Top 10 Recent FDA & DEA Developments — And What's Next in 2025

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2024 was another year of major developments affecting companies regulated by the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA). For example, a major agency reorganization fundamentally restructured how the FDA conducts its enforcement activities; major rules on good manufacturing practices for medical devices and the regulation of laboratory developed tests were finalized; and important rules affecting food labeling and medical product promotion through testimonials were finalized. In addition, the DEA undertook a process that would reform its approach to the regulation of marijuana.

Developments during 2024 related to FDA and DEA regulatory and enforcement activities will continue to reverberate throughout 2025 and beyond — particularly with the end of the Biden presidency and the beginning of the Trump administration.

Below is our list of the 10 most important FDA and DEA developments of 2024 — and our view of what's to come in the near future.

FDA Launches Office of Inspections and Investigations

On Oct. 1, 2024, the FDA's Office of Regulatory Affairs (ORA), which had supervised the agency's enforcement actions, transitioned to the Office of Inspections and Investigations (OII).

The core mission of OII focuses on the agency's investigations, inspections and import operations. As part of the largest reorganization in the agency's history, which affected approximately 8,000 FDA staff members, most ORA compliance functions and staff were realigned to the agency's product centers and the Human Foods Program with the goal of simplifying operations and speeding decision-making.

Commissioner of Food and Drugs Dr. Robert M. Califf said that the restructuring of ORA "has an impact on how the FDA oversees all FDA-regulated products."

OII, he added, was to have "an enterprise-wide structure that will enhance collaboration between our field investigators and other subject matter experts throughout the agency and modernize and strengthen the entire agency to work more cohesively and collaboratively in accomplishing our collective public health mission."

With OII focused on inspections, investigations and imports, other compliance functions that had been managed by ORA were transferred to the compliance offices within the FDA's product centers and the Human Foods Program.

The reorganization was the subject of an FDA Statement of Organization, Functions and Delegations of Authority published in the *Federal Register* on June 3, 2024 (89 Fed. Reg. 47567).

Reasons for the reorganization. The agency had announced in January 2023 that it would propose a reorganization to create a unified Human Foods Program that would include functions transferred from the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Food Policy and Response, as well as certain functions of ORA. The reorganization also would broadly restructure the FDA's field operations, previously conducted by ORA.

Part of the impetus behind the proposal came from a December 2022 report prepared by an independent panel that had been convened by the Reagan-Udall Foundation in response to a July 2022 request by Califf. The foundation is an independent nonprofit organization created by Congress "to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient and cosmetic product development, accelerate innovation, and enhance product safety."

The commissioner's request came in the wake of food safety oversight challenges that the FDA had faced, including issues related to the recall of Abbott Nutrition infant formula products in February 2022.

Examination of May 2017 ORA reorganization. The authors of the report examined the fallout from a May 2017 reorganization of ORA that had been designed to realign the office's field staff by product area and to coordinate its product-specific enforcement activities with other FDA personnel.

It had been hoped that the 2017 ORA reorganization would help "create a new food safety system that emphasizes prevention and accountability" through implementation of the preventative measures enacted under the FDA Food Safety Modernization Act (FSMA) in 2011, the independent panel reported.

"ORA made some important structural changes, and its staff has become more specialized — and these changes are significant improvements," the panel said in its report.

"However," the panel continued, "based on what the panel heard from internal and external food program stakeholders, it appears that fully embracing a culture of cooperation and accountability, in particular as it relates to fully embracing the prevention ethic of FSMA, has not yet happened. This shortcoming has prevented the program alignment goals from being fully realized in FDA's human foods program."

Moreover, the panel reported, the implementation of food safety-related policies and the food-related field work accomplished by ORA were "largely independent of [CFSAN], the organization that is responsible for developing and writing the policies that are then discharged with a majority of ORA's funding."

Goal of the reorganization. During a January 2024 webinar sponsored by the Alliance for a Stronger FDA on the proposed October 2024 agency reorganization, Dr. Janet Woodcock, at that time the agency's principal deputy commissioner, described the reorganization of ORA as a modernization that would make the FDA more efficient and effective at a time when the agency's mission "seems to be continually broadening."

Through the changes to ORA beyond those related to the creation of the Human Foods Program, she said, "we're trying to move to more of an enterprise-system, holistic look at how the FDA functions" — with one goal being increased uniformity in the functions previously overseen by ORA.

Impact on industry. One major feature of the reorganization is centralizing the FDA's compliance functions within the agency's product centers and the Human Foods Program.

Woodcock stressed that the change would eliminate past duplication and would streamline the FDA's compliance enforcement activities.

The result for the regulated industry, she said, would be "more clarity and promptness in our enforcement actions" — which she said will benefit industry by, for example, helping resolve alleged Form FDA 483 inspectional observations more quickly. The streamlining, she said, was to be "an immediately obvious benefit for everyone."

Medical devices. With respect to medical devices and the FDA's Center for Devices and Radiological Health (CDRH) — which has adopted a total product life cycle approach to regulation, particularly within CDRH's Office of Product Evaluation and Quality, in lieu of maintaining a separate compliance office within CDRH — Woodcock reported that CDRH personnel were sure that the reorganization would help the center quickly bring the appropriate scientific expertise to bear with respect to a particular compliance situation involving a particular product.

This is important, she added, because device compliance issues frequently raise product shortage issues and product substitution issues.

In the past, she explained, when a compliance issue arose, ORA frequently would come to an understanding concerning the alleged violation committed, but only afterwards would the FDA product center involved bring its expertise to bear — at which point concerns such as possible product shortages would arise.

"Here," she said, "we're going to try and unify this, so all the information is brought to bear on the issue from the get-go."

Changes in FDA contacts. Woodcock acknowledged that, in light of the reorganization, as compliance situations arise it is important for industry to know whom in the agency to contact and how the revised processes work.

Michael C. Rogers — then the FDA's associate commissioner for regulatory affairs, and later the agency's associate commissioner for inspections and investigations and the head of OII — said that in the past ORA frequently could not act without engaging the agency centers. Now that approach would be standardized, he said. For example, he noted, with the reorganization the agency centers and the Human Foods Program would make the final classification decisions for all inspections.

Fundamentally, he said, the primary contact person with whom industry had in the past worked to resolve a compliance situation would now be in the product centers or in the Human Foods Program rather than in OII, which was to work to help make sure that a company knows who the proper contact person will be.

Realignment of FDA functions and staff. With the reorganization, Rogers stressed, most ORA compliance functions and staff, with the exception of import operations, were to be realigned to the compliance programs within the FDA's product centers and the Human Foods Program.

The change, he said, was to eliminate "a lot of duplication" and bring FDA investigators closer to the program staffs of the centers and the Human Foods Program, "especially when the agency needs to react to and evaluate an ongoing violative inspection."

Consumer complaints. Also, Rogers said, most consumer complaint responsibilities within ORA were to be reassigned to the product centers and the Human Foods Program.

OII was to conduct any field evaluations related to complaints when requested by those FDA components. Also, OII was to retain a small team of complaint personnel to ensure that those field evaluations are conducted in a streamlined manner.

OII also was to ensure that all serious complaints are elevated to the appropriate senior leadership.

FDA laboratories. Also with the reorganization, the FDA's human foods laboratories were aligned to the Human Foods Program, and the medical product laboratories were aligned to the agency's Office of the Chief Scientist (OCS).

To manage the agency laboratories, OCS established two offices: the Office of Analytical and Regulatory Laboratories and the Office of Specialty Laboratories and Enforcement Support.

OII structure. The structure of OII is as follows, as outlined by the FDA in October 2024:

Associate commissioner for inspections and investigations. OII is headed by the associate commissioner for inspections and investigations, who reports directly to the FDA commissioner. The associate commissioner oversees the agency's field operations — inspections, investigations and import operations — in support of the agency's product centers and programs.

Principal deputy associate commissioner for inspections and investigations. In addition to leading OII functions and projects on behalf of the associate commissioner, the principal deputy associate commissioner oversees information technology, education and training, emergency operations, operational policy, and recalls.

Inspectorate offices. OII's inspectorate offices conduct domestic and foreign inspections and other field activities for their individual product portfolios. The inspectorate includes the following offices:

- *Office of Bioresearch Monitoring Inspectorate*
- *Office of Biologics Inspectorate*
- *Office of Medical Devices and Radiological Health Inspectorate*
- *Office of Human and Animal Drug Inspectorate*
- *Office of Animal Food Inspectorate*
- *Office of Human Food Inspectorate*

Tobacco-related inspections are conducted by OII's Office of Field Operations and Response.

"Cross-cutting functions." Three OII offices conduct what the agency called "specialized operations across the FDA's portfolio":

- *Office of Criminal Investigations (OCI):* OCI, which Rogers said was to remain "essentially unchanged," continues to conduct criminal investigations dealing with FDA-regulated products.

