

## II. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA's September 28, 2022, proposed rule on "Protection of Human Subjects and Institutional Review Boards" (87 FR 58733), which this draft guidance is intended to interpret, and with previously approved collections of information described in the revised Federal Policy for the Protection of Human Subjects (the revised Common Rule). The proposed collections of information in the proposed rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). As required by the PRA, FDA has published an analysis of the information collection provisions of the proposed rule (87 FR 58733 at 58744) and they have been approved under OMB control number 0910–0130. The collections of information in 45 CFR 46 and the final rule entitled, "Federal Policy for the Protection of Human Subjects" (Common Rule) have been approved under OMB control number 0990–0260.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, <https://www.fda.gov/about-fda/office-clinical-policy-and-programs/office-clinical-policy>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, <http://www.hhs.gov/ohrp/newsroom/rfc/index.html>, or <https://www.regulations.gov>.

Dated: February 26, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R09–OAR–2023–0626; FRL–11614–03–R9]

### Air Plan Disapproval; California; Los Angeles-South Coast Air Basin; 1997 8-Hour Ozone; Extension of Comment Period

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

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

**SUMMARY:** The Environmental Protection Agency (EPA) is extending the comment period for a proposed rule published February 2, 2024. The current comment period for the proposed rule was set to end on March 4, 2024. In response to requests from several commenters, the EPA is extending the comment period for the proposed action to April 3, 2024. **DATES:** The comment period for the proposed rule published on February 2, 2024, at 89 FR 7320 is extended. Comments must be received on or before April 3, 2024.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R09–OAR–2023–0626 at <https://www.regulations.gov>. For comments submitted at [Regulations.gov](https://www.regulations.gov), follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [Regulations.gov](https://www.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, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please

contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** Ginger Vagenas, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3964 or by email at [vagenas.ginger@epa.gov](mailto:vagenas.ginger@epa.gov).

**SUPPLEMENTARY INFORMATION:** On February 2, 2024, the EPA published a proposal to disapprove a state implementation plan revision submitted by the State of California to meet Clean Air Act (CAA) requirements for the 1997 8-hour ozone national ambient air quality standards (NAAQS) in the Los Angeles-South Coast Air Basin, California ozone nonattainment area. This submission, titled "Final Contingency Measure Plan—Planning for Attainment of the 1997 80 ppb 8-hour Ozone Standard in the South Coast Air Basin," addresses the CAA requirements for the submission of contingency measures that will be implemented if emissions reductions from anticipated technologies associated with the area's 1997 ozone NAAQS attainment demonstration are not achieved. For more detailed information about this matter, please refer to the February 2, 2024 **Federal Register** document.

The notice of proposed rulemaking initially provided for comments to be submitted to the EPA on or before March 4, 2024 (a 30-day public comment period). The EPA received several comments requesting an extension of the comment period. To ensure the public has sufficient time to evaluate the proposal and develop comments, the EPA is extending the comment period until April 3, 2024.

Dated: February 23, 2024.

**Matthew Lakin,**

*Acting Director, Air and Radiation Division, Region IX.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R03–OAR–2023–0617; FRL–11781–01–R3]

### Air Plan Approval; Delaware; Amendments to Delaware's Requirements for Public Notice of Certain Permits

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

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve a