 2024, requiring certain fragrance allergens to be listed on cosmetic labels. FDA has yet to issue a proposal, and the rule is now anticipated by May 2026.
- Reporting Guidance: MoCRA required that responsible persons must report serious adverse events within 15 business days. In September 2025, FDA released information explaining how consumers, health professionals, and industry can report complaints, adverse events, product defects, or serious adverse events related to cosmetics. The webpage provides clear steps for consumers and health professionals to report issues through MedWatch, online, by mail or fax, or by calling FDA's Food and Cosmetics Information Center, and outlines industry requirements for reporting serious adverse events electronically or in paper form.
- Use of PFAS in cosmetic products: MoCRA mandated that FDA evaluate and report on the use of PFAS in cosmetic products. In December 2025, FDA released this report, which focused on PFAS intentionally added as cosmetic ingredients, rather than those present as contaminants. After reviewing available scientific evidence on potential safety concerns, the FDA concluded that current data is insufficient to make definitive safety determinations, highlighting significant uncertainty due to gaps in knowledge about PFAS exposure through cosmetics. The Agency stated it will continue monitoring emerging scientific data to support MAHA's efforts to reduce PFAS in the food and consumer product supply chain.
- Mandatory cosmetics recalls: MoCRA granted FDA authority to mandate recalls of cosmetics products. In December 2025, FDA issued its Questions and Answers Regarding Mandatory Cosmetics Recalls, addressing common questions and explaining the Agency's current approach to implementing these requirements.
- In November 2025, FDA withdrew its proposed rule for Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products that would have required manufacturers of talc-containing cosmetic products to test their products, or the talc components of those products, for asbestos, and to maintain records showing their compliance with the rule. In its withdrawal notice, FDA explained that the decision was based on comments received during the proposed rule's comment period, which raised issues requiring further review before finalizing regulations to establish standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products, as mandated by MoCRA.

In 2026, we await FDA issuance of a proposed rule to prohibit the use of formaldehyde (FA) and formaldehyde-releasing chemicals (*e.g.*, methylene glycol) as an ingredient in hair smoothing or hair straightening products marketed in the US. The publication of this proposed rule was pushed back from March to December 2025, but it was not published by year end.

FDA issued 18 warning letters in November 2025 to companies selling unapproved and misbranded injectable botulinum toxin products marked as cosmetic treatments.

Tobacco

2025

In January 2025, FDA issued its Validation and Verification of Analytical Testing Methods Used for Tobacco Products guidance, which provides recommendations on producing validation and verification data for analytical procedures and methods used to support regulatory submissions to the Center for Tobacco Products (CTP). Specifically, the guidance covers analytical testing of tobacco product constituents, ingredients and additives as well as chemical stability testing of finished tobacco products.

In January 2025, FDA also issued a proposed rule, Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products, which would regulate nicotine yield by establishing a maximum nicotine level in certain combustible tobacco products, including cigarettes, in order to reduce the addictiveness of these products. The draft rule would limit nicotine levels in most combustible tobacco products to 0.7 mg/g of tobacco, which the Agency derived from FDA's analysis of studies regarding the likely effects of reducing nicotine. These studies demonstrated that "extended exposure to very low nicotine content (VLNC) combusted cigarettes is associated with reduced addiction potential, dependence levels, number of cigarettes smoked per day and increased quit attempts among people who currently smoke cigarettes, without increasing toxicant exposure, craving, withdrawal, or compensatory smoking."

In September 2025, FDA announced the launch of a pilot program to streamline the review of premarket tobacco product applications (PMTAs) and to evaluate tobacco products on a "continuum of risk," with the Agency acknowledging that combustible products are typically the most harmful to health while non-combustible products may pose lower health risks. As of December 2025, FDA had authorized six nicotine pouch products through the pilot program. Even with this pathway, some tobacco manufacturers launched new smokeless tobacco products without receiving FDA authorization owing to delays in FDA's review processes and asserting that FDA has not made approval decisions within the legally prescribed timeframes.