- *Office of Field Operations and Response:* This office provides "enterprise inspectorate support, including leading organizational quality efforts," the agency said. The office includes the following:
    - *Division of Tobacco Inspectorate*, which conducts inspections dealing with tobacco products.
    - *Office of Emergency Response*, which coordinates the FDA's response to emergencies and natural disasters involving agency-regulated products (except human foods) and/or agency facilities.
    - *Office of Field Regulatory Operations*, which manages investigations that are not included in commodity inspections, and which leads the development of inspectorate policy, coordinates reviews, directs health fraud inspectorate activities, and provides consultation about product recalls managed by inspectorate offices.
- *Office of Imports Operations:* The office, which also remains essentially unchanged, will continue to manage the FDA's field import responsibilities.

OII business management offices. The following offices manage internal OII functions:

- *Office of Training*, *Education and Development*, which covers training, education and other professional development for OII personnel and state partners.
- *Office of Management*, which manages OII's budget, travel, 227 field facilities, and workforce.
- *Office of Business Informatics and Solutions Management,* which manages OII's information systems and technology along with the agency's Office of Digital Transformation and the FDA's Office of Enterprise Transformation, an office created in May 2024 within the Office of the Commissioner that was intended to "drive high-priority cross-cutting business process improvement efforts" to ensure a "more strategic and efficient use of agency resources."

OII Staff Management Guides. The agency has fleshed out the functions and structure of OII and its components in a series of FDA Staff Management Guides (SMG 1120A.1 through SMG 1122A.46).

The OII SMGs are available online at https://www.fda.gov/about-fda/staff-manual-guides/organizations-and-functions-volume-i-1000-1300.

Ninth Circuit Says FDA Can Regulate Stem Cell Clinic Procedure, Reversing Lower Court's Holding

Reversing an August 2022 district court decision, a federal appeals court held that the FDA has the authority to regulate a stem cell treatment, concluding that stem cell mixtures injected into a treatment center's patients were drugs regulated by the agency *(United States v. California Stem Cell Treatment Center, Inc.*, 117 F.4th 1213 (9th Cir. 2024)).

Physicians at a treatment center that had clinics in Beverly Hills and Rancho Mirage, California, created the stem cell mixtures by removing fat tissue from patients and breaking the tissue down to concentrate the portion containing stem cells. The resulting liquified mixture, which contained stem cells, other cells and cell debris, was called stromal vascular fraction (SVF). The mixture was subsequently injected into patients seeking treatment for a range of diseases.

The FDA inspected the clinics in 2017. Agency investigators concluded that the clinics were manufacturing and administering unapproved drug products, and they alleged violations of the FDA's manufacturing requirements and a lack of proper documentation of adverse events related to the clinics' treatments.

Injunction action. In May 2018, the Department of Justice (DOJ), acting on the FDA's behalf, filed an injunction action in the U.S. District Court for the Central District of California seeking to permanently enjoin the treatment center and two physician co-owners from performing various stem cell treatments on patients, alleging that the treatments caused the adulteration and misbranding of drugs and the receipt of misbranded drugs (*United States v. California Stem Cell Treatment* Center, No. 5:18-cv-01005-JGB-KK (C.D. Cal.)).

Following a seven-day bench trial, the district court entered judgment in favor of the defendants, holding that the physicians' treatments were not subject to FDA regulation.

According to the district court, the physicians' SVF was not a drug. "Defendants are engaged in the practice of medicine, not the manufacture of pharmaceuticals," it said.

Moreover, the court determined, the physician's use of SVF fell within the "same surgical procedure" (SSP) exception from regulation, which covers the removal of human cells, tissues, or cellular or tissue-based products (HCT/Ps) from an individual and the implantation of the HCT/Ps into the same individual during the same surgical procedure (21 C.F.R. §1271.15).

The district court found that the same-day SVF was "not altered, chemically or biologically" and that the procedure "does not create any new material or introduce any foreign article" into the body (*United States v. California Stem Cell Treatment Center*, 624 F. Supp. 3d 1177 (C.D. Cal. 2022)). The FDA appealed the ruling.

Is it a drug? On appeal, a panel of the U.S. Court of Appeals for the Ninth Circuit first considered whether the physicians' SVF constituted a drug as defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. §321(g)(1)).

"Defendants administer a particular thing — a liquified concentrate of cells and cell debris," the appeals court said. "And they do so with the undisputed intent, as reflected in their marketing, to treat a long list of diseases and to affect structures of the body, such as to regulate cartilage."

The physicians "do not seem to dispute that the 'admittedly capacious' language of the [FD&C Act], read literally, encompasses their treatments," the Ninth Circuit panel said. "Instead, they assert that the definition should not be read literally because the breadth is intolerable."

However, the court noted, the Supreme Court had held that it is error to "[refuse] to apply the [FD&C Act's] language as written," holding that "Congress fully intended that the Act's coverage be as broad as its literal language indicates — and equally clearly, broader than any strict medical definition might otherwise allow" (*United States v. Article of Drug, Bacto-Unidisk*, 394 U.S. 784 (1969)).

The physicians argued that a broad interpretation of the term "drug" would impermissibly intrude upon the practice of medicine, which is regulated by the states.

The appeals court rejected the argument, pointing to a decision in which it had said that although the regulation of medicine is delegated to the states, "when a physician misuses medical devices and threatens public health, the physician may run afoul of the [FD&C Act]" (*United States v. Kaplan*, 836 F.3d. 1188 (9th Cir. 2016)).

Major questions doctrine. To support their position, the physicians also raised the major questions doctrine, which when applicable requires an agency to point to "clear congressional authorization" for the power that the agency claims (*West Virginia v. EPA*, 597 U.S. 697 (2022)).

The Ninth Circuit panel dismissed this argument as well, saying, "This is far from the sort of extraordinary case that would give us reason to hesitate before concluding that Congress meant to confer such authority."

"The FDA is not asserting authority over surgery as a general category," the appeals court said. "Rather it is asserting authority over doctors' creation or use of products that fall within Congress's definition of 'drugs.' That is unlike the situations in which the major questions doctrine has been applied."

The doctrine also did not apply, the appeals court said, because:

- the case did not present a matter of extreme economic and political significance;
- the regulation of HCT/Ps did not represent a sudden assertion or transformative expansion of authority; and
- there was no mismatch between the physicians' SVF and the statutory scheme at issue.

"Consistent with the Supreme Court's instruction that the [FD&C Act's] definition of 'drug' is 'as broad as its literal language indicates,'" the appeals court panel concluded, "we hold that defendants' SVF is a 'drug.'"

SSP exception. The court then turned to the SSP exception. Although the parties offered competing interpretations of the exception, the court noted, they agreed that:

- the exception applies to a procedure only if the removed HCT/P and the implanted HCT/P are the same;
- fat tissue is an HCT/P, and the procedure removes fat tissue and implants SVF;
- the physicians subject the removed fat tissue to significant processing to produce SVF; and
- the fat tissue and SVF are not the same.

"In the FDA's view," the Ninth Circuit panel said, "all this adds up to an easy case: Because fat tissue and SVF are not the same, the SSP exception does not apply to the SVF procedure."

However, the physicians noted, the cells they extract from the fat tissue are also by definition HCT/Ps, and the SVF can be characterized as removing two different kinds of HCT/Ps: the fat tissue and the cells within the fat tissue. Thus, they said, the SSP exception applied, because the procedure removed and implanted the same HCT/Ps.

In other words, they said, the SVF procedure removes and implants the same HCT/Ps even though the physicians subject the removed fat tissue to significant processing to extract and isolate the targeted cells. The exception applied, they said, no matter how much processing the removed tissue undergoes, so long as the extracted cells are implanted in the same surgical procedure.

The appeals court determined that the parties' views of the text of the exception did not fully resolve the issue. "Although the FDA's reading is more straightforward and consistent with the SSP exception's plain text," the court said, "defendants' reading is plausible."

In the end, the regulation's purpose and history weighed in favor of the FDA's position, the court concluded.

"Consistent with the FDA's proposal, the final rule established a tiered, risk-based regulatory scheme that tailors the degree of scrutiny afforded to different HCT/Ps to the risks associated with each of them," the appellate panel said.

"The SSP exception," it continued, "is at the bottom tier: procedures covered by the SSP exception are completely exempt from regulation. This means that covered procedures should involve relatively low risk — risk no greater than that typically associated with conventional surgery. And, because processing HCT/Ps introduces risk, covered procedures should not involve significant processing."

The physicians' interpretation of the exception conflicted with the structure and purpose of the HCT/P regulations, the court concluded, because it would exempt surgical procedures that subject HCT/Ps to substantial processing, "perhaps in ways currently unimaginable," even if the processing introduces risk far greater than that associated with conventional surgery, the court reasoned.

"The FDA's interpretation is more consistent with the SSP exception's plain meaning," the appeals court concluded. "And it is the only interpretation that makes sense in light of the HCT/P regulations' tiered, risk-based framework, and its purpose and history. The seeming textual ambiguity is resolved in the FDA's favor."

Thus, it said, the exception did not apply to the physicians' procedure, in which the removed HCT/P is the fat tissue, not the cells targeted for implantation. "Because the SVP procedure removes fat tissue but implants SVF," the court concluded, "the procedure is not exempt from regulation under the SSP exception."

