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Subject: **Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use; Order ID OTC000008; Docket No. FDA-1978-N-0018**

The Household & Commercial Products Association[1] (HCPA) appreciates the opportunity to offer comments regarding the Food and Drug Administration (FDA) Proposed Order Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use (Proposed Order). The Proposed Order is similar to the FDA's 2019 Tentative Final Monograph on sunscreen products, which HCPA previously provided comments on. As FDA expressed that they will review public comments from 2019 in addition to those received in 2021, HCPA will use this opportunity to reiterate some of the comments made in 2019.

HCPA provides the following comments for consideration, primarily on behalf of the HCPA Aerosol Products Division which represents the interests of its members that manufacture, formulate and market a wide variety of products packaged in the aerosol form, including OTC sunscreen drug products. HCPA's comments focus specifically on OTC sunscreen products that are in the aerosol delivery form.

In the Proposed Order, FDA raised two safety concerns specific to spray sunscreen dosage forms: (1) the potential risk of respiratory harm from inhaling sunscreen ingredients and (2) the potential flammability risk when consumers are exposed to flame or heat before spray solvents have completely dried. To address these concerns, FDA proposed additional conditions in the monograph to mitigate concerns by proposing formulation limitations, labeling requirements and additional testing to ensure that sunscreen products in a spray dosage form are GRASE.

[1] The Household & Commercial Products Association (HCPA) is the premier trade association representing companies that manufacture and sell $180 billion annually of trusted and familiar products used for cleaning, protecting, maintaining, and disinfecting homes and commercial environments. HCPA member companies employ 200,000 people in the U.S. whose work helps consumers and workers to create cleaner, healthier and more productive lives.

I. HCPA Comments on Mitigating Inhalation Toxicity Concerns

FDA proposes to limit the risks of unintentional exposure and potential associated adverse events to respirable particles in spray sunscreens by limiting the size of particles dispensed from these products. FDA proposes that 90 percent of the particles dispensed from the consumer container be at least 10 µm or greater in order to limit exposure beyond the larynx. Additionally, to prevent deposition in the deep lung, the minimum particle size dispensed from the consumer container must be no less than 5 µm.

HCPA requests that FDA amend the specification for particle size because as written, the "must be no less than 5 µm" could be interpreted to mean that even one particle less than 5 µm would be unacceptable. Instead, HCPA requests that the specification be amended to allow "no more than 1% of particles may be below 5 µm" so that the full specification reads "90 percent of the particles dispensed from the consumer container must be at least 10 µm or greater and no more than 1 percent of the particles dispensed from the consumer containers may be less than 5 µm." As sunscreen spray applications is not a direct inhalation dosage, we would not expect that this minimal allowance would pose a hazard to consumer when the product is used as intended in accordance with label directions.

While HCPA agrees that manufacturers need to analyze the spray of their products to determine compliance with this specification, HCPA recommends that sunscreen manufacturers be required to ensure particle size testing for their sunscreen sprays during the qualification and validation of the product rather than be conducted on each lot of final product. Individual lot testing would not improve consumer safety but does place a significant burden on industry. Thus, HCPA requests that the required testing be modified.

II. HCPA Comments on Mitigating Flammability Concerns

FDA proposes to limit a potential flammability risk by requiring all batches of sunscreen products to be tested for flammability in accordance with the 16 CFR 1500.43a as part of batch release testing. Any product that meets the Consumer Product Safety Commission's (CPSC) definition[2] of extremely flammable would not be considered GRASE and not able to be marketed under the OTC sunscreen monograph. FDA also proposes to add labeling requirements for spray sunscreen products that are flammable or combustible.

First and foremost, while the test method in 16 CFR 1500.43a is appropriate for determining the flammability of liquid sunscreen products, FDA needs to include additional test methods for determining the flammability of aerosol sunscreen products. In the United States, there are different test methods that aerosol manufacturers must comply with depending on the authority for the product. If FDA follows CPSC test methods, as is with liquid sunscreen products, then FDA should utilize the test method for determining extremely flammable and

[2] 16 CFR 1500.3

flammable contents of self-pressurized containers[3]. The 16 CFR 1500.45 is the appropriate test method for determining the flammability of consumer aerosol products. The Occupational Safety and Health Administration (OSHA) utilizes different flammability test methods that can be found with the 29 CFR 1910.1200. HCPA would support FDA's use of these methods as well for classifying the flammability of aerosol products.

HCPA is in agreement that flammability testing needs to be conducted when a product contains flammable components; however, HCPA recommends that sunscreen manufacturers be required to classify the flammability of their sunscreen sprays during the qualification and validation of the product rather than be conducted on each lot of final product. Similarly to the particle size, HCPA does not believe consumer safety is improved with individual lot testing and the burden of testing each lot isn't justified.

III. HCPA Comments Regarding Sunscreen-Insect Repellent Combination Products

Combination sunscreen-insect repellent products are both convenient and provide a significant health benefit to consumers. HCPA recommends that FDA continue its enforcement discretion to allow the marketing of these products while working in coordination with EPA to address concerns in the disparities in the required labeling of sunscreen and insect repellents. Rather than trying to merge both FDA's and the Environmental Protection Agency's (EPA) labeling requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), HCPA suggests that the two agencies collaborate together to create a new labeling requirement for this specific product category that would satisfy both agencies. HCPA believes that it is better for consumers to use one product that is designed to offer protection from the sun and repel insects rather than using two products to accomplish this protection in which the combination of the two different products can result in unforeseen complications and hopes that FDA engages with EPA to resolve the different requirements.

IV. Conclusion

In conclusion, HCPA appreciates the opportunity to provide input and thanks FDA for taking these comments into consideration. If you have any questions about these comments or aerosol products, please contact me at ngeorges@thehcpa.org or 202-872-7304.

Respectfully,

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[3] 16 CFR 1500.45