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TREATMENT
OF ANIMALS

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Submitted via email [redacted]

On behalf of People for the Ethical Treatment of Animals (PETA), we thank ICCVAM for its continued leadership in advancing the development, validation, regulatory acceptance, and use of reliable and relevant non-animal methods that protect human health and the environment.

We congratulate the NIH on establishing the Office of Research Innovation, Validation, and Application (ORIVA), and we commend the appointment of Dr. Warren Casey as its director. Dr. Casey has an extensive track record of strong science and collaboration across sectors and geographies and is ideally suited to lead this office. Under his leadership, ORIVA can serve as a central hub for coordinating the advancement of robust toxicity testing approaches across federal agencies while improving reproducibility, translatability, and efficiency in biomedical research. We are also encouraged by the NIH's recent efforts to expand support for organoids, microphysiological systems, computational approaches, and other innovative methods that can help modernize science.

Advancing the best science requires clear communication about the flexibility to generate data using new approach methods and how the data will be considered during regulatory review. We commend the Environmental Protection Agency (EPA) Office of Pollution Prevention and Toxics for the recent publication of its decision framework for hazard identification of skin irritation and corrosion, which provides practical guidance on assessing the severity of skin irritants and needed transparency and consistency to the data submission and review processes. We strongly support the development of these and additional useful guidance that provides transparency regarding the use and acceptance of specific approaches by the agency.

Direct, specific activities, such as those described above, are vital to achieving concrete progress. Another example is the EPA Office of Pollution Prevention and Toxics' maintenance of a List of Alternative Test Methods and Strategies (or New Approach Methodologies [NAMs])—a list that was recently updated and accompanied by a process for nominating new methods to be considered for the list. We hope the agency will update this list at least annually to maintain pace with updates at the Organisation for Economic Co-Operation and Development (OECD) and beyond.

Additionally, we have heard encouraging statements from the Food and Drug Administration (FDA) regarding its commitment to increasing reliance on non-animal methods, and we welcome initiatives such as the FDA's *Draft Guidance on Reducing Testing on Non-Human Primates for Monoclonal Antibodies*. However, many of FDA's stated commitments have yet to be translated into clear regulatory policies or guidance documents, or reviewer-level implementation. Consequently, sponsors and stakeholders continue to face uncertainty about what data are acceptable and how non-animal data will be evaluated. This uncertainty inhibits sponsors from bringing animal replacement proposals forward for consideration by the agency and/or has resulted in FDA rejecting proposals that are in line with the agency's animal replacement guidance. Clarity is needed to encourage sponsors to submit data from reliable new approach methods and to ensure the consistent acceptance of appropriate data from agency reviewers. To address this gap, we encourage the FDA

Entities
- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Switzerland
- PETA Netherlands
- PETA Foundation (U.K.)

to prioritize the incorporation of specific non-animal methods into guidance and facilitate training opportunities for reviewers that enable a greater understanding and consistent acceptance of new approach methods across the agency. For example, the FDA could immediately issue updated guidance to support the use of non-animal methods for skin irritation testing for medical devices, sunscreen (UV filter) safety evaluation, and anticaries testing of fluoridated over-the-counter products. The intentional, coordinated adoption of non-animal methods into FDA guidance can promote internal alignment, support consistency among reviewers, and give companies the confidence needed to adopt modern, human-relevant tools.

Thank you for the opportunity to provide these comments. We look forward to continued collaboration with ICCVAM agencies to accelerate the adoption of reliable and relevant non-animal testing approaches.

Sincerely,
Amy J. Clippinger, PhD
Managing Director, Regulatory Toxicology
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