PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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October 13, 2025

Dr. Martin Makary
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Makary,

I am writing to express our deep concern regarding the U.S. Food and Drug Administration's (FDA's) continued expectation that sunscreen manufacturers conduct tests on animals, despite overwhelming scientific evidence and public opposition to such practices.

More than 50,000 individuals have signed PETA petitions urging the FDA to modernize its approach to sunscreen safety testing (attached). In recent months, four peer-reviewed scientific papers have demonstrated that widely used sunscreen ingredients can be evaluated for safety using existing human, *in vivo* animal, and *in vitro* data, as well as advanced non-animal methodologies.[i,ii,iii,iv] These findings—some of which were submitted to the FDA years before the data were published—reinforce an internationally-established understanding that further animal tests will not yield meaningful safety insights and will only result in the suffering and death of thousands of animals. Additional forthcoming publications will continue to support this understanding.

Unfortunately, the FDA's recently released statement[v] on sunscreen safety reflects a troubling disconnect with the agency's own stated goal of reducing animal testing and the overwhelming scientific consensus regarding their safety. The statement misleadingly names animal tests that are not required while implying animal tests that are expected. For example, "the FDA does not request fertility studies or cancer studies in a second species" leads readers to conclude that cancer and reproductive toxicity tests *are* required in one animal species. This conclusion is in direct opposition to the current state of the science, the opinion of scientists and regulators that review sunscreen safety data around the world, and the FDA's stated commitment to reducing animal testing.

In addition, the statement notes that "the FDA strongly encourages companies to continue to develop new, reliable ways to minimize animal testing and to provide the data necessary for the FDA to make a GRASE determination for sunscreen active ingredients." In fact, public records show that companies have submitted non-animal testing strategies to the FDA that the agency has summarily disregarded, without engagement or supportive collaboration with the submitters.

The animal tests that the agency is asking for—carcinogenicity and reproductive toxicity tests—will take a minimum of a decade to complete and kill more than 24,000 animals (at least 2,000 animals per chemical tested with expectations for testing up to 12 UV filters[vi]). The results of these specific tests have been shown to be unreliable and of limited relevance to human health, leaving us with no better protection for Americans.

Instead, in less time than it would take to conduct the animal tests, the agency can choose to work collaboratively with the experts who are asking the agency to actively engage in discussions on modern risk assessment approaches. In addition to the abundance of decades of accumulated safety data from real-world human use and the many animal studies that were used to bring these products to the market, there is opportunity for the FDA to participate in the design of a modern testing strategy that uses *in vitro*, *in silico*, and human clinical studies to answer any further questions. This approach can incorporate new approach methodologies, such as maximum usage (MUsT) trials, and *in vitro* and *in silico* models that provide human-relevant mechanistic information about UV filters' capacity to penetrate human skin, distribute throughout the human body, enter tissues and cells of concern, activate human hormone

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receptors, generate metabolites of concern, and to understand the exposure levels at which these capacities can be considered risks to human health.

Importantly, these risk assessment approaches can be used to further evaluate existing sunscreens that are on the US market, and they can be used to bring new UV filters to market. Both the agency and the public are eager for innovative UV filters that enhance the safety and efficacy profiles of sunscreen products, but FDA's process has been insurmountable for the past 25 years. The one company that is poised to gain FDA approval for the first new UV filter during that time has conducted animal studies mandated by the FDA but that no other regulatory authority or manufacturer considers necessary for protecting human health. To ensure Americans have access to modern, globally available ingredients, the FDA's process for evaluating UV filters needs to be updated.

The data-rich field of UV filters provides the perfect opportunity for the FDA to uphold its promise to reduce animal testing. The availability of non-animal testing approaches that can be used to answer any outstanding questions and the willingness of subject matter experts to collaborate with the FDA on this topic will allow the FDA to evaluate the safety of UV filters without using animals. The FDA's insistence on animal testing in this area would show that the agency is not sincere in its promise to reduce animal testing or to better protect the American public with modern testing approaches.

I urge the FDA to take meaningful action to collaborate with the subject matter experts who are eager to engage on the use of more scientifically sound toxicity testing approaches.

Sincerely,

Amy J. Clippinger, PhD
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[i] Norman KG, Kaufman LE, Griem P, Loretz L, Kowcz A, Cohen SM, Scialli AR, Boobis AR, Jacobson-Kram D, Schoeny R, Rosol TJ, Williams GM, Kaminski NE, Guengerich FP, Nash JF. Comprehensive review of ensulizole toxicology data and human exposure assessment for personal care products. *Crit Rev Toxicol*. 2025. doi.org/10.1080/10408444.2025.2541392.