As part of the 2026 Appropriations Bill, CTP must submit a report detailing its activities to educate retailers in determining which products are legal for sale. FDA also must update its "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization" to expand FDA's prioritized enforcement to flavored disposable ENDS products and to define the term "disposable ENDS product." CTP is also required to submit a semi-annual written report to Congress on the progress it is making in removing all illegal ENDS products from the market. As part of the legislation, Congress also amended section 801(a) of the FDCA to expressly include tobacco products throughout.

At the state level, at least 14 states have enacted laws that require manufacturers of ENDS products to certify to the state that their products have received a marketing order from FDA or are the subject of a pending review (*i.e.*, under FDA's enforcement discretion). These state "directories," which are a response to lax federal enforcement against noncompliant ENDS products, have been the subject of legal challenges with varied outcomes. In some cases, the courts have concluded that these directories are preempted under the FDCA, while others have concluded that manufacturers without marketing orders lack standing to challenge the directories. We will continue to monitor the legal status of these directories.

Cannabis and kratom

2025

The biggest news in the cannabis space is that Congress passed and President Trump signed legislation as part of the 2026 Appropriations Bill that bans most consumable hemp products starting November 2026, effectively outlawing intoxicating cannabinoids like delta-8 tetrahydrocannabinol (THC), delta-10 THC, tetrahydrocannabinolic acid (THCA), hexahydrocannabinol (HHC), and THC acetate (THC-O). This action effectively closed the "hemp loophole" in the 2018 Farm Bill that only restricted delta-9 THC levels in hemp, leading to a proliferation of "hemp-derived" intoxicating products, such as those with delta-8 THC and THCA. This last minute amendment, discussed in detail here, in the 2026 Appropriations Bill will have substantial impacts on hemp market by:

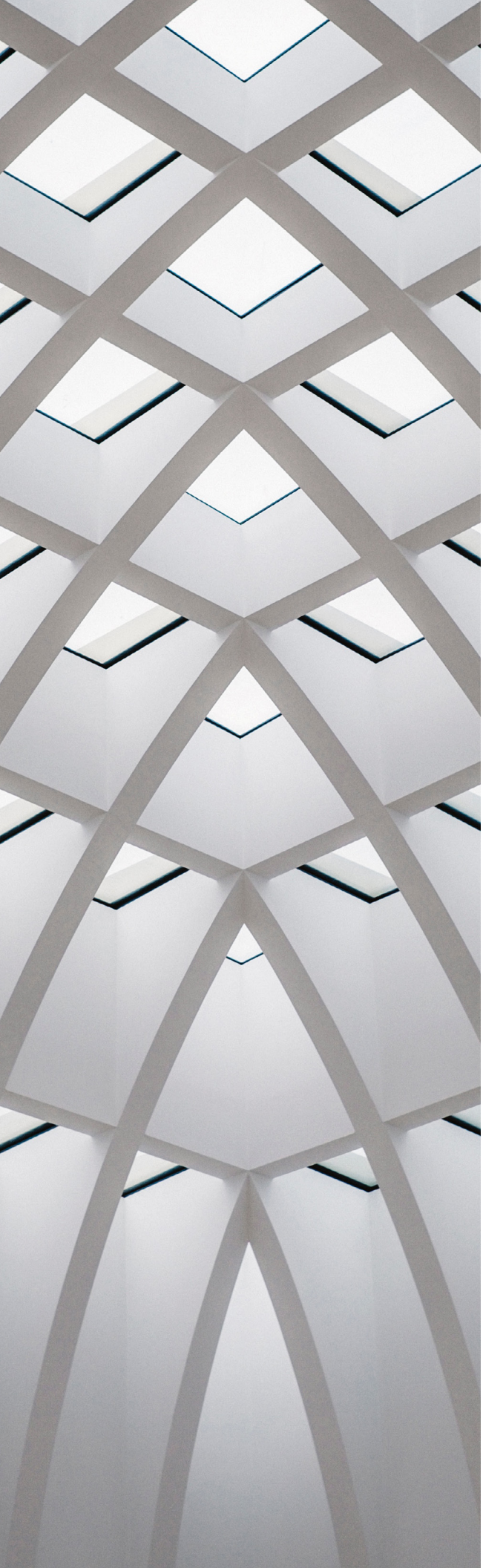
- Redefining hemp by restricting total THC (including THCA) to levels at or below 0.3 percent on a dry-weight basis
- Clarifying that synthetic cannabinoids, such as delta-8 and THCA, are excluded from the definition of hemp, even when derived from legal hemp
- Establishing a limit of 0.4 milligrams of total THC (including THCA) per container in a final hemp-derived product