On this basis, the Ninth Circuit reversed the judgment of the district court.

DOJ Launches Pilot Program Offering NPAs to Individuals Who Self-Disclose Criminal Conduct

Under a DOJ policy launched in April 2024, individuals who self-disclosure information about criminal conduct — "including the complete extent of their own role in the misconduct" — can enter into non-prosecution agreements (NPAs) with the department.

"In exchange for self-disclosing, fully cooperating with authorities, and paying any applicable victim compensation, restitution, forfeiture or disgorgement, including returning any ill-gotten gains, the Criminal Division will enter into [an NPA]" with the disclosing individual "where certain specified conditions are met," the department said.

The division's Pilot Program on Voluntary Self-Disclosures for Individuals, announced by Principal Deputy Assistant Attorney General Nicole M. Argentieri, "provides transparency regarding the circumstances in which Criminal Division prosecutors will offer mandatory NPAs to incentivize individuals (and their counsel) to provide original and actionable information," the DOJ said.

The pilot program can encompass criminal conduct related to health care fraud, health care kickbacks fraud in federal contracting, and violations of the Foreign Corrupt Practices Act (FCPA).

Goals of the program. The information disclosed will help the Criminal Division investigate and prosecute violative conduct "that might otherwise go undetected or be impossible to prove," the DOJ said.

The program also should help companies "create compliance programs that help prevent, detect and remediate misconduct and to report misconduct when it occurs," the government noted.

"Critical sources of information." "Sometimes, the best evidence of corporate wrongdoing involves a company insider," Argentieri said in a DOJ blog post about the pilot program. "Our experience shows that individuals who are involved in criminal conduct and are willing to accept responsibility and cooperate with us are critical sources of information."

She noted that NPAs "have been a part of the federal criminal system for decades, and prosecutors have long exercised discretion to offer NPAs as an essential tool to get culpable individuals in the door. … At bottom, making NPAs available to individuals who come forward to report corporate crime and cooperate allows us to prosecute more culpable individuals and to hold companies to account."

Argentieri also stressed that "by providing incentives to the first person to report misconduct to the government, it puts pressure on everyone — including companies — to disclose misconduct as soon as they learn about it. … And that increases the likelihood the department will learn about serious misconduct that might have gone otherwise undetected."

"Upping the ante." She also noted that when deciding whether to self-disclose, companies "assess not only the benefits of self-reporting laid out in our Corporate Enforcement Policy, but also the risk that the department will learn about the misconduct from other sources."

"The department is upping the ante in that calculus," Argentieri said, "by increasing the incentives for individuals to come forward."

"With this announcement," she added, "we are telling employees everywhere — at nearly every level of an organization — if you've been involved in a crime, now is your time to come forward to the Criminal Division. Call us before we call you."

Program Criteria

Original information. According to the criteria for the pilot program, the reporting individual "must disclose original information, meaning nonpublic information not previously known to the Criminal Division or to any component of the [DOJ]."

In addition, the original information must relate to at least one of the following:

- violations by financial institutions, their insiders or agents, including schemes involving money laundering, anti-money laundering, registration of money transmitting businesses, and fraud statutes, and fraud against or compliance with financial institution regulators;

- violations related to integrity of financial markets undertaken (1) by financial institutions, investment advisors or investment funds, (2) by or through public companies or private companies with 50 or more employees, or (3) by any insiders or agents of any such entities;

- violations related to foreign corruption and bribery by, through or related to public or private companies, including violations of the FCPA, violations of the Foreign Extortion Prevention Act, and violations of the money laundering statutes;

- violations related to health care fraud or illegal health care kickbacks committed by or through public companies or private companies with 50 or more employees;

- violations by or through public or private companies with 50 or more employees related to fraud against, or the deception of, the United States in connection with federally funded contracting, where such fraud does not involve health care or illegal health care kickbacks; and

- violations committed by or through public or private companies related to the payment of bribes or kickbacks to domestic public officials.

Voluntary disclosure. Under the pilot program, the information disclosure must be voluntary — meaning that:

- before any request, inquiry or demand relating to the subject matter of the submission is directed to the individual or anyone representing the individual (for example, his or her legal representative) by the DOJ in connection with any investigation, or by a federal law enforcement, regulatory or civil enforcement agency regarding the same misconduct;

- where the individual has no preexisting obligation pursuant to an agreement in connection with a criminal prosecution or civil enforcement action to report the information to the Criminal Division, any DOJ component, or any federal law enforcement, regulatory or civil enforcement agency; and

- in the absence of any government investigation or threat of imminent disclosure to the government or the public.

Truthful and complete. Also, the information disclosed must be truthful and complete — i.e., it must "include all information known to the individual related to any misconduct in which the individual has participated and/or of which the individual is aware, including the complete extent of the individual's own role in the misconduct, and all matters about which the [DOJ] may inquire."

Full cooperation; substantial assistance. The individual must agree to fully cooperate with and be willing and able to provide substantial assistance to the DOJ in its investigation of related conduct and prosecution of "equally or more culpable individuals or entities."

Cooperation includes providing truthful and complete testimony and evidence (in interviews, before a grand jury, or at any trial or other court proceeding); producing documents, records and other evidence when called upon by the Criminal Division; and, if requested, working "in a proactive manner" under the supervision of and in compliance with federal law enforcement officers and agents.

Also to qualify for the program, the reporting individual:

- must not have engaged in any criminal conduct involving violence, the use of force, threats, substantial patient harm, any sex offense involving fraud, force or coercion or relating to a minor, or any offense involving terrorism;

- must not be a CEO (or the equivalent) or the chief financial officer (or the equivalent) of a public or private company, and must not be the organizer/leader of the scheme;

- must not be an elected or appointed official of a foreign government;

- must not be an employee of a law enforcement agency or a domestic government official at any level; and

- must not have a previous felony conviction or a conviction of any kind for conduct involving fraud or dishonesty.

More information about the pilot program, including contact information and a link to an intake form for self-disclosing individuals, is available online at https://www.justice.gov/criminal/criminal-division-pilot-program-voluntary-self-disclosures-individuals.

FDA Issues Quality Management System Regulation Final Rule, Incorporating ISO 13485 Standards

On Jan. 31, 2024, the FDA issued its long-awaited final rule amending the cGMP requirements of the QS regulation, 21 C.F.R. Part 820, to align more closely with the international consensus standard for device quality, ISO 13485, thereby converging with the quality management system (QMS) requirements established by other countries.

The agency set a Feb. 2, 2026, effective date for the final rule, which establishes the new Quality Management System Regulation (QMSR). The final rule was published in the *Federal Register* on Feb. 2, 2024 (89 Fed. Reg. 7496).

A proposed rule to amend the QS regulation was issued in February 2022 (87 Fed. Reg. 10119).

The final rule incorporates International Organization for Standardization (ISO) 13485:2016, Medical devices — Quality management systems — Requirements for regulatory purposes, Third Edition 2016-03-01, by reference, It also establishes additional requirements and makes conforming edits to clarify the device cGMP requirements.

“This final rule is the latest action taken by the FDA to promote global harmonization in device regulation to help assure that patients and providers have timely and continued access to safe, effective and high-quality medical devices both at home and abroad,” said Dr. Jeffrey E. Shuren, then director of CDRH, when the final rule was issued.

“By harmonizing key areas of a medical device manufacturer’s quality management system (QMS) with the international standard,” Shuren added, “the FDA is streamlining actions device manufacturers must take to meet requirements by multiple regulatory authorities.”

New requirements “substantially similar.” The FDA said that it had determined that the requirements of ISO 13485 “are, when taken in their totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm’s QMS and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the [FD&C Act].”

The agency said that in the final rule it was “retaining the scope of the QS regulation” while amending many of its provisions.

Among the changes are a change of the name of the regulation from the Quality System Regulation to the Quality Management System Regulation. Other changes are intended to ensure that incorporating ISO 13485 by reference does not create inconsistencies with other FDA requirements.

The final rule also makes conforming edits to 21 C.F.R. Part 4 to clarify the QMS requirements for combination products. The FDA said that the edits do not change the cGMP requirements for those products.

Benefits of the final rule. In the past, device manufacturers registered with the FDA have been required to comply with Part 820 while manufacturers in many other jurisdictions as well as U.S. manufacturers that export devices have been required to comply with ISO 13485.

"The redundancy of effort to comply with two substantially similar requirements creates inefficiency," the FDA said in the preamble to the final rule.

"FDA expects that the aligned requirements will reduce the burden on industry to prepare documents and/or records for inspections and audits," the agency said. "In addition, the final rule will result in establishments conducting internal audits and management reviews based on aligned requirements as opposed to auditing and assessing separately to comply with the requirements of the previous QS regulation and ISO 13485 individually. The harmonization of requirements will reduce training costs of industry in that internal training can now cover an aligned set of requirements."

Even though the requirements under the QS regulation "are effective and substantially similar to those in ISO 13485," the FDA said, "incorporating ISO 13485 by reference will further the agency's goals for regulatory simplicity and global harmonization and should reduce burdens on the regulated industry overall."

