



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0352]

Intent to Prepare an Environmental Impact Statement for Certain Sunscreen Drug Products for Over-The-Counter Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: Under the National Environmental Policy Act of 1969 (NEPA), as implemented by the Council on Environmental Quality (CEQ) regulations, the Food and Drug Administration (FDA or Agency) announces its intent to prepare an environmental impact statement (EIS) to evaluate the potential environmental effects of revised conditions for marketing certain sunscreen products for over-the-counter (OTC) use without prior approval of a new drug application (NDA). By this notice, FDA is announcing the beginning of the scoping process to solicit public comments and identify issues to be analyzed in this EIS.

DATES: This notice initiates the public scoping process that will close on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. FDA will consider comments in response to this notice to determine the need for any public scoping meetings prior to the preparation of a draft EIS. In order to be considered during the preparation of the draft EIS, all comments must be received prior to the close of the public scoping period. FDA anticipates that if any public scoping meetings are necessary, due to the impact of this COVID-19 pandemic, such meetings will be held virtually via a live webcast. See FDA's website for periodic updates, available at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information> and search for Environmental Impact Statement. FDA will provide additional opportunities for public participation upon publication of the draft EIS.

ADDRESSES: You may submit comments, identified by the above docket number by any of the

following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-0352 for "Intent to Prepare an Environmental Impact Statement for Certain Sunscreen Drug Products

for Over-The-Counter Use.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Trang Q. Tran, Center for Drug Evaluation and

Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4139, Silver Spring, MD 20993; 240-402-7945.

SUPPLEMENTARY INFORMATION: Sunscreens are topically applied OTC drug products indicated to help prevent sunburn and/or to decrease the risk of skin cancer and early skin aging caused by the sun. FDA regulates sunscreen products to ensure they meet safety and effectiveness standards.¹ Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, signed into law on March 27, 2020, FDA is required to issue a proposed order addressing sunscreens by September 27, 2021. While the CARES Act does not establish a deadline for the final sunscreen order, it specifies that this order may not go into effect earlier than 1 year after its issuance. FDA expects that the final sunscreen order will establish revised conditions for marketing a sunscreen product without the prior approval of an NDA, and that among the conditions addressed will be the permissibility of including certain active ingredients in sunscreen products marketed without an NDA.

Before engaging in a major Federal action, NEPA requires Federal agencies to consider the potential environmental consequences of proposed actions, and any reasonable alternatives. Under FDA regulations, FDA will prepare an EIS when data or information in an environmental assessment or otherwise available to the Agency leads to a finding that the proposed agency action may significantly affect the quality of the human environment.² Because of questions raised about the extent to which two sunscreen active ingredients (oxybenzone and octinoxate) may affect coral and/or coral reefs, FDA is initiating the public scoping process to consider any potential environmental impacts associated with the use of oxybenzone and octinoxate in sunscreens so that an EIS, if necessary, can be completed prior to issuance of a final sunscreen order addressing sunscreens containing these ingredients.

We note the Agency's docket to the 2019 proposed rule "Sunscreen Drug Products for

¹ Learn more about the history of FDA's regulation of sunscreen products at <https://www.fda.gov/drugs/status-otc-rulemakings/rulemaking-history-otc-sunscreen-drug-products>.

² See 21 CFR 25.22(b); 40 CFR 1508.27.

Over-the-Counter Human Use” (84 FR 6204 February 26, 2019) received comments that raised concerns about the potential impacts from sunscreens containing oxybenzone or octinoxate on coral and/or coral reefs. FDA is also aware that the National Oceanic and Atmospheric Administration (NOAA) Coral Reef Conservation Program is currently evaluating research related to coral reef health, including the potential impacts of sunscreen products that include oxybenzone and octinoxate on coral reefs and other aquatic systems.³ The Agency is also aware that at least one state has restricted the sale of sunscreens that include the active ingredients oxybenzone or octinoxate. On July 3, 2018, the state of Hawaii signed into law S. 2571, Act 104, prohibiting the sale, offer of sale, and distribution of sunscreens that contain oxybenzone and/or octinoxate, to protect Hawaii’s marine ecosystems, including coral reefs. This law became effective January 1, 2021. All of these actions raise questions about the potential environmental impacts of sunscreens containing oxybenzone and/or octinoxate on coral and/or coral reefs that warrant further evaluations.

The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, including potential alternatives and the extent to which those issues and impacts will be analyzed. At this initial stage of the scoping process, we have identified the following four alternatives: (1) FDA will conclude that the inclusion of oxybenzone and octinoxate in sunscreens marketed without an NDA is impermissible; (2) FDA will conclude that the inclusion of oxybenzone and octinoxate in sunscreens marketed without an NDA is permissible; (3) FDA will conclude that inclusion of oxybenzone in sunscreens marketed without an NDA is permissible but that the inclusion of octinoxate in sunscreens marketed without an NDA is impermissible; or (4) FDA will conclude that inclusion of octinoxate in sunscreens marketed without an NDA is permissible but that the inclusion of oxybenzone in sunscreens marketed without an NDA is impermissible.

³ See NOAA’s Coral Reef Information article “The effects of ultraviolet filters and sunscreen on corals and aquatic ecosystems,” available at the NOAA web page <https://www.coris.noaa.gov/activities/effects-ultraviolet-filters-sunscreen-corals/welcome.html>.

The EIS will be prepared in accordance with section 102(2)(C) of NEPA, 42 U.S.C. 4332(2)(C), FDA's NEPA implementing regulations (21 CFR part 25), and the CEQ regulations for implementing NEPA (40 CFR parts 1500-1508).⁴ Federal, State, and local agencies, along with Tribes and other stakeholders that may be interested in or affected by the sunscreen proposed order are invited to participate in the scoping process. Some Federal agencies may request or be requested by the FDA to participate in the development of the environmental analysis as a cooperating agency. FDA encourages other stakeholders to comment on this scoping process, on what specific issues, alternatives, mitigation measures, or other information FDA should include for further analysis in the EIS.

Dated: May 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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⁴ FDA began activities relating to the environmental assessment of the use of oxybenzone and octinoxate in sunscreens marketed without an NDA before September 14, 2020. Consistent with 40 CFR 1506.13, FDA will apply the regulations in place prior to implementation of the new CEQ regulations. See the Council on Environmental Quality's final rule, "Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act" (40 CFR 1506.13, 85 FR 43304 at 43372 (July 16, 2020)).