TESTIMONY
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EXAMINING THE FDA'S REGULATION OF OVER-THE-COUNTER MONOGRAPH DRUGS

Introduction

Chair Carter, Ranking Member DeGette, and distinguished Members of the Subcommittee, it is an honor to testify before you today on behalf of dsm-firmenich and in my capacity as the former Chair of the Sunscreen Consortium for the Personal Care Products Council (PCPC) to discuss how the Food and Drug Administration (FDA) regulates over-the-counter drugs, mainly it's regulation of sunscreen ingredients.

I am Carl D'Ruiz, Senior Manager of the Beauty and Care Business North America for dsm-firmenich and former Chair of the Personal Care Products Council's Sunscreen Consortium. I have dedicated my career to public health, innovation, and industry leadership, focusing on advancing sunscreen standards in the United States. For the past twenty-five years, the last seven with dsm-firmenich, I have led efforts to seek FDA approval of Bemotrizinol, an advanced sunscreen filter available in other parts of the world since 2001.

Dsm-firmenich is a global leader in health, nutrition, and bioscience. We are a purpose-led and science-backed company, leveraging over a century of innovation to support the health and well-being of people, animals, and the planet at every stage of life through vitamins and nutritional ingredients, fragrances, and biomaterials. Dsm-firmenich proudly employs more than 5,000 American workers and growing, including more than 2,500 in manufacturing roles, at 43 sites across 21 states, most of which are either located in or close to the districts that the Members on this Subcommittee serve.

dsm-firmenich is the leading manufacturer of organic and mineral ultraviolet (UV) light filters, with over 40 years of experience producing, selecting, and blending UV filters for nearly every sunscreen manufacturer in the United States. Notably, dsm-firmenich is the first and only company sponsoring the approval of a new sunscreen filter, Bemotrizinol, via the FDA's new Over-the-Counter Monograph Order Requests (OMOR) Tier 1 approval pathway. DSM initially submitted for approval of this product for FDA approval in 2005, yet 20 years later, we are still waiting to authorize this ingredient – despite robust evidence demonstrating that this ingredient is safe and effective for its intended use and a long track record of safe use outside of the United States.

We are also a proud member of the Personal Care Products Council (PCPC), the leading national trade association representing cosmetics and personal care products companies in the United States. Founded in 1894, PCPC's approximately 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States, contributing to more than 4.7 million jobs and $309 billion, or about 2.2 percent of the total United States gross domestic product (GDP). As Chair of the PCPC Sunscreen Consortium, I defended the safety of existing over-the-counter (OTC) sunscreen ingredients and actively supported the Skin Cancer Foundation's cancer detection and prevention programs.

We appreciate this Subcommittee holding this hearing and are pleased to offer our views on the OTC Monograph reform generally and on specific steps Congress can take during the Over-the-

Counter Monograph Drug User Fee Program (OMUFA) reauthorization process to facilitate expanded access to safe and effective sunscreen products in the United States.

Background on FDA's Treatment and Approval of Sunscreen

Skin cancer remains the fastest-growing cancer in the United States. More than 6.1 million adults are treated for skin cancer, at a cost of about $8.9 billion annually.[1] Fortunately, unlike many cancers, most forms of skin cancer can largely be prevented by taking precautions, which includes using sunscreens. Despite its importance for preventing skin cancer, Americans are at a severe disadvantage relative to other countries globally – particularly European and some Asian countries – when it comes to having the safest and most innovative UV filters and sunscreen products, largely due to the FDA's delays in approving new UV filters.

The FDA has not approved a new active ingredient or UV filter for use in sunscreen since ensulizole's approval in 1999, more than twenty-five years ago. While there has been significant innovation in sunscreen manufacturing over the past several decades, American consumers have not had access to these formularies due to the overly complex and burdensome regulatory hurdles, outdated testing requirements, and a lack of data protection standards. According to the CDC, skin cancer is the most common form of cancer in the United States.[2]

In the United States, sunscreen is regulated as a non-prescription, over-the-counter (OTC) drug, subjecting it to the same safety and efficacy standards as other topical drug products, including prescription topical drugs. Consequently, United States sunscreen manufacturers only have access to 16 UV filters to create sunscreen products and truly utilize only seven of these, compared to the nearly 30 safe and effective filters approved in Europe and other regions with decades of proven track records of safety and efficiency. This lack of approved UV filters in America, including and especially more advanced sunscreen technologies more suitable and preferable for a wide range of skin colors and types, severely hampers the ability to bring forward a broader selection of more modern, efficient, and safer sunscreen products that help protect Americans from skin cancer and the harmful effects of the sun.