The agency estimated that the new QMSR will save the device industry between $532 million and $554 million per year. The final rule also will provide "quicker access to newly developed medical devices for patients, leading to improved quality of life of the consumers."

More cost savings will result from aligning Part 820 with other related programs, according to the FDA.

Changes to proposed rule. The agency noted that after considering the comments received on the proposed rule, it modified the proposed rule "primarily for clarity and accuracy and to improve understanding of the QMSR."

The FDA added that on its own initiative it had made minor technical changes "to further align the QMSR with requirements of the FD&C Act and its implementing regulations."

In the preamble to the final rule, the agency listed 18 "more significant revisions, additions and removals" that it had made to revise the proposed rule.

The agency has posted a set of frequently asked questions and answers about the QMSR final rule (https://www.fda.gov/medical-devices/quality-system-qs-regulationmedical-device-current-good-manufacturing-practices-cgmp/quality-management-system-regulation-final-rule-amending-quality-system-regulation-frequently-asked).

Final Rule Applies Device Regulatory Requirements to LDTs; Enforcement Discretion To Be Phased Out

On April 29, 2024, the FDA issued its long-anticipated final rule amending its regulations to specify that laboratory developed tests (LDTs) are subject to regulation as devices under the FD&C Act.

Under the final rule, the agency will phase out its multiyear enforcement discretion approach for LDTs so that in vitro diagnostic products (IVDs) manufactured by a laboratory "will generally fall under the same enforcement approach as other IVDs," the FDA stated in the preamble to the final rule, which was published in the *Federal Register* on May 6, 2024 (89 Fed. Reg. 37286).

The final rule amends the definition of in vitro diagnostic products at 21 C.F.R. §809.3(a) to specify that the products are devices as defined in the FD&C Act (21 U.S.C. §321(h)(1)) and may also be biological products subject to Section 351 of the Public Health Service Act (42 U.S.C. §262), "including when the manufacturer of these products is a laboratory."

The effective date for the final rule was July 6, 2024. However, the FDA set a four-year period for the phaseout of its general enforcement discretion approach for LDTs, and it announced additional targeted enforcement discretion policies with respect to some LDTs.

The agency issued its proposed rule to regulate LDTs in September 2023 (88 Fed. Reg. 68006, Oct. 3, 2023).

Rationale for the final rule. Because LDTs "are being used more widely than ever before — for use in newborn screening, to help predict a person's risk of cancer, or aid in diagnosing heart disease and Alzheimer's," said Commissioner of Food and Drugs Dr. Robert M. Califf, "the agency cannot stand by while Americans continue to rely on results of these tests without assurance that they work."

For years the FDA "has generally exercised enforcement discretion for most LDTs," the agency said in releasing the final rule — meaning that the FDA "generally has not enforced applicable requirements with respect to most LDTs." However, the agency continued, "the risks associated with most modern LDTs are much greater than the risks associated with LDTs used when the FDA's enforcement discretion approach was adopted many decades ago."

Although in the past many LDTs "were lower-risk, small-volume and used for specialized needs of a local patient population," the FDA said, the tests now are used "more widely, for a larger and more diverse population, with large laboratories accepting specimens from across the country" — and with the tests "increasingly rely[ing] on high-tech instrumentation and software," being performed "in large volumes" and being used "more frequently to help guide critical health care decisions."

Moreover, the agency said, "a growing body of evidence" shows that some IVDs offered as LDTs "do not provide accurate test results or do not perform as well as FDA-authorized tests." The FDA cited published scientific studies, the agency's own experience in reviewing IVDs offered as LDTs, news articles, and class action lawsuits.

The agency said that "increased compliance with device requirements under the FD&C Act (such as premarket review, [QS] requirements, adverse event reporting, establishment registration and device listing, labeling requirements and investigational use requirements) will put patients and health care providers in a better position to have confidence in IVDs regardless of where they are manufactured."

Phaseout policy. The FDA decided to phase out its general enforcement discretion approach for LDTs over four years.

The agency said that its intention was to avoid undue disruption to patient care as it assured the safety and effectiveness of the tests. The FDA also hoped to foster test innovation and "facilitate the collective efforts of the scientific and medical communities to identify promising technologies, new therapies or areas worthy of future research."

The agency stressed that it had adjusted the phaseout policy outlined in the proposed rule in light of the "large volume" of comments on the notice of proposed rulemaking (NPRM) that the FDA had received.

However, the FDA said, the general phaseout period retained the general structure, sequencing and timelines proposed in the NPRM:

- ***Stage 1:*** Beginning on May 6, 2025 (one year after the publication date of the final rule), the FDA will expect compliance with medical device reporting (MDR) requirements, correction and removal reporting requirements, and QS requirements under 21 C.F.R. §820.198 (complaint files).

- ***Stage 2:*** Beginning May 6, 2026 (two years after the publication date of the final rule), the FDA will expect compliance with requirements not covered during other stages of the phaseout policy, including registration and listing requirements, labeling requirements, and investigational use requirements.

- ***Stage 3:*** Beginning on May 6, 2027 (three years after the publication date of the final rule), the FDA will expect compliance with QS requirements under 21 C.F.R. Part 820 (other than requirements under 21 C.F.R. §820.198 (complaint files), which are addressed in Stage 1).

- ***Stage 4:*** Beginning on Nov. 6, 2027 (3 1/2 years after the publication date of the final rule), the FDA will expect compliance with premarket review requirements for high-risk IVDs offered as LDTs, unless a premarket submission has been received by the beginning of this stage — in which case the FDA intends to continue to exercise enforcement discretion for the pendency of its review.

- ***Stage 5:*** Beginning on May 6, 2028 (four years after the publication date of the final rule), the FDA will expect compliance with premarket review requirements for moderate-risk and low-risk IVDs offered as LDTs (that require premarket submissions), unless a premarket submission has been received by the beginning of this stage — in which case the FDA intends to continue to exercise enforcement discretion for the pendency of its review.

New enforcement discretion policies. The agency said that it intended to exercise enforcement discretion with regard to premarket review and QS requirements for certain categories of IVDs, including the following:

- ***Currently marketed IVDs offered as LDTs that were first marketed before the date of issuance of the final rule.*** "This enforcement discretion policy is intended to address the risk that the perceived costs of compliance with such requirements could lead to a widespread loss of access to beneficial IVDs on which patients currently rely," the FDA said.

- ***LDTs manufactured and performed by a laboratory integrated within a health care system to meet an unmet need of patients receiving care within the same health care system when an FDA-authorized test is not available.*** This policy of enforcement discretion "is intended to help avoid patients being deprived of critically needed LDTs where certain risk mitigations exist that may help laboratories to identify any problems with their LDT and may help inform appropriate use and interpretation of such LDTs," the agency explained.

Also afforded enforcement discretion were LDTs approved by the New York State Clinical Laboratory Evaluation Program (CLEP), "where that program's review of analytical and clinical validity helps to mitigate the risk of harm from inaccurate and unreliable LDTs."

A set of frequently asked questions and answers about LDTs was made available at the FDA's website (https://www.fda.gov/medical-devices/laboratory-developed-tests/laboratory-developed-tests-faqs).

Joint FDA-OHRP Draft Guidance Details 'Key Information' in Informed Consent

In March 2024, the FDA and the Department of Health and Human Services Office for Human Research Protections (OHRP) released joint draft guidance addressing the revised Common Rule requirement to begin informed consent with "key information" to aid subject understanding.

The draft guidance, "Key Information and Facilitating Understanding in Informed Consent" (https://www.fda.gov/media/176663/download), proposed recommendations for developing a key information section of consent documents for clinical trials, including strategies to make consent information as a whole more understandable for prospective research subjects.

The guidance also proposed a sample approach to the key information section that is based in part on research regarding subject understanding of information found in labeling for prescription drugs. "By using simple phrases and plain language principles, as well as formatting and organizational tools," the agencies said, "researchers found that presenting information in a discrete bubble format with topics organized or grouped together can facilitate consumer understanding."

Revised Common Rule requirement. One of the major informed consent changes under the revised Common Rule was the requirement to begin consent information "with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research" (45 C.F.R. §46.116(a)(5)(i)).

The FDA's proposed regulations implementing the revised Common Rule would add identical language to 21 C.F.R. §50.20(e)(1) (87 Fed. Reg. 58733).

"We recommend that the key information section of a consent document be relatively short (e.g., generally no more than a few pages)," the agencies said.

Multiple approaches are possible. There are multiple ways to provide key consent information that would be consistent with the new federal rules, "depending on the distinctive attributes and design of the study, the prospective subject population, the condition being examined, and other relevant factors," the agencies said in the draft guidance said.

"We encourage interested parties to develop innovative ways and utilize available technologies to provide key information that will help prospective subjects better understand the reasons why one might or might not want to participate in the research," the agencies said.

The FDA and OHRP noted that alternate ways to present key information could be developed by "consulting in advance with patient advocacy groups or prospective subjects about their views on key information."

The key information section, they said, could also be presented "using alternative media, such as illustrations, video, and electronic tablets, to meet the goals of improving clarity and increasing prospective subjects' understanding of consent information."