Meanwhile, FDA still remains active in overseeing cannabis products. In January, FDA took steps to address the use of cannabis-derived products in animal products by publishing an RFI seeking input from veterinarians and the public on the use of cannabis-derived products, especially cannabidiol (CBD), in animals. This effort, led by the CVM, aims to fill significant knowledge gaps about the safety and effectiveness of hemp-derived products in veterinary practice. In particular, the Agency is gathering data on usage trends, product types, safety concerns, potential drug interactions, adverse events, and perceived benefits, noting that no FDA-approved animal drugs currently contain CBD.

In addition, FDA continues to take enforcement actions in this area. FDA issued several warning letters in 2025 to companies marketing unapproved cannabis alternative products, including CBD, delta-8 THC, and other novel cannabinoids. FDA emphasized that no cannabis derived products (including CBD and deta-8 THC are approved for food (human or animal) or dietary supplements. The letters cited unapproved drug claims, inaccurate or misleading labeling around cannabinoid content and dosage, and lack of evidence for effectiveness as well as safety risks. The Drug Enforcement Administration's (DEA's) long-anticipated hearing to move cannabis from Schedule I to Schedule III was indefinitely postponed in January 2025, but on December 18, 2025, President Trump signed an Executive Order to direct the Attorney General to take all necessary steps to complete the rulemaking process related to rescheduling marijuana to Schedule III.

FDA continued issuing warning letters to companies marketing products containing CBD and delta-8 THC, even when no disease claims were made. Enforcement focused on products deemed adulterated, especially those appealing to children or mimicking established brands. These letters were often joint actions with the Federal Trade Commission (FTC). Products marketed as foods or dietary supplements with cannabis derivatives remain a priority for FDA enforcement under the FDCA, particularly when sold across state lines without proper approvals.

FDA identified 7-hydroxymitragynine (7-OH) – a concentrated kratom derivative – as an emerging opioid threat. In July 2025, the Agency recommended scheduling 7-OH under the Controlled Substances Act and issued warning letters to companies selling products with synthetic or chemically manipulated 7-OH. Warning Letters cited illegal marketing, adulteration, and unapproved drug claims for products like gummies, drink mixes, and shots containing 7-OH. FDA emphasized that 7-OH is not lawful in dietary supplements or conventional foods and highlighted its potency, which can exceed that of morphine.



Clinical trials

2025

In January 2025, FDA issued draft guidance, entitled, "Study of Sex Differences in the Clinical Evaluation of Medical Products: Guidance for Industry" and "Evaluation of Sex Differences in Clinical Investigations: Information Sheet Guidance for Industry," which provide recommendations for increasing enrollment of females in clinical trials and non-interventional studies. In March 2025, FDA issued a revised "Evaluation of Sex-Specific Data in Medical Device Clinical Studies: Guidance for Industry and Food and Drug Administration Staff," which provides guidance on the study and evaluation of sex-specific data in medical device clinical studies.

As discussed here, in February 2025, FDA removed its "Removal of Diversity in Clinical Trials" guidance after President Trump issued an EO on January 27, 2025 ordering a pause on certain diversity, equity, and inclusion (DEI) efforts.

FDA issued the following IRB-related guidance documents in February 2025:

- "Information Sheet: Institutional Review Boards Frequently Asked Questions: Guidance for Institutional Review Boards and Clinical Investigators": FDA provides, in question-and-answer format, information about IRB organization, membership, procedures, and records as well as informed consent process and document content and other general questions about clinical investigations
- "Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs": The guidance is part of an effort to harmonize HHS Office for Human Research Protections (OHRP) and FDA regulatory requirements and guidance for human subjects research. Most significantly, it incorporates a checklist with both agencies' requirements for written procedures for the IRB and the type of operational details to include in support of these requirements

During the COVID-19 pandemic, FDA adopted remote regulatory assessments (RRAs) to continue oversight of FDA-regulated products and FDA-regulated establishments. In June 2025, FDA issued an updated "Conducting Remote Regulatory Assessments Questions and Answers: Guidance for Industry." RRAs may be mandatory or voluntary, depending on the product area or type of review. For example, FDA may initiate a mandatory RRA for food importers as part of a Foreign Supplier Verification Program (FSVP) inspection, or for inspections conducted under section 704(a)(4) of the FDCA to review records or information in advance of – or in place of – a bioresearch monitoring (BIMO), drug, or device inspection. RRAs could help address gaps in FDA's resources for pre-approval inspections or inspections involving certain types of manufacturing changes as well as for foreign manufacturing operations.