This issue is not new for the FDA. However, past attempts to address barriers to innovation in the United States sunscreen market have fallen short. For example, the 2014 Sunscreen Innovation Act was enacted to expedite the review and approval process for active ingredients that help protect the skin from ultraviolet (UV) rays. Yet, despite its intent, the Sunscreen Innovation Act did not result in the approval of any additional filters in the United States. In 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) included provisions that govern the way certain OTC drugs were regulated to improve the efficiency, timeliness, and predictability and facilitate

1 [illegible]

2 [illegible]

innovation in the OTC market, including the sunscreen market,[3] which led to the creation of the OMUFA program. Despite this, no new sunscreen filters have been approved in the five years since the CARES Act passed.

The OMUFA reauthorization process presents a unique opportunity to examine the challenges associated with the FDA's review and approval of new sunscreen filters and consider potential solutions that will unlock much-needed innovation in the United States sunscreen market to put the United States on par with other nations globally when it comes to bringing safe and more innovative sunscreens to market.

I. Modernizing Safety Assessments

As the committee considers reauthorizing the OTC monograph process, we strongly advocate for prioritizing modern toxicological approaches and innovative methodologies, specifically in the review of OTC drug active ingredients like sunscreens. This includes the adoption of non-animal, mechanistic-based methods, including in silico models, New Approach Methodologies (NAMs), and other cutting-edge non-clinical risk and safety assessment tools.

Many test methods currently embedded in OTC monographs were established decades ago and do not reflect the latest scientific advancements. Outdated testing requirements can unnecessarily delay innovation and hinder the introduction of safer and more effective products. Modernizing these methods will:

- Enhance the accuracy and relevance of safety data for consumers.
- Reduce reliance on animal testing, aligning with global trends toward ethical and sustainable practices.
- Improve regulatory efficiency by incorporating high-throughput, data-rich approaches.

We urge the FDA to accelerate the adoption of these modern toxicological methods for OTC monograph evaluations. Moving to modern safety assessments, specifically NAMs, would align the OTC sunscreen testing with the FDA's Center for Food Safety and Applied Nutrition use of NAMs and accelerate the approval process of new filters in a manner that does not compromise safety and allow for the review of more innovative UV filters.

II. Encouraging Innovation

Companies like dsm-firmenich and others in the personal care products industry, many of which belong to the PCPC, are committed to delivering consumers the safest, most innovative, and highest-quality products. We seek a regulatory system that works as intended, enabling the best, safest, and most innovative products to reach consumers in a timelier and more efficient manner. Industry-wide, more than $3 billion is invested annually in scientific research and development to ensure product and ingredient safety. This results in approximately 2,000 new products launched each year, all designed to meet the trust and safety millions of consumers place in us.

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[3] [illegible]

However, regulatory barriers often limit the speed at which customers can access these better products.

In addition, the United States does not provide confidentiality and data protection for companies sponsoring OTC sunscreens with the FDA, which is in direct conflict with other parts of the world, where the submitted data for sunscreen approval is kept confidential and may only be released by the sponsor. As a result, in the United States, companies are reluctant to make significant investments (estimated to be around $18.5 million) to pioneer new UV filters to market, as other companies – many of which are based in China – that do not contribute to the development of the product or the data can get a "free ride" at the expense of the pioneer company bringing the product to market.

We strongly encourage a more streamlined, modern regulatory framework and pathway to incentivize the development of safer and more innovative products. This includes promoting modern testing methods, which will lower development costs and encourage market competition. Further, we encourage reforms to align the United States confidentiality and data protections with other countries globally.

III. Increasing Consumer Trust and Confidence

Consumer frustration and a lack of optimism that new filters will be available soon have drawn many American consumers to purchase internationally approved sunscreen products that they like on the internet, skirting the FDA. This trend is driven by the perception that international products offer better protection and more advanced formulations, which are not yet available in the United States market due to regulatory delays. The timely approval of new filters is vital to ensuring consumer confidence in the United States regulatory system.

Consumer trust and confidence in US sunscreens are also being eroded by the FDA's call for further animal testing of ingredients that have been used safely in the US and worldwide for nearly 50 years and whose safety can be more efficiently reaffirmed via the development and use of standardized non-animal toxicological new approach methods (NAMs). These methods are seen as more ethical and scientifically advanced alternatives to traditional animal testing. The ongoing reliance on animal testing is viewed as outdated and unnecessary, further diminishing consumer confidence in the regulatory process.

Conclusion

As Congress works on the OMUFA reauthorization process, we encourage you to consider common-sense reforms that will help nurture sunscreen innovation and provide Americans with access to more modern, safe, efficient, and sustainable UV filters that help protect against skin cancer and the harmful effects of the sun. These could include:

- Ensuring prioritization, transparency, accountability, and appropriate funding for the development and validation of new approach methodologies (NAMs) that can be used by the FDA for making risk-based safety decisions without conducting animal testing.
- The OMUFA process should include continued interaction between the FDA and regulated industries.
- Aligning confidentiality and data privacy standards with other countries globally for companies sponsoring OTC sunscreens with OTC.

We welcome the opportunity to explore these potential improvements with the Subcommittee and others. Thank you again for the opportunity to participate in this hearing, and we look forward to continuing to work with you to advance these important initiatives.