Proposed recommendations. The draft guidance recommended that the key information section "begin with an introductory statement to frame the key information included in the consent form and to guide prospective subjects when reading the entire document."

"We do not recommend that the key information section of the consent form necessarily include each element of informed consent contained in 45 C.F.R. §46.116(b) and (c) or in 21 C.F.R. §50.25(a) and (b)," the agencies said in the draft guidance. "One approach to developing the content of the key information section is for prospective subjects and other interested parties to advise on which basic and additional elements of informed consent may be considered 'key' from the perspective of prospective subjects for a particular study."

The agencies also recommended that "the most important elements for a particular study be included at the beginning of the key information section. Which basic and additional consent elements should be included in the key information section may vary based on factors such as the study attributes and its design; the condition(s), behavior(s), or outcome(s) being examined; and the prospective subject population."

Basic and additional elements of informed consent, or parts of such elements, that are not addressed or fully addressed in the key information would need to be included elsewhere in the consent form (21 C.F.R. §50.25(a)-(b); 45 C.F.R. §46.116(b)-(c)).

The draft guidance noted that "for studies using a short form written consent in conjunction with an oral presentation of informed consent, the revised Common Rule (45 C.F.R. §46.117(b)(2)) requires, and FDA's proposed 21 C.F.R. §50.27(b)(2) would require, that the key information be presented to a prospective subject or their legally authorized representative at the beginning of the informed consent process, before other information. In addition, consent documents developed for FDA-regulated clinical investigations allowed to proceed under 21 C.F.R. §50.24 (Exception From Informed Consent Requirements for Emergency Research) also would be required to begin with a key information section. Similarly, consent documents developed for expanded access use of an investigational drug would be required to begin with a key information section (21 C.F.R. §312.305(c)(4))."

FTC Approves Final Rule on Product Reviews and Testimonials

In August 2025, the Federal Trade Commission (FTC) approved a final rule that tightened the commission's product review and testimonial regulations. The new rule — 16 C.F.R. Part 465 – became effective on Oct. 21, 2024.

The final rule prohibited:

- ***Fake or false consumer reviews, consumer testimonials and celebrity testimonials.*** The final rule addressed reviews and testimonials that misrepresent that they are by someone who does not exist,

such as AI-generated fake reviews, that are by someone who did not have actual experience with the business or its products or services, or that misrepresent the experience of the person. It prohibits businesses from creating or selling such reviews or testimonials. It also prohibits them from buying such reviews, procuring them from company insiders, or disseminating such testimonials, when the business knew or should have known that the reviews or testimonials were fake or false.

- ***Buying positive or negative reviews.*** The final rule prohibits businesses from providing compensation or other incentives conditioned on the writing of consumer reviews expressing a particular sentiment, either positive or negative. The conditional nature of the offer of compensation or incentive may be expressly or implicitly conveyed.

- ***Insider reviews and consumer testimonials.*** The final rule prohibits certain reviews and testimonials written by company insiders, including officers and managers, that fail to clearly and conspicuously disclose the giver's material connection to the business. It also prohibits a business from disseminating such a testimonial that the business should have known was by an officer, manager, employee or agent. Finally, it imposes requirements when officers or managers solicit consumer reviews from their own immediate relatives or from employees or agents or when they tell employees or agents to solicit reviews from relatives and such solicitations result in reviews by immediate relatives of the employees or agents.

- ***Company-controlled review websites.*** The final rule prohibits a business from misrepresenting that a website or entity it controls provides independent reviews or opinions about a category of products or services that includes its own products or services.

- ***Review suppression.*** The final rule prohibits a business from using unfounded or groundless legal threats, physical threats, intimidation or certain false public accusations to prevent or remove a negative consumer review. The final rule also bars a business from misrepresenting that the reviews on a review portion of its website represent all or most of the reviews submitted when reviews have been suppressed based upon their ratings or negative sentiment.

- ***Misuse of fake social media indicators.*** The final rule prohibits anyone from selling or buying fake indicators of social media influence, such as followers or views generated by a bot or hijacked account. This prohibition is limited to situations in which the buyer knew or should have known that the indicators were fake and the fake indicators misrepresent the buyer's influence or importance for a commercial purpose.

"Fake reviews not only waste people's time and money but also pollute the marketplace and divert business away from honest competitors," FTC Chair Lina Khan said in announcing the final rule. "By strengthening the FTC's toolkit to fight deceptive advertising, the final rule will protect Americans from getting cheated, put businesses that unlawfully game the system on notice, and promote markets that are fair, honest and competitive."

The commission's position was that case-by-case enforcement without civil penalty authority might not be enough to deter clearly deceptive review and testimonial practices. Moreover, the FTC noted, the Supreme Court's decision in *AMG Capital Management, L.L.C. v. Federal Trade Commission*, 141 S. Ct. 1341 (2021), restricted the commission's authority to seek equitable monetary relief for consumers under the FTC Act. The rule will enhance deterrence and strengthen FTC enforcement actions, the commission said.

"The *AMG* ruling has made it significantly more difficult for the commission to return money to injured consumers, particularly in cases that do not involve rule violations," the commission said. "Since *AMG*, the primary means for the Commission to return money unlawfully taken from consumers is Section 19 of the FTC Act, 15 U.S.C. §57b, which provides two paths for consumer redress."

The longer path, under Section 19(a)(2), requires the commission to file two separate actions to obtain monetary relief. The more efficient path to monetary relief, under Section 19(a)(1), allows the commission to recover redress in one federal court action for violations of a commission rule relating to unfair or deceptive acts or practices.

"The commission believes that the final rule will substantially improve its ability to combat certain specified, clearly unfair or deceptive acts or practices involving consumer reviews or testimonials," the FTC said in the preamble to the final rule (89 Fed. Reg. 68034). Although these unfair or deceptive acts or practices are already unlawful under Section 5 of the FTC Act, the commission said, "the rule will increase deterrence of such conduct by allowing courts to impose civil penalties against the violators."

In addition, the final rule allows the FTC to seek court orders requiring violators to compensate consumers for the harms caused by their unlawful conduct. "The commission believes that the rule will accomplish these goals without significantly burdening honest businesses and that the rule will provide significant benefits to consumers and honest competitors," the FTC said.

The final rule also allows courts to impose civil penalties under Section 5(m)(1)(A) of the FTC Act (15 U.S.C. §45(m)(1)(A)), against "those who engage in the deceptive or unfair conduct that the final rule prohibits," the notice said. "The ability to obtain civil penalties is important because it can be difficult to quantify consumer losses that stem from the use of unfair or deceptive consumer reviews and testimonials. Without civil penalties, persons who engage in such conduct might avoid monetary consequences for their unlawful conduct simply because there is insufficient evidence to link their unlawful conduct to quantifiable losses suffered by consumers."

Because the final rule will allow courts to impose civil penalties for violations, "it provides the deterrence necessary to incentivize compliance with the law, even in cases where it is difficult to quantify consumer harm," the FTC said.

The commission vote to approve the final rule was 5-0.

FDA Updates Requirements for 'Healthy' Food Labeling Claim; FSIS Issues 'Product of USA' Label Claim Rule

(1) 'Healthy' Claims

In December 2024, the FDA issued a final rule to update the definition of the voluntary nutrient content claim "healthy." It was the first change in the rule in 30 years.

The compliance date for the final rule is Feb. 25, 2028. However, manufacturers who choose to use the claim can use the new criteria sooner.

The final rule, published in the *Federal Register* on Dec. 27, 2024 (89 Fed. Reg. 106064), revised the requirements for when the term "healthy" or derivative terms "health," "healthful," "healthfully," "healthfulness," "healthier," "healthiest," "healthily" and "healthiness" can be used as an implied nutrient content claim in the labeling of human food products to help consumers identify foods that are particularly useful as the foundation of a nutritious diet that is consistent with dietary recommendations.

To qualify as "healthy" under the updated definition, food products must contain a certain amount of a food from at least one of the food groups or subgroups outlined by the Dietary Guidelines for Americans (available online at https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf) including fruits, vegetables, protein foods, dairy and grains. Foods that qualify for the "healthy" claim also must meet certain limits on saturated fat, sodium and added sugars.

As an example, to include the "healthy" claim on the package, a cereal needs to contain a certain amount of whole grains and adhere to limits for saturated fat, sodium and added sugars.

Nuts and seeds; higher fat fish, such as salmon; certain oils, such as olive oil; and water are examples of foods that did not qualify for the "healthy" claim before but are foundational to a healthy eating pattern and recommended by the Dietary Guidelines. These foods now qualify to bear the "healthy" claim. "Many foods that fit into a range of budgets such as some peanut butters and canned fruits and vegetables also qualify," the FDA said.

The rule also established food group equivalents (FGEs) that identify qualifying amounts of foods from each food group based on nutritional content. An FGE contains the following:

- Vegetable — 1/2 cup equivalent
- Fruit — 1/2 cup equivalent
- Grains — 3/4 oz. equivalent whole grain
- Dairy — 2/3 cup equivalent
- Game meat — 1 1/2 oz. equivalent
- Seafood — 1 oz. equivalent
- Egg — 1 oz. equivalent
- Beans, peas or lentils — 1 oz. equivalent
- Nuts and seeds, or soy products – 1 oz. equivalent.