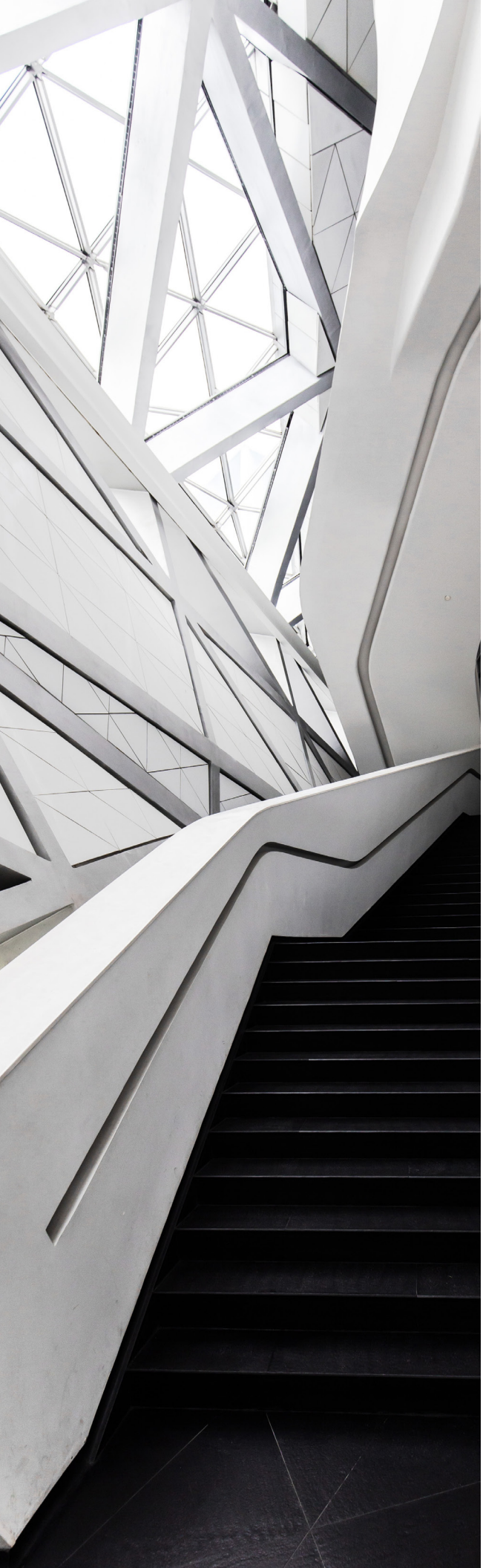
Because RRAs are not considered inspections, FDA will not issue a Notice of Inspection (FDA Form 482) or Notice of Inspectional Observations (FDA Form 483) following an RRA. Nevertheless, similar to the Form 483 process, FDA may conduct a close-out meeting and present a written list of observations to which a company is encouraged to respond within 15 business days.

There still may be challenges to using RRAs as a substitute for inspections from a transparency and confidentiality perspective. RRAs are not published to FDA's Inspections Classification Database. Additionally, RRA reports and other records provided to FDA during an RRA may be subject to Freedom of Information Act (FOIA) requests.