[ii] Norman KG, Kaufman LE, D'Ruiz C, Loretz L, Kowcz A, Cohen SM, Scialli AR, Boobis AR, Jacobson-Kram D, Schoeny R, Rosol TJ, Williams GM, Kaminski NE, Guengerich FP, Nash JF. Comprehensive review of avobenzone (butyl methoxydibenzoylmethane) toxicology data and human exposure assessment for personal care products. *Crit Rev Toxicol*. 2025. doi.org/10.1080/10408444.2025.2535394.

[iii] Punt A, Baltazar MT, Nicol B, Cable S, Hewitt NJ, Cubberley R, Spriggs S, Dent MP, Li H. Building confidence in PBK model predictions in the absence of human kinetic data: benzophenone-4 case study. *ALTEX*. 2025. doi.org/10.14573/altex.2501211.

[iv] Baltazar MT, Cable S, Cubberley R, Hewitt NJ, Houghton J, Kukic P, Li H, Malcomber S, Nicol B, Pendlington R, Punt A, Reynolds J, Scott S, Spriggs S, Dent MP. Making safety decisions for a sunscreen active ingredient using next-generation risk assessment: benzophenone-4 case study. *ALTEX*. 2025;42(3):511-530.

[v] https://www.fda.gov/news-events/fda-voices/fda-encourages-development-new-reliable-alternatives-animal-testing-sunscreen?utm_medium=email&utm_source=govdelivery

[vi] FDA. September 27, 2021. Final Administrative Order (OTC000006) Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use. 86 FR 53322. FR Doc. 2021-20780. Available at https://www.federalregister.gov/documents/2021/09/27/2021-20780/amending-over-the-counter-monograph-m020-sunscreen-drug-products-for-over-the-counter-human-use-over

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March 26, 2025

Martin Makary, MD, MPH
Commissioner
U.S. Food and Drug Administration

Via e-mail*:* Commissioner@fda.hhs.gov

Dear Commissioner Makary:

Congratulations on your confirmation as Commissioner of the Food and Drug Administration (FDA). We are hopeful you will guide the FDA to ensure that the best science is used to get medicines to patients efficiently and without undue agency or regulatory burden.

While previous statements from the agency have indicated strong support for implementing efficient and effective non-animal methods, in practice, the FDA has largely failed to grab the low-hanging fruit. Instead, the FDA has created roadblocks to the use of non-animal methods, including stalling the use of existing well-characterized methods, overlooking the disadvantages of tests on animals, failing to provide transparency to the regulated industry and consumers, and ignoring calls for accountability.

This is why PETA scientists, along with nearly 47,000 supporters (signatures enclosed), are urging the new FDA leadership to right the wrongs of its predecessors by applying the most reliable and relevant testing approaches to best protect human health. In your new role, we hope you will consider the following five actions that are ready to roll:

1. Instead of insisting that manufacturers test sunscreens using unreliable animal tests, embrace modern tools, such as using existing human information and non-animal test methods.
2. Update a decades-old policy for assessing toothpastes and other fluoridated over-the-counter products with available, human-relevant and reliable methods that industry prefers to use because of their demonstrated effectiveness.
3. Enact a policy to accept human tissue models to assess the skin irritation potential of medical devices, joining scientists from around the world in replacing the test on rabbits.
4. Replace tests on animals to identify toxins in shellfish with well-established non-animal methods that can better protect human health.
5. Accept the use of human tissue models to evaluate personal lubricant products instead of the outdated rabbit vaginal irritation test.

As *Blind Spots* posits, when modern medicine issues recommendations based on good scientific studies, it shines. As someone who understands the importance of accountability and transparency, we are hopeful you will align the FDA with

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public interest and practical, sensible toxicology testing. As you reference in *Blind Spots*, misleading groupthink can harm millions. Right now, you have the power to turn off the faucet of bad ideas by embracing human-relevant, forward-thinking science.

We would appreciate a meeting with you and any members of your FDA team to further discuss how the agency can tackle these issues and bring about a new and improved testing paradigm. Thank you for your continued efforts, and I look forward to the positive changes you will accomplish.

Sincerely,

Amy J. Clippinger, PhD
Managing Director, Regulatory Toxicology
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