To bear a "healthy" claim, individual food products, mixed products, main dishes and meals must meet FGEs and specific limits for added sugars, saturated fat and sodium based on a percentage of the Daily Value (DV) for those nutrients.

In addition, the final rule provides that individual foods or mixed products that are comprised of one or more foods encouraged by the Dietary Guidelines (vegetable, fruit, whole grains, fat-free and low-fat dairy, lean meat, seafood, eggs, beans, peas, lentils, or nuts and seeds), with no other added ingredients except for water, automatically qualify for the "healthy" claim, without having to meet the FGE and nutrients-to-limit requirements, because of their nutrient profile and positive contribution to an overall healthy diet.

The final rule also provides that all water, tea and coffee with less than 5 calories per RACC and per labeled serving automatically qualify for the "healthy" claim.

The rule also requires the establishment and maintenance of records for foods bearing the "healthy" claim where the FGE contained in the product is not apparent from the label of the food. These records — such as analyses of databases, recipes, formulations, information from recipes or formulations, or batch records — will verify that the food meets the FGE requirements. These records must be kept for at least two years after introduction of the food into interstate commerce. During an inspection, the records must be provided to the FDA upon request for official review and photocopying.

(1) 'Product of USA' Claims

The Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) finalized a rule to align the voluntary "Product of USA" label claim with consumer understanding of what the claim means.

The final rule, published on March 18, 2024 (89 Fed. Reg. 19470), "is a vital step toward consumer protection," Agriculture Secretary Tom Vilsack said in announcing the rule's release. "This final rule will ensure that when consumers see 'Product of USA' they can trust the authenticity of that label and know that every step involved, from birth to processing, was done here in America."

The rule allows the voluntary "Product of USA" or "Made in the USA" label claim to be used on meat, poultry and egg products only when they are derived from animals born, raised, slaughtered and processed in the United States.

"The rule will prohibit misleading U.S. origin labeling in the market and help ensure that the information that consumers receive about where their food comes from is truthful," the agency said.

Under the final rule, the "Product of USA" or "Made in the USA" label claim will continue to be voluntary. It will also remain eligible for generic label approval, meaning it would not need to be pre-approved by FSIS before it can be used on a regulated product, but would require the establishment to maintain documentation on file to support the claim.

The final rule also allows the use of other voluntary U.S. origin claims on meat, poultry and egg products sold in the marketplace. These claims need to include a description on the package of the preparation and processing steps that occurred in the United States upon which the claim is made.

Establishments voluntarily using a claim subject to the final rule will need to comply with the new regulatory requirements by Jan. 1, 2026, and are encouraged to do so as soon as practicable.

FSIS Guideline for Label Approval. In March 2024, USDA published an updated labeling guidance to provide information based on the final rule about voluntary "Product of USA," "Made in the USA," or alternative claims that specify processing or preparation steps that occur in the United States, as well as examples of claims and the types of documentation that establishments may maintain to support use of the claims.

The revised version of the FSIS Guideline for Label Approval (https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS-GD-2024-0001.pdf) replaced the January 2023 version of the guideline.

The guideline is focused on small and very small establishments in support of the Small Business Administration's initiative to provide small businesses with compliance assistance under the Small Business Regulatory Enforcement Fairness Act. "However, all establishments may apply the recommendations in this guideline," the agency added.

According to the revised guidance, voluntary U.S.-origin claims on labels of products under FSIS mandatory inspection or voluntary inspection services may be generically approved, "provided that the labeling record is sufficient to support the claim."

"Product of USA"/"Made in the USA" claims. To make a "Product of USA" or "Made in the USA" claim, the product must be derived from an animal born, raised, slaughtered and processed in the United States.

- For single ingredient items, the entire product must be derived from an animal born, raised, slaughtered and processed in the United States (9 C.F.R. §412.3(a)).

- For a multi-ingredient product, the product must be derived from animals born, raised, slaughtered and processed in the United States; all other ingredients in the product, other than spices and flavorings, must be of domestic origin; and the preparation and processing steps for the multi-ingredient product must have occurred in the United States (9 C.F.R. §412.3(b)).

Other U.S.-origin claims. Factual U.S.-origin claims other than "Product of USA" and "Made in the USA" may be made to designate the U.S.-origin component of a FSIS-regulated product's preparation and processing (9 C.F.R. §412.3(c)).

"The claims must include a description of the preparation and processing steps that occurred in the United States upon which the claim is made," FSIS said in the guidance. "This claim description should provide meaningful consumer information about the specific type of preparation and processing steps that occurred in the United States."

For example, the generalized claims "Processed in the United States" or "Manufactured in the United States" are so broad as to not provide the consumer meaningful information about what preparation and processing steps occurred in the United States, FSIS said.

State- or locality-specific claims. Labels that make a factual claim about a specific U.S. state, territory or locality can be approved generically, provided the claim meets the requirements for use of U.S.-origin claims under 9 C.F.R. §412.3(a)-(c) with regards to the U.S. state, territory or locality origin.

DOJ Proposes To Transfer Marijuana to Schedule III, Adopting HHS's Views on Its Current Medical Use

In May 2024, the DOJ released its long-anticipated NPRM that would transfer marijuana from Schedule I to Schedule III under the Controlled Substances Act (CSA).

The NPRM was published in the *Federal Register* on May 21, 2024 (89 Fed. Reg. 44597).

The release of the NPRM was the latest step in a process initiated in October 2022, when President Biden asked the DOJ and the Department of Health and Human Services (HHS) to initiate a scientific review of the scheduling of marijuana under the CSA.

In announcing his request, Biden noted that Schedule I is "the classification meant for the most dangerous substances."

"This is the same schedule as for heroin and LSD, and even higher than the classification of fentanyl and methamphetamine — the drugs that are driving our overdose epidemic," Biden noted.

In August 2023, HHS recommended that marijuana be controlled in Schedule III, based on findings corresponding to the criteria for placing a controlled substance in Schedule III (21 U.S.C. §812(b)(3)).

The DEA has not yet made a determination as to its views of the appropriate schedule for marijuana, the DOJ noted in the preamble to the NPRM. "DEA believes that additional information arising from this rulemaking will further inform the findings regarding the appropriate schedule for marijuana," the department said in the preamble.

Eight-factor analysis. The NPRM includes a detailed recounting of HHS's scientific and medical determinations with respect to the eight factors that HHS and the DOJ must consider when recommending or determining whether a drug should be controlled and, if so, under what schedule (21 U.S.C. §811(c)):

- the drug's actual or relative potential for abuse;
- scientific evidence of the drug's pharmacological effect, if known;
- the state of current scientific knowledge regarding the drug or other substance;
- its history and current pattern of abuse;
- the scope, duration and significance of the abuse;
- what, if any, risk there is to the public health;
- the drug's psychic or physiological dependence liability; and
- whether the substance is an immediate precursor to a substance already controlled.

Reclassification standards. Marijuana has been a Schedule I controlled substance ever since the CSA was enacted in 1970.

The DEA and HHS last considered the issue of whether to reschedule marijuana in 2016. At the time, HHS said that marijuana should remain in Schedule I because it met the three criteria for placement there.

Under CSA, Schedule I controlled substances are those that have:

- a high potential for abuse;
- no currently accepted use in treatment in the United States (i.e., no currently accepted medical use (CAMU)); and

- a lack of accepted safety for use of the substance under medical supervision.

By contrast, under the statute, Schedule III controlled substances are drugs:

- that have a potential for abuse that is less than the abuse potential of substances in Schedule I and Schedule II;
- that have a CAMU; and
- abuse of which may lead to low or moderate physical dependence or high psychological dependence.

HHS, DOJ determinations. The DOJ's NPRM included HHS's three findings regarding the appropriate schedule in which to place marijuana, which tracked the three criteria for inclusion of the substance in Schedule III:

- the substance's abuse potential;
- whether the substance has a CAMU; and
- the safety or dependence potential of the substance.

For purposes of initiating the rulemaking proceedings, the DOJ concurred with HHS's recommendations and concluded that:

- marijuana has a potential for abuse less than the drugs or other substances in Schedules I and II;
- there is a CAMU for marijuana; and
- the abuse of marijuana may lead to moderate or low physical dependence, depending on the frequency and degree of marijuana exposure.

"Currently accepted medical use." Since 1992, the DEA has determined that a controlled substance has a CAMU only if (1) the FDA has approved the drug for marketing under the FD&C Act, or (2) the drug meets a five-part test that tracks the "core standards developed under the [FD&C Act]" (57 Fed. Reg. 10499).

Under the five-part test, a controlled substance has a CAMU if:

1. the drug's chemistry is known and reproducible;

2. there are adequate safety studies;

3. there are adequate and well-controlled studies proving efficacy;

4. the drug is accepted by qualified experts; and

5. scientific evidence about the drug is widely available.