In September 2025, FDA issued its final "E6(R3) Good Clinical Practice (GCP): Guidance for Industry," providing a unified standard to facilitate mutual acceptance of clinical trial data between ICH member countries and regions. The updated guidance clarifies sponsor and investigator responsibilities; increases flexibility around trial design, data sources, and technology; and promotes quality by design and risk-based quality management in clinical trial conduct and oversight. In December 2025, FDA issued the following guidance documents related to the conduct of clinical trials:

- "Investigator Responsibilities — Safety Reporting for Investigational Drugs and Devices: Guidance for Industry" and "Sponsor Responsibilities — Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies," which replace the 2012 "Safety Reporting Requirements for INDs and BA/BE Studies" and 2009 "Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Reporting to IRBs — Improving Human Subject Protection," and more clearly delineate the respective roles of investigators and sponsors
- "Enhancing Participation in Clinical Trials — Eligibility Criteria, Enrollment Practices, and Trial Designs," which replaces the December 2020 guidance that emphasized "diversity" in trial populations and shifts focus to demographic factors (sex, race, ethnicity, age, location) as well as non-demographic characteristics, such as comorbid conditions, organ dysfunction, disabilities, extremes of weight, and populations with rare or low-prevalence diseases

The Agency also issued its "Processes and Practices Applicable to Bioresearch Monitoring Inspections: Guidance for Industry" in December 2025 to comply with section 3612(b)(2) of the Food and Drug Omnibus Reform Act of 2022 (FDORA). This section of FDORA directed FDA to issue guidance to describe processes and practices applicable to BIMO inspections of sites and facilities in section 704(a)(5)(C)(i) of the FDCA. These inspections include those sites or facilities used in developing an application or submission to FDA related to a marketing authorization; preparing, conducting, or analyzing the results of a clinical or non-clinical study submitted to FDA or a postmarket safety study; or holding records or information related to clinical or non-clinical studies.



Advertising and promotion of medical products

2025

The most significant development in the advertising and promotion landscape was President Donald Trump's issuance of a Presidential Memorandum in September 2025, directing the Secretary of HHS to ensure transparency and accuracy in DTC prescription drug advertisements. The Memorandum, which was not characterized as an EO, also directed FDA to take action to enforce existing prescription drug advertising laws to ensure that DTC ads are truthful and not misleading. The Memorandum and key takeaways are discussed in detail in our client alert, which is available here.

Later in September 2025, FDA issued approximately 100 Untitled Letters and Warning Letters to companies with a focus on DTC broadcast prescription drug advertisements. This is a significant uptick in enforcement; in contrast, CDER's Office of Prescription Drug Promotion only issued five untitled letters and no warning letters. The key violations cited in the letters included:

- Failing to communicate any or adequate risk information, particularly when compared to the presentation of the benefits or by otherwise minimizing risks
- Representing products as therapeutically equivalent without approval
- Failing to present the major statement in a clear, conspicuous, or neutral manner
- Failing to submit the advertisements under a Form FDA-2253 at the time of initial dissemination or publication
- Failing to adequately disclose contraindications
- Overrepresenting the benefits or magnitude of change or relief a patient may expect to experience
- Using frequent scene changes or attention-grabbing visuals that compete with the comprehension of the major statement

Another notable development took place in January 2025, when FDA issued its final "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers." The revised draft, issued in October 2023, replaced the March 2014 "Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices" (which had replaced the January 2009 "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Device"). Of note, in the final guidance, FDA clarified that scientific information on unapproved uses (SIUU) communication that is not squarely within FDA's articulated enforcement policy does not mean that FDA intends to rely on the communication alone to establish a new intended use.

FDA also clarified that certain communication techniques are not within the scope of the guidance or enforcement policy. These include celebrity endorsements, emotional appeals unrelated to scientific content, gifts, promotional tag lines, jingles, and premium offers (previously characterized as "persuasive marketing techniques" in the revised draft guidance). It also does not extend to "calls to value," which pre-judge the benefits of a product for individual patients (*e.g.*, "It's the best option for your X patients!"). FDA will apply existing interpretations and enforcement policies to these types of communications.

FDA stated that companies should use "scientifically sound" source publications, which follow generally accepted scientific principles for design and methodology (*e.g.*, for the relevant product or therapeutic area) rather than "clinically relevant" ones. FDA places the burden of assessing whether a study or analysis in a source publication is scientifically sound on the company, stating that they should be evaluated "in light of its limitations" (*e.g.*, flaws in study design or analysis, subsequently refuted conclusions). Also, FDA removed a statement indicating that early-stage data is unlikely to be reliable, but it also removed a statement that real-world data or real-world evidence could be scientifically sound or clinically relevant, seemingly taking a neutral position as to the evidentiary value of these types of evidence.

