



FDA and NIH Take Actions to Reduce Reliance on Animal Testing with New Draft Guidance and Funding Announcement

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On March 18, 2026, the Food and Drug Administration (FDA) issued **draft guidance** entitled “General Considerations for the Use of New Approach Methodologies in Drug Development.” The guidance is meant to provide drug developers with a validation framework and general recommendations for using new approach methodologies (NAMs) in drug development. The use of NAMs can improve predictive toxicology in humans and reduce reliance on animal testing.

FDA defines NAMs to include a broad range of methods such as complex in vitro, 2D in vitro, in chemico and in silico studies. The recommendations in the draft guidance are intended to highlight scientific principles of study design and reporting that can be applied broadly in the validation of NAMs used in drug development. The guidance does not address specific NAMs but is meant to encourage the use of NAMs in regulatory submissions. The guidance includes validation considerations, focusing on four key features of any validation approach: context of use, human biological relevance, technical characterization, and fit-for-purpose.

The National Institutes of Health (NIH) also recently announced the availability of more than \$150 million in funding under the Complement Animal Research in Experimentation (Complement-ARIE) program to develop, validate and standardize human-based research methods, also known as NAMs, to reduce reliance on animal models, further underscoring the administration’s focus on reducing animal testing.

The issuance of the NAM guidance marks the latest action by the agency to implement its **roadmap to reducing animal testing** in preclinical safety studies released last year. This issue

was also included in the Make America Health Again (MAHA) Commission's **Strategy Report** released in September 2025 and continues to be an active area of interest for policymakers on Capitol Hill seeking to build on the FDA Modernization Act 2.0. The latest example of this is the **provisions** included as part of the Over-The-Counter Monograph Drug User Fee Program (OMUFA) reauthorization enacted last year, urging FDA to further allow alternatives to animal testing when considering certain drugs intended for topical administration.

The sustained, bipartisan focus by members of Congress and the Trump administration on reducing animal testing through expanding and increasing the utilization of NAMs, and ongoing interests in modernizing drug development, makes this an evolving policy issue worth watching as policymakers prepare to reauthorize the Prescription Drug User Fee Act (PDUFA VIII) currently set to expire in September 2027.

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