In its August 2023 recommendation, HHS concluded that, whether or not a drug was approved by the FDA or satisfied the DEA's five-part test, a drug could have a CAMU if it satisfied a new two-part test — i.e.:

1. if licensed health care providers have "widespread current experience with medical use" of the drug "in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine"; and

2. if there is "some credible scientific support for at least one of the medical uses."

In the preamble to the final rule, the DOJ noted that since 1996, 38 states, the District of Columbia and four U.S. territories have legalized the use of medical marijuana. Moreover, since fiscal year 2015, Congress has annually adopted an appropriations rider that prohibits the DOJ from using funds to prevent states, territories and the District of Columbia from implementing their own medical marijuana laws.

OLC legal memorandum. After receiving the HHS recommendation, Attorney General Merrick Garland asked for advice from the DOJ's Office of Legal Counsel (OLC) on three important issues.

- *Determining CAMU.* In an April 11, 2024, memorandum, the OLC concluded that the DEA's five-part test for determining whether a drug has a CAMU "is impermissibly narrow" and that satisfying HHS's new two-part test "is sufficient to establish that a drug has a CAMU even if the drug has not been approved by FDA and would not satisfy DEA's five-part test."

- *Status of HHS recommendations.* The OLC also determined that the HHS CAMU recommendation was not binding on the DEA, but that the DEA must accord HHS's scientific and medical determinations "significant deference" and that the DEA cannot undertake a de novo assessment of HHS's findings.

- *Effect of Single Convention.* Under 21 U.S.C. §811(d)(1), the DEA must control a drug under the schedule that is most effective to carry out its obligations under the 1961 United Nations Single Convention on Narcotic Drugs, which covers marijuana. The OLC concluded that neither the Single Convention nor the CSA requires the DEA to place marijuana in Schedule I or Schedule II.

Criminal prohibitions would remain. In the preamble to the NPRM, the DOJ said that if marijuana is transferred into Schedule III, "the manufacture, distribution, dispensing and possession of marijuana would remain subject to the applicable criminal prohibitions of the CSA" (21 U.S.C. §§841-844).

Treaty obligations. In the NPRM, the DOJ said that as part of the rulemaking the DEA "will consider the marijuana-specific controls that would be necessary to meet U.S. obligations" under both the Single Convention and the Convention on Psychotropic Substances if marijuana is rescheduled to Schedule III.

To the extent that new regulations are needed to comply with the treaties if marijuana is rescheduled, the department added, the DEA "will seek to finalize any such regulations as soon as possible."

Rite Aid $409M Settlement Resolves CSA, False Claims Allegations Related to Dispensing Practices

Rite Aid Corp. and 10 company subsidiaries and affiliates entered into an agreement with the DOJ to resolve allegations that the company's pharmacies illegally dispensed controlled substances, including opioids, and caused false reimbursement claims to be filed with federal health care programs (*United States ex rel. White v. Rite Aid Corp*., No. 1:21-cv-1239 (N.D. Ohio)).

Under the terms of the settlement agreement, Rite Aid agreed to pay the government $7.5 million within 10 days following the effective date of the company's Chapter 11 plan of reorganization, which was pending in the U.S. Bankruptcy Court for the District of New Jersey (*In re Rite Aid Corp.*, Bankr. Case No. 23-18993-MBK (Bankr. D.N.J.)).

In addition, the government was to have an allowed, unsubordinated, general unsecured claim of $401,868,524 in the bankruptcy case. The exact amount that the government was to recover would depend on the ultimate amount of assets available to the bankruptcy estate for distribution to unsecured creditors, the DOJ said.

Allegations in complaint in intervention. In a complaint in intervention filed in March 2023 in the U.S. District Court for the Northern District of Ohio, the government had alleged that between May 2014 and June 2019 Rite Aid "knowingly dispensed at least hundreds of thousands of unlawful prescriptions for controlled substances that (1) lacked a legitimate medical purpose and were not issued in the usual course of professional practice and/or (2) were not valid prescriptions, were not for a medically accepted indication or were medically unnecessary," the DOJ said in announcing the settlement on July 10, 2024.

Specifically, the government alleged, the controlled substances illegally dispensed included "dangerous, highly diverted" combinations of drugs known as "the trinity"; prescriptions for excessive quantities of opioids, including oxycodone and fentanyl; and "prescriptions issued by prescribers who Rite Aid pharmacists had repeatedly identified internally as suspicious and as writing unlawful, unnecessary prescriptions."

Moreover, according to the DOJ, the prescriptions were illegally dispensed despite clear red flags indicating that the prescriptions were illegal, despite "specific concerns raised by its pharmacists," and despite internal notes written by the pharmacists (for example, "writing excessive dose[s] for oxycodone" and "DO NOT FILL CONTROLS") that purportedly were intentionally deleted.

"By knowingly dispensing unlawful prescriptions for controlled substances," the DOJ said, "Rite Aid violated the CSA and, where Rite Aid sought reimbursement from federal health care programs, also violated the [False Claims Act]."

Washington state allegations. The settlement agreement also stated that the government had additional civil claims arising under the CSA involving conduct at Rite Aid pharmacies in Washington state that had not been alleged in the DOJ's March 2023 complaint in intervention.

Specifically, the government contended, between January 2017 and January 2022 those pharmacies violated the CSA "by filling prescriptions for controlled substances issued by individual practitioners who did not have valid state licenses to practice medicine or otherwise lacked state prescribing authority to prescribe controlled substances."

Allocation of settlement amount. The $409,368,524 total settlement amount was to be allocated as follows:

- $236,090,058 in CSA penalties to settle the DOJ's allegations under the CSA in the complaint in intervention, none of which was designated as restitution;

- $167,973,926 (including the entire initial payment of $7.5 million) to settle the DOJ's allegations under the False Claims Act in the complaint in intervention, of which $80,236,964 was designated as restitution; and

- $5,304,539 in CSA penalties to settle the Washington state allegations, none of which was designated as restitution.

Qui tam action. The settlement resolved allegations originally brought under the False Claims Act in a qui tam action filed by three relators in October 2019 in the U.S. District Court for the Eastern District of Pennsylvania. The case was later transferred to the U.S. District Court for the Northern District of Ohio.

The DOJ intervened in the case in November 2022 and filed its complaint in intervention four months later. In the complaint, the government alleged that through its dispensing of prescriptions for controlled substances in violation of the CSA, Rite Aid had submitted false reimbursement claims or caused false reimbursement claims to be submitted to the Medicare, Medicaid and TRICARE programs.

Under the terms of the settlement agreement, the relators were to receive 17% of the initial $7.5 million payment as part of the relators' share of the settlement. They also were to receive 17% of the general unsecured claim up to a maximum of $28,555,567.

On June 28, 2024, the bankruptcy court approved the settlement as part of Rite Aid's reorganization plan.

Memorandum of agreement. Also, as part of the agreement Rite Aid entered into a memorandum of agreement (MOA) with the DEA that was designed to increase communication among the company, its retailers and the agency.

Under the MOA, employees will receive additional training to help them identify illegitimate prescriptions and minimize the risk of drug diversion, according to the DOJ. The agreement also required Rite Aid to create and maintain materials relevant to DEA investigations for at least five years, as well as to create and manage an anonymous hotline through which employees, patients and the public may report suspected illegal dispensing of highly diverted controlled substances and suspected violations of the CSA.

Corporate Integrity Agreement. Rite Aid also entered into a five-year Corporate Integrity Agreement (CIA) with the HHS Office of Inspector General.

Under the CIA, Rite Aid was to establish an Independent Review Organization that would review retail pharmacy claims submitted by Rite Aid and reimbursed by Medicare and Medicaid. The reviews were intended to determine whether:

- the claims were consistent with the underlying prescription documentation maintained by Rite Aid;
- Rite Aid maintained appropriate documentation of a valid prescription for each drug dispensed, including any refills;
- any prior authorization required by the payor was obtained; and
- the retail pharmacy claims were correctly billed and reimbursed.

What's Next in 2025

FDA Will Be a Target for Change During the Trump Administration

Given the statements of key players who potentially will determine FDA policy during the second Trump administration, it is clear that "the FDA will be a target for change," says Wayne L. Pines, senior director for health care at APCO Worldwide L.L.C., a former FDA associate commissioner for public affairs, and the editor-in-chief of Thompson's *FDA Advertising and Promotion Manual.*

Individuals in Trump's orbit who have been nominated for leadership roles at HHS and the FDA during his administration have expressed views that would diverge from traditional agency policy, Pines noted in an FDA Compliance Expert posting. For example, some have expressed skepticism about vaccines, including COVID-19 vaccine boosters; some have called for the food nutrition staff at the FDA to be replaced; and some have suggested that some drugs should be approved on the basis of safety considerations alone, with the efficacy of a drug being determined post-approval during actual patient use.

"One hopes that all the candidates will support some key principles that are essential for the FDA to protect the public health: science-based decision-making, reliance on sound research, maintaining a truly expert staff as medical science and patient care move into the age of AI, and adequate funding for an agency that has historically been underfunded," Pines said. "The FDA is rightly regarded as the gold standard for regulation by the international community. We must not tamper with the basics."