FDA clarified that communications can be based on a variety of source publications beyond reprints (*i.e.*, published scientific or medical journal articles), such as clinical practice guidelines or resources or reference texts, and encourages companies to make source publications available as part of a firm-generated communications.

Additionally, companies may use presentational elements or other communication techniques to help explain or illustrate scientific content, provided these are not used only to emphasize positive information, distract from unfavorable attention, or otherwise mislead or misrepresent. FDA also clarified that SIUU communications do not have to be separate and distinct; rather, appropriate separation (*e.g.*, no direct links between webpages for promotional and SIUU communications) minimizes the risk of representing that a product is safe or effective for unapproved uses.

In December 2025, FDA issued its finalized "Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers" guidance. The Agency clarifies that the guidance applies regardless of the medium of communication (*e.g.*, paper versus digital). In the prior draft guidance, FDA indicated that, if a promotional communication described a study in which a non-US-approved biological product was used as a comparator, the product should be accurately identified as such. FDA removed this recommendation from Question 2 in the final guidance. FDA also expressly states that sponsors may use non-US-licensed version of a US-licensed reference product as a comparator in certain studies to support similarity to the US-licensed reference product. Finally, FDA also includes more examples of scenarios in which comparative discussions between reference and biosimilar products may misleadingly suggest that a biosimilar is less safe or effective.

Enforcement and litigation

2025

Enforcement by the numbers

In 2025, domestic inspections rose to 12,538 from 10,786 in 2024, while foreign inspections decreased slightly to 2,223 from 2,783. The food and cosmetics sectors dominated FDA inspections, accounting for about 63.9 percent of all inspections. The most frequent citation was failure to develop a FSVP, consistent with trends observed in FY 2024.

In FY 2025, FDA issued more than 12,000 Warning Letters, slightly fewer than the 13,372 issued in FY 2024. The vast majority – more than 96 percent – were related to tobacco products. There was a 50-percent increase in Warning Letters issued by CDER in 2025. Of CDER's latest 100 Warning Letters, 40 percent included common violations such as cGMP non-compliance across formulation, testing, and documentation, adulterated finished pharmaceuticals, and unlawful sale of unapproved or misbranded drugs online.

In 2025, there were more than 2,160 recalls, showing no increase compared to the slightly more than 2,180 recalls reported in 2024. Of these, in 2025, more than 950 involved medical devices, approximately 304 were for biologics, 317 were for drugs, and just over 537 were related to food and cosmetics.

In March 2025, three former executives of Magellan Diagnostics pleaded guilty to federal charges for concealing a malfunction in the company's lead exposure testing devices, widely used between 2013 and 2017, that produced inaccurately low results for thousands of patients, including children. The government alleged that Magellan misled both customers and FDA about the devices' defects and their risks. The government concluded that the Company's actions triggered recalls and endangered public health, which led to Magellan agreeing to pay $42 million to resolve related criminal charges.

As described above, in September 2025, FDA launched a major crackdown on deceptive prescription drug advertising. It issued thousands of warning letters and about 100 cease-and-desist notices to pharmaceutical companies that used misleading ads. The Agency also began rulemaking to close what it described as the "adequate provision" loophole, which purportedly refers to FDA's practice of permitting manufacturers to provide a summary of the major risks associated with a prescription drug rather than the complete recitation of all risks identified in the approved labeling. To align with FDA's current DTC advertising guidance, manufacturers include a "major risk statement" in DTC ads for prescription drugs. Following an announcement by HHS, FDA stated that this practice allowed companies to obscure critical safety risks in broadcast and digital ads. This initiative and proposed rulemaking will focus on both traditional media and social platforms, where the Agency claims that undisclosed influencer promotions and content lacking fair balance between benefits and risks has become widespread.

