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Examining the Differences in Current Regulatory Processes for Sunscreens and Proposed Safety Assessment Paradigm

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6 **Introduction**

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8 Ultraviolet radiation (UVR) in sunlight is the most ubiquitous environmental carcinogen, and
9 consequences of UVR exposure include melanoma and non-melanoma skin cancer. These skin cancers
10 have reached epidemic proportions and their associated morbidity and mortality are substantial. This
11 manuscript serves to provide updated results from clinical and investigative studies which have provided
12 new insights into how UVR induces skin cancers and the importance of broad spectrum sunscreens as
13 part of the strategy to protect the public. This work also serves to point out the barriers to effective
14 sunscreen use, including that many of the most effective sunscreen filters are not available in the United
15 States due to the delays from the Food and Drug Administration (FDA) on their approval. The purpose
16 of this paper therefore is to examine the different requirements for safety assessment of sunscreen
17 products and, considering the differences in regulatory requirements between the US and EU, outline a
18 harmonized, scientifically acceptable scheme for the safety testing of sunscreen products. Details as to
19 the current state of testing of filters in the US and abroad are provided. Most importantly,
20 recommendations for appropriate testing of filters are outlined which can assist in providing a pathway
21 for their approval to provide the US public improved protection.

22 As established in 1932 by the Second International Congress on Light, UVR is divided into ultraviolet C
23 (UVC; 270-290 nm); ultraviolet B (UVB; 290-315) and ultraviolet A (UVA; 315-400 nm) (Coblentz, 1932).

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