FDA Policy Shifts Transform Terrain for Product Approvals and Enforcement

Major FDA policy changes are reshaping approvals, enforcement & strategy. ACI's FDA Boot Camp provides expert legal and regulatory insights.

NEW YORK CITY, NY, UNITED STATES, February 5, 2026 /EINPresswire.com/ -- The U.S. Food and Drug Administration (FDA) launched new policies in 2025 that could dramatically impact drug approvals and enforcement activity in the coming year. From broadening its advertising enforcement to accelerating development programs and publishing Complete Response Letters (CRLs), FDA has created new uncertainties for the life sciences industry.

The 44th Annual FDA Boot Camp takes place March 25-26, 2026, at the New York City Bar.

Against this backdrop, the American Conference Institute (ACI) announced today that its 44th Annual FDA Boot Camp, to be held March 25-26, 2026, at the New York City Bar in New York City, will provide insights on how to navigate these changes. During a recent webinar, the conference co-chairs gave an overview of developments that will be discussed at the meeting.

American Conference Institute

For over 40 years, American Conference Institute has brought together global business leaders and experts to connect, learn, and grow through high-impact conferences and information-driven networking opportunities.

Advertising and Promotion

Co-chair Melissa Mannion, of counsel at Jones Day, noted that the agency's advertising enforcement letters are focusing on different aspects of pharmaceutical promotional activity. FDA has shifted its

> It's been an interesting past year in FDA world as we've seen lots of changes with the new Trump Administration. We're likely to see more coming down the pike in terms of a sea change at FDA."
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> *Kurt Karst, Director at Hyman, Phelps & McNamara*

attention to compounding pharmacies and telehealth platforms. For example, it has objected to ads for compounded GLP-1 products that imply they are the same as FDA-approved products by saying they have the same active ingredient or proven effectiveness.

In addition, Mannion said FDA has expanded what it views as problematic. FDA is now using its AI tool Elsa to identify ads it believes are even slightly misleading. Thousands of general warning letters have been sent without citing specific regulatory violations.

Mannion said most of the letters point to general reasons why an advertisement might be misleading rather than a specific provision of the Food, Drug, and Cosmetic Act or regulation that is being violated. "We're seeing an expanded reinterpretation of what constitutes fair balance in these ads and promotional materials," she said.

Complete Response Letters (CRLs)

In a move that FDA called "radical transparency," the agency changed its historic policy of keeping CRLs to drug and biologic applicants confidential.

Co-chair Kurt Karst, a director at Hyman, Phelps & McNamara said making CRLs public takes away companies' ability to control their narrative and gives competitors insights into FDA concerns. Companies could put together pieces from several CRLs in a particular therapeutic area to "leapfrog over a potential competitor," he said.

On the positive side, he noted that companies gain insight into FDA decision-making and the most common deficiencies identified in CRLs. In addition, he said "FDA has cracked the door open" to seek additional information in FDA reviews, such as generic drug exclusivity decisions for abbreviated new drug applications.

Commissioner's National Priority Review Voucher

FDA has taken numerous steps to speed up product reviews. Its most notable and controversial action was the launch of the Commissioner's National Priority Review Voucher pilot program. Companies selected for the program receive a voucher entitling them to an approval decision within one to two months. To qualify, their products must support U.S. national interests.

Mannion said there is skepticism as to whether product reviews can be completed in 30 to 60 days. Karst questioned where reviewers would come from given staff cuts, what other areas would suffer because of the reallocation of work, and if reviews would be rushed.

Members of Congress have criticized the program for being launched without congressional authorization or rulemaking. In a letter to FDA Commissioner Martin Makary, Rep. Frank Pallone, Jr., D-NJ, House Energy and Commerce Committee Ranking Member, and Sen. Bernie Sanders, I-VT, Senate Health, Education, Labor, and Pensions Committee Ranking Member, said the program's "absurdly short timelines" are inconsistent with those in user fee agreements. They said the program could undermine public confidence in FDA's decisions, raise safety concerns and benefit those politically favored by President Trump.

Pathway for Ultra Rare Diseases

The agency is also seeking to speed approval of drugs for ultra rare diseases. In November, Vinay Prasad, director of the Center for Biologics Evaluation and Research, and Commissioner Makary published a paper announcing a new "plausible mechanism pathway" to accelerate drug approval for ultra rare diseases, based on mechanism of action and limited clinical data.

Mannion noted that under this pathway the agency would accept a much smaller amount of pre-market data than it does for other accelerated pathways and will likely have very robust post-marketing requirements.

Accelerating Biosimilar Development

The agency also aims to speed up development of biosimilars by eliminating the need for comparative efficacy studies for many biosimilars.

FDA issued draft guidance in October stating that a human pharmacokinetic similarity study and an assessment of immunogenicity may be sufficient to evaluate whether there are clinically meaningful differences between the proposed biosimilar and the reference product in terms of safety, purity and potency.

Mannion noted that removing clinical data from the approval requirements would have implications for the patent litigation process as well as biosimilar development. A faster biosimilar timeline raises "questions around potential earlier initiation of the patent dance and IP considerations," she said.

ANDA Priority Reviews

On the manufacturing front, the FDA has sought to incentivize testing and manufacturing of generic drugs in the United States. The agency announced a new pilot program to prioritize review of abbreviated new drug applications for applicants who conduct bioequivalence testing in the U.S. and whose active pharmaceutical ingredient supplier and finished dosage manufacturer are located in the U.S.

Karst questioned how beneficial the program would be since almost no ANDA sponsors meet these criteria. Mannion agreed, noting that generic manufacturers do not have deep pockets to make investments to bring manufacturing back to the U.S.

Facility Inspections

Among other actions last year, FDA expanded the use of unannounced inspections at foreign manufacturing facilities. The agency said it sought to end a double standard as American manufacturers do not receive notice of inspections while foreign firms often have weeks to prepare.

The agency also issued final guidance on conducting remote regulatory assessments of a company's compliance, such as by video livestream or teleconference. Mannion said she expects the agency will be using RRAs more frequently to increase the number of facilities it is communicating with. FDA conducts approximately 12,000 domestic inspections and 3,000 foreign inspections each year in more than 90 countries.

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