Litigation

On March 31, 2025, the United States District Court for the Eastern District of Texas issued its final judgment in *American Clinical Laboratory Association v. FDA*, No. 4:24-CV-479-SDJ, 2025 U.S. Dist. LEXIS 59869 (E.D. Tex. Mar. 31, 2025). The Court vacated and set aside the LDT Final Rule, holding that the Agency exceeded its authority under the FDCA because LDTs are not devices. Rather, the Court held that FDA's device authorities are limited to "tangible, physical products" and that LDT services are "professional medical services that are qualitatively and categorically distinct." Further, the Court held that use of a medical device as part of an LDT service offering "does not transform [the] medical service into" a device. The Court also pointed to Congress' failure to enact legislation to expressly provide FDA with jurisdiction over LDTs as further evidence that the Agency currently lacks authority over them. The Court remanded the matter to the Secretary of HHS for further consideration, and the Agency rescinded the LDT Final Rule in September 2025.

On April 2, 2025, in *FDA v. Wages and White Lion Investments, LLC dba Triton Distribution*, et al. the U.S Supreme Court unanimously upheld FDA's denial of two companies' marketing authorization for certain flavored e-liquids products used in ENDS.

The Court held that FDA's decision to deny marketing applications for failure to compare health risks of flavored products to other tobacco-flavored alternatives was not arbitrary and capricious, as it was "sufficiently consistent" with prior Agency guidance and the statutory mandate of the Family Smoking Prevention and Tobacco Control Act (Pub. Law 111-31 (2009)). Further, the Court held that FDA is entitled to require rigorous scientific data (*e.g.*, "well-controlled investigations") or comparable valid scientific evidence) to support claims that the products advanced public health.

On August 15, 2025, the US District Court for the District of Columbia issued its opinion in *Vanda Pharmaceuticals, Inc. v. FDA*, No. 2401049 (D.C. Cir. 2025). The Court held that FDA improperly denied Vanda a hearing regarding its application to add a new indication to its sleep disorder drug, tasimelteon. Vanda had provided results from five clinical trials as part of its NDA submission to FDA to assess the drug's efficacy on the proposed new indication. CDER issued a CRL because it stated that the trials did not satisfy the "substantial evidence" burden required to demonstrate the drug's safety and efficacy, specifically that it was not clear how the primary endpoints assessed effectiveness for the new proposed indication. The Court held that, while FDA can deny an NDA without holding a hearing if no material facts are genuinely disputed, here, FDA's refusal to hold a hearing was arbitrary and capricious because Vanda's expert evidence created genuine disputes over the adequacy of the clinical trials.

2026 outlook

FDA will likely continue to be a focus for the Trump Administration in 2026. The unprecedented changes in FDA leadership and the number of vacancies in key senior leadership positions will necessitate new appointments from within the Agency as well as potentially result in surprise appointments from industry.

