

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:**

With regard to Docket No. FDA-2021-N-0286: Sheila Brown, Office of Clinical Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-6563. With regard to Docket No. FDA-2019-N-2175: David Markert, Office of Clinical Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-0752.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 28, 2022, FDA published two proposed rules with a 60-day comment period to request comments on proposed changes to its regulations regarding obtaining and documenting informed consent from research participants, and institutional review board membership and functions, including continuing review, as well as a change to its regulations that would require any institution located in the United States participating in FDA-regulated cooperative research to rely on approval by a single IRB for that portion of the research that is conducted in the United States, with some exceptions. Comments on the proposed rules will inform FDA's rulemaking to establish regulations for Protection of Human Subjects and Institutional Review Boards.

The Agency has received requests for a 60-day extension of the comment period for both proposed rules. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop a

meaningful or thoughtful response to the proposed rules.

FDA has considered the requests and is extending the comment periods for the proposed rules for 30 days. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: November 8, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 51 and 52

**[EPA-HQ-OAR-2004-0014; FRL-4940.2-04-OAR]**

#### **Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR): Reconsideration of Fugitive Emissions Rule; Extension of Comment Period**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** On October 14, 2022, the Environmental Protection Agency (EPA) proposed a rule titled, "Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR): Reconsideration of Fugitive Emissions Rule," FR Doc 2022-22259. The EPA has received a request for additional time to review and comment on the proposed rule revisions. The EPA is extending the comment period on the proposed rule that was scheduled to close on December 13, 2022, for sixty days.

**DATES:** The public comment period for the proposed rule published in the **Federal Register** on October 14, 2022 (87 FR 62322), is being extended for sixty days. Written comments must be received on or before February 14, 2023.

**ADDRESSES:** The EPA has established docket number EPA-HQ-OAR-2004-

0014 for this action. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION CONTACT:** For additional information on this action, contact Mr. Ben Garwood, Air Quality Policy Division, Office of Air Quality Planning and Standards (C539-01), Environmental Protection Agency, 109 TW Alexander Drive, Research Triangle Park, NC 27711; telephone number: (919)-541-1358; email address: [Garwood.ben@epa.gov](mailto:Garwood.ben@epa.gov).

**SUPPLEMENTARY INFORMATION:** After considering the requests to extend the public comment period received from various parties, the EPA has decided to extend the public comment period until February 14, 2023. This extension will ensure that the public has additional time to review the proposed rule. At the party's request, the EPA will add a redline/strikeout of the rule text to the docket. This will provide specificity and clarity to the proposed rule text changes.

**Scott Mathias,**

*Director, Air Quality Policy Division, Office of Air Quality Planning and Standards.*

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