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NEWS RELEASE

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NPA Calls for Added Clarification of FDA’s GRASE Evaluation of OTC Sunscreens

“Clarity and transparency in FDA’s guidance to evaluate safety and effectiveness of OTC sunscreens are what we are striving for,” said Dr. Fabricant.

WASHINGTON, D.C. – The Natural Products Association (NPA) in a recent public filing with the Food and Drug Administration (FDA) encouraged the adoption of standardized equivalent active ingredient controls across OTC sunscreen clinical trials, clarification of “non-diseased” skin, further guidance on submitting Maximum Usage Protocols, and conscious efforts by FDA to reduce the number of animals used in clinical testing protocols submitted to FDA.

“Giving consumers access to more safe and effective sunscreen products and supporting the goal of reducing skin cancer in the United States is something NPA will always promote. The safety and effectiveness of sunscreen products containing nanoparticles should not be taken lightly. Advocating for reductions in the number of animals used to support studies of safety and effectiveness for OTC sunscreens is also a fundamental guiding principle of NPA’s natural standard,” said Dr. Daniel Fabricant, CEO and Executive Director of NPA.

Given the high rate of skin cancer in the United States, NPA considers sun protection to be a matter of public health and strongly encourages the FDA to take these specific steps to benefit consumers. While the NPA supports aspects of the current draft guidance entitled, “Over-the-Counter Sunscreens: Safety and Effectiveness Data” and the implementation of the Sunscreen Innovation Act, NPA urges FDA to consider all points made in our comments to ensure the draft guidance is clear and comprehensive.

These comments follow on to NPA’s call last month for FDA to clarify what it considers an active ingredient in sun protection products and to also amend the approval process to allow more applications for new products.

NPA’s comments can be viewed in their entirety [HERE](#)



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Natural Products Association

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