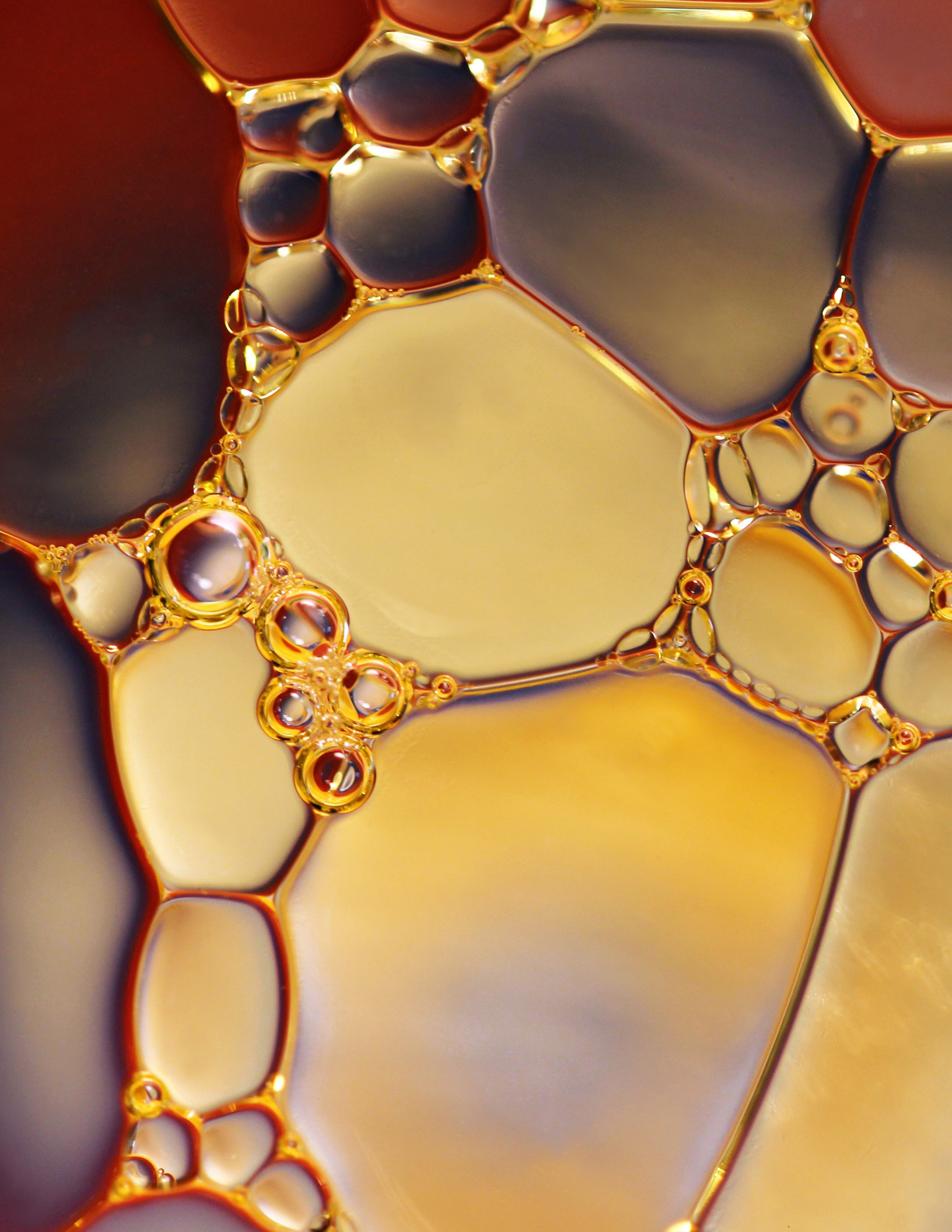
While career personnel continue to drive the mission-critical functions of product review, inspections, and enforcement, anticipated changes at the senior leadership levels will likely create additional shifts in policy and direction for key programs. Further, the pace and consistency of product review may continue to evolve and pose challenges, as departures of experienced senior regulatory and compliance personnel are expected to continue in 2026.

The Trump Administration's continued focus on creating efficiencies could result in additional layoffs or more targeted staff reductions in 2026. The decrease in FDA's overall program budget for 2026 will likely impact hiring and current staffing levels for functions that are not directly supported by user fees as well as impact funding for contracted services.

With the allocation of significant portions of the Agency's FY 2026 budget to MAHA initiatives and the increase in spending on food safety programs, 2026 will likely bring significant enforcement and regulatory activity focused on food safety, UPFs, labeling, and ingredients. Other MAHA focus areas, such as clinical data transparency, use of technology to improve health outcomes, and targeted focus on prescription drug prescribing activity and healthcare provider influence, may take center stage in 2026.

The new year may also see continued enforcement activity with respect to DTC advertising and new initiatives focused on digital media, influencer advertising, and content-creator-driven marketing for FDA-regulated products. This seems to be an area of focus for the current administration, especially as it relates to the impact of influencer marketing on children. Enforcement activity directed at foreign-manufactured goods is expected to increase, particularly with respect to medical devices, APIs, and food. FDA's focus on optimizing its data and IT infrastructure, including the use of AI/ML for more coordinated and data-driven enforcement activities, suggests a potential uptick in recall and import detention activities in 2026.

Given the move toward fewer regulations as described in the 10-to-1 policy, FDA may continue to use existing enforcement authorities and regulations to achieve its initiatives rather than pushing for new legislative authorities. The Agency may also continue to interpret and re-interpret existing regulations through enforcement activities (*e.g.*, as seen with the DTC advertising) and evolve or expand old policies to fit new agendas and interpretations (e.g., as with the CRL policies). For regulated industry, ongoing change will likely serve as the overall trend, calling for active monitoring, adaptability, and potential new models for engaging with FDA.



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