FDA Proposed Rule for OTC Sunscreen Drug Products Addresses Combination Sunscreen-Insect Repellent Products

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The U.S. Food and Drug Administration (FDA) is scheduled to publish a proposed rule in the Federal Register on February 26, 2019, that would put into effect a final monograph for nonprescription, over-the-counter (OTC) sunscreen drug products. The proposed rule describes the conditions under which FDA proposes that OTC sunscreen monograph products are generally recognized as safe and effective (GRASE) and not misbranded. Under the proposed rule, products that combine sunscreens with insect repellents would not be GRASE. Publication of the proposed rule in the Federal Register will begin a 90-day comment period.

Sunscreen-insect repellent products are jointly regulated by FDA as sunscreen drugs and by the U.S. Environmental Protection Agency (EPA) as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). On February 22, 2007, FDA and EPA both issued advance notices of proposed rulemaking (ANPR) requesting comment on the appropriate regulatory status of these products. FDA published a notice seeking information to formulate a regulatory position on insect repellent products that contain OTC sunscreen ingredients. 72 Fed. Reg. 7941. EPA published a similar notice announcing that it was also seeking information to determine how insect repellent-sunscreen combination products should be regulated to complete the reregistration review described in the Reregistration Eligibility Decision document for the insect repellent N,N-diethyl-meta-toluamide (DEET). 72 Fed. Reg. 7979.

In the proposed rule, FDA states that it reviewed comments submitted in response to the 2007 ANPRs, as well as pertinent scientific literature and publicly available EPA regulatory documents. Based on that review, FDA has tentatively concluded that sunscreen-insect repellent combination products, as a class, are not GRASE and are misbranded because conflicting labeling requirements for the sunscreen and insect repellent components cannot be reconciled to create labeling that will sufficiently ensure the safe and effective use of the sunscreen component, as well as adequate directions for use as a sunscreen. FDA states that even if it did not have this labeling concern, it would still tentatively determine that available data regarding the safety and effectiveness of these products for their use as sunscreens are insufficient to classify these sunscreen products as GRASE for such use. Specifically, according to FDA, evidence suggests that interactions between some sunscreen active ingredients and insect repellents may decrease safety by increasing systemic absorption of one or both components, and potential synergistic effects on the efficacy of sunscreen active ingredients apparently have not been studied.

The proposed rule states that FDA tentatively determines that sunscreen-insect repellent combination products are not GRASE for nonprescription sunscreen use. FDA seeks comment on this tentative determination. Publication of the proposed rule in the Federal Register on February 26, 2019, will begin a 90-day comment period. More information on the proposed rule is available in our memorandum, "FDA Will Publish Proposed Rule..."