FDA Investigator Workforce Attrition May Force the Agency Increasingly To Rely on Remote Regulatory Assessments, Information From Non-U.S. Regulators

The FDA's struggle to retain its inspection workforce has resulted in the agency having "a large number of relatively inexperienced investigators" and is affecting the FDA's ability to meet its inspection goals, a November 2024 report issued by the Government Accountability Office (GAO) concluded.

In the report, "Drug Safety: FDA Should Implement Strategies To Retain Its Inspection Workforce" (https://www.gao.gov/assets/gao-25-106775.pdf), the GAO said that the FDA needs to identify the resources and possible new authorities that it needs to reduce the number of vacancies in the ranks of investigators who conduct drug manufacturer inspections.

The GAO reported that the FDA had not yet developed action plans to fully address the causes of investigator attrition — the amount of travel investigators face in their jobs, their workload, and work-life balance issues — because potential solutions may not allow FDA to meet its inspection needs.

For example, agency officials reportedly discussed options to temporarily move some investigators to other positions that do not require travel or that reduce the total number of weeks of foreign travel that investigators are expected to complete in a year.

However, the officials have not pursued the options further, the GAO said, "because of the potential effect on current inspection capacity that would be caused by reducing the number of inspections or weeks of foreign travel conducted by individual investigators."

Another GAO report, "Clinical Research: FDA Should Evaluate Its Efforts To Recruit and Retain Its Inspection Workforce" (https://www.gao.gov/assets/d24106383.pdf), issued in February 2024, revealed similar challenges faced by the FDA with respect to recruiting and retaining Bioresearch Monitoring (BIMO) program investigators.

Investigator attrition may lead the FDA to rely more on remote regulatory assessments in place of on-site inspections.

For example, through a pilot program launched in 2023, the agency is exploring the use of remote regulatory assessments for conducting on-site institutional review board (IRB) inspections. FDA officials have said that remote regulatory assessments could be an effective tool for IRB oversight, given that IRB inspections rely more heavily on document reviews than do other clinical research inspections.

Moreover, the FDA may increasingly rely on inspectional observations provided by non-U.S. regulators with which the FDA has mutual recognition agreements (MRAs), such as the agency's MRAs with regulatory agencies in the European Union and the United Kingdom.

Revised Final Rule on Research Misconduct May Prompt Reviews of Institutional Guidelines

In September 2024, HHS issued a revised final rule updating its regulations on research integrity and how the federal government handles alleged research misconduct (89 Fed. Reg. 76280).

Among other things, the revised final rule was intended to clarify institutional confidentiality obligations and to provide a clearer description of research misconduct investigation requirements. On the other hand, the revised final rule sought to recognize the role of institutional best practices and to identify areas where institutional discretion can be exercised.

The revised final rule will apply beginning in January 2026 to research funded by the Public Health Service. During 2025, the HHS Office of Research integrity suggested, research institutions can prepare for the final rule by reviewing forthcoming sample policies, procedures and guidance, and by drafting policies and procedures specific to a particular institution that can be implemented when the final rule goes into effect.

New Administration May Rethink DTC Advertising of Medical Products

As Wayne Pines also notes in his posting on the incoming Trump administration, some in the president's circle have suggested banning direct-to-consumer (DTC) ads for medical products.

He writes: "The FDA has permitted product-specific DTC TV and radio advertising since 1997. They are part of our culture. … But for some, DTC drug commercials are seen either as a nuisance or as a stimulus for drug overuse, something that [FDA Commissioner-designate Dr. Martin A. "Marty" Makary] has expressed concerns about."

"Some drug companies may even support a ban as long as it applies across the board to all companies," Pines suggested. "Major opposition to a ban would probably come from the networks whose shows are supported by DTC ads."

"The FDA could effectively ban or limit DTC advertising by changing its policy regarding what constitutes adequate communication of efficacy and safety information," Pines noted. "The agency could say that ads need to disclose significantly more detailed safety information than they now do, and thus make DTC advertising ineffective and more cumbersome. Such policies would affect not only TV and radio advertising but also the burgeoning advertising on social media."

Pines said that Makary "is an experienced communicator who surely will have views on DTC advertising and drug marketing via social media. Makary will need to consider the reality that DTC advertising on TV and in social media involves constitutional issues as well as financial issues for TV networks and social media outlets."

Litigation, Legislation May Determine the Future of the FDA's Final Rule on Laboratory Developed Tests

Following the release of the FDA's final rule regulating LDTs as medical devices, at least two legal challenges to the final rule were filed in federal district courts.

In May 2024, a trade association representing clinical laboratories and one of its member companies filed a complaint in the U.S. District Court for the Eastern District of Texas seeking to block the final rule. The plaintiffs asserted that "Congress has never granted FDA authority to regulate the professional testing services that laboratories provide, which are federally regulated by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA)" (*American Clinical Laboratory Association v. U.S. Food & Drug Administration*, No. 4:24-cv-00479-SDJ (E.D. Tex.)).

In August 2024, a molecular diagnostic professional society and a physician filed a complaint in the U.S. District Court for the Southern District of Texas also seeking to block the final rule. In their complaint, the plaintiffs said that they were challenging "a historically unprecedented power grab that will jeopardize the health of hundreds of millions of Americans and, by FDA's own admission, impose tens of billions of dollars in new regulatory mandates on thousands of laboratories and laboratory professionals by subjecting their customized analytical processes (called [LDTs]) to burdensome, duplicative and unnecessary FDA regulation for the first time in American history" (*Association for Molecular Pathology v. U.S. Food and Drug Administration*, No. 3:24-cv-00241 (S.D. Tex.)).

Rulings in these cases may determine the fate of the FDA's final rule on LDTs. In addition, some in Congress still believe that legislation is the appropriate way to determine how LDTs should be regulated, and past legislative proposals may be reintroduced.

Recent Food Labeling Final Rules, Proposals Will Face Scrutiny as Nutrition Policy Shifts

The flurry of food labeling regulations finalized and proposed at the end of the Biden administration — including the final rules on "healthy" claims and "Product of USA" claims, a proposed rule on front-of-package labeling issued by the FDA in January 2025 (90 Fed. Reg. 5426), and proposals to clarify food date labeling such as "use by" or "best by" statements — will probably also be reviewed by the Trump administration.

The review may involve a balancing of possibly conflicting goals within the new administration: to make the American diet healthier and more nutritious, and to reduce the regulatory burden on the food product industry.

Extent of Pharmacies' Corresponding Responsibility Under DEA Regulations Will Continued To Be Questioned

An ongoing source of regulatory uncertainty for pharmacies and pharmacists is the requirement under DEA regulations that they meet their corresponding responsibility to ensure that controlled substances are dispensed properly.

Under the agency's regulations, a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.

However, although "the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner," "a corresponding responsibility rests with the pharmacist who fills the prescription," the regulations specify (21 C.F.R. §1306.04(a)).

The DEA states in its 2022 Pharmacist's Manual: "The law does not require a pharmacist to dispense a prescription of doubtful, questionable or suspicious medical legitimacy. To the contrary, the pharmacist who deliberately ignores the high probability that a prescription was not issued for a legitimate medical purpose and fills the prescription may be prosecuted along with the issuing practitioner for knowingly and intentionally distributing controlled substances. Such action is a felony offense, which upon conviction may result in a term of imprisonment and a fine."

In recent DOJ enforcement actions targeting pharmacy chains accused of violating the CSA and DEA regulations in their dispensing of controlled substances, the pharmacies have questioned the extent of their responsibility to not fill valid-looking prescriptions written by DEA-registered physicians. For example, after the government sued it for allegedly dispensing controlled substances illicitly, Walmart Inc. called for the DOJ and the DEA to "go through the proper rulemaking channels to clarify going forward what the agencies expect of pharmacies and pharmacists."

However, the DEA took a hard line on the issue during a recent registration revocation proceeding. Counsel for a Louisiana pharmacy that allegedly dispensed controlled substances in violation of agency requirements contended during the proceeding that there was a "profound dearth of regulation or guidance clarifying the nature, scope and extent of a pharmacy's 'corresponding responsibility' and what it specifically requires."

The agency rejected the argument, saying, “DEA regularly publishes detailed decisions sanctioning pharmacies for violating their corresponding responsibility, which summarize DEA’s interpretation of the relevant statutes, cite to relevant federal court decisions and prior agency decisions, and apply the legal principles to the facts of the case. These decisions provide ample notice to the registrant community of DEA’s expectations.”

“Moreover,” the agency said, the pharmacy’s violations did not involve “the application of complex or obscure statutes or regulations. Rather, [the pharmacy’s] deficiencies outlined in this decision — such as failure to resolve and document blatant red flags of drug abuse — are core failures that violate bedrock principles of the CSA” (*Neumann’s Pharmacy, L.L.C.; Decision and Order*, 90 Fed. Reg. 8039 (Jan. 23, 2025)).

Pharmacies and pharmacists should keep abreast of the ongoing government enforcement actions against the pharmacy chains as well as individual DEA registration revocation actions as a means of clarifying the parameters of their corresponding responsibility under Section 1306.04(a).

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