10-1-2021

Food and Drug Administration's proposed sunscreen final administrative order: How does it affect sunscreens in the United States?

Henry W. Lim
Henry Ford Health, hlim1@hfhs.org

Tasneem F. Mohammad
Henry Ford Health, TMOHAMM2@hfhs.org

Steve Q. Wang

Recommended Citation
Lim HW, Mohammad TF, and Wang SQ. Food and Drug Administration's proposed sunscreen final administrative order: How does it affect sunscreens in the United States? J Am Acad Dermatol 2021.

Food and Drug Administration's proposed sunscreen final administrative order: How does it affect sunscreens in the United States?

To the Editor: On September 24, 2021, the US Food and Drug Administration (FDA) released a proposed final administrative order for sunscreen drug products.[1,2] The release of this proposed order replaces the 2019 Proposed Rule in order to fulfill the statutory provisions of the Coronavirus Aid, Relief, and Economic Security Act, signed into law on March 27, 2020. The Coronavirus Aid, Relief, and Economic Security Act replaced the FDA monograph rulemaking process, which is laborious and time-consuming, with an administrative order process that should be more efficient.[3] There is a 45-day comment period. After the FDA addresses all comments, a final administrative order will be issued, which would become effective no sooner than 1 year after its release.

Once the final order is issued, companies will only be able to continue marketing sunscreens with a given active ingredient if the FDA has determined the active ingredient is generally recognized as safe and effective (GRASE), unless they first seek FDA approval. Until then, the FDA does not require companies to remove products from the market.

Highlights of the proposed order, which is similar to the FDA Proposed Rule released in February 2019,[4] are shown below:

1. GRASE status of approved UV filters:
   GRASE: zinc oxide and titanium dioxide;
   Not GRASE due to safety issues: paraaminobenzoic acid and trolamine salicylate;
   Not GRASE because additional data are needed (12 ingredients): cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone, and avobenzone.

Of note, paraaminobenzoic acid and trolamine salicylate are no longer used in sunscreens marketed in the US. For the other 12 ingredients with "not GRASE" status, if data are not available at the end of the 45-day comment period, the FDA would be prepared to defer the final decision on the ingredients provided the FDA is satisfied that timely progress is being made on the necessary studies. Such a deferral would be for a period of not more than 1 year, with a possible extension.

At the time of this writing, industry is working with the FDA on testing requirements for 8 of the 12 ingredients. These 8 are avobenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, and oxybenzone.

2. Maximum sun protection factor: 60+. However, marketing of products with a sun protection factor of up to 80 would be permissible.
3. Broad spectrum requirements: These would be required for all products with a sun protection factor of ≥15; a proposed new requirement of a UV-A I/UV ratio of 0.7 or higher would need to be met.
4. Dosage forms: Oils, lotions, creams, gels, butters, pastes, ointments, and sticks are proposed to be GRASE. Sprays, subject to testing and labeling requirements, are also proposed to be GRASE. Additional data are needed for powders before a determination of GRASE status can be made.
5. Labeling: Active ingredients are to be listed alphabetically on the principal display panel (ie, the panel visible on the retail shelf).
6. Sunscreen-insect repellent combinations: These products are proposed to be considered not GRASE.

Henry W. Lim, MD,[a] Tasneem F. Mohammad, MD,[a] and Steve Q. Wang, MD[b]

From the Photomedicine and Photobiology Unit, Department of Dermatology, Henry Ford Health System, Detroit, Michigan[a]; and Dermatology Service, Memorial Sloan Kettering Cancer Center, New York, New York.[b]

Funding sources: None.

IRB approval status: Not applicable.

Correspondence and reprint requests to: Henry W. Lim, MD, Department of Dermatology, Henry Ford Medical Center—New Center One, 3031 West Grand Blvd, Suite 800, Detroit, MI 48202

E-mail: hlim1@hfhs.org

Conflicts of interest

Dr Lim is an investigator for Incyte, L'Oréal, Pfizer, and PCORI. He has served as consultant for Pierre Fabre, ISDIN, Ferndale, La Roche-Posay, Cantabria, and Beiersdorf. He has also participated as a speaker in general educational sessions for La Roche-Posay and Cantabria Labs. Dr Mohammad is an investigator for Incyte, Pfizer, Arcutis, National Institute of Allergy and Infectious Diseases, and Unigen. Dr Wang has served as a speaker for La Roche-Posay and Neutrogena.

REFERENCES

1. United States Food and Drug Administration. OTC Monographs@FDA. Accessed September 25, 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTCMonograph_M020-SunscreenDrugProductsforOTCHumanUse09242021.pdf

2. United States Food and Drug Administration. Questions and Answers: FDA posts deemed final order and proposed order for over-the-counter sunscreen. Accessed September 25, 2021. https://www.fda.gov/drugs/understanding-over-counter-medicines/questions-and-answers-fda-posts-deemed-final-order-and-proposed-order-over-counter-sunscreen
3. Mohammad TF, Lim HW. The important role of dermatologists in public education on sunscreens. *JAMA Dermatol*. 2021;157(5):509-511. https://doi.org/10.1001/jamadermatol.2020.5393
4. Wang SQ, Lim HW. Highlights and implications of the 2019 proposed rule on sunscreens by the US Food and Drug Administration. *J Am Acad Dermatol*. 2019;81(2):650-651. https://doi.org/10.1016/j.jaad.2019.04.007

https://doi.org/10.1016/j.jaad.2021.09.052