

With the statutory deadline approaching, FDA issues a proposed sunscreens rule

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Focus On Regulation

On 26 February, the U.S. Food and Drug Administration (FDA) published the [proposed rule](#), "Sunscreen Drug Products for Over-the-Counter Human Use," which describes the conditions under which over-the-counter (OTC) sunscreen monograph products are generally recognized as safe and effective (GRASE) and not misbranded.

Primarily, the proposed rule seeks additional information on sunscreen ingredients so that FDA can evaluate their GRASE status in light of changed conditions, including substantially increased sunscreen usage and exposure, and evolving information about the potential risks associated with these products.

Read More: [With the statutory deadline approaching, FDA issues a proposed sunscreens rule](#)

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