V. Comments

Regardless of attendance at the public meeting, interested persons may submit either electronic comments regarding this document to the Federal eRulemaking Portal at http://www.regulations.gov or written comments or the Division of Dockets Management (HFA–305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20857. Because multiple docket numbers are associated with this document, please include with your comments the docket number(s) that corresponds with the section of FDASIA and topic on which you are commenting (see table 2 of this document for a list of docket numbers and corresponding sections and topics).

Comments that address more than one docket must be filed with each docket to ensure consideration. The deadline for submitting comments to the docket is August 12, 2013. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

VI. Transcripts

Transcripts of the meeting will be available for review at the Division of Dockets Management and http://www.regulations.gov approximately 30 days after the meeting. A transcript will also be made available in either hardcopy or on CD–ROM, upon submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Dated: June 12, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2013–14549 Filed 6–18–13; 8:45 am]

BILLING CODE 4160–01–P
ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 49


Approval of Air Quality Implementation Plans; Navajo Nation; Regional Haze Requirements for Navajo Generating Station; Notice of Intent To Hold Public Hearings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of intent to hold public hearings.

SUMMARY: On February 5, 2013, EPA proposed a Best Available Retrofit Technology (BART) determination for emissions of oxides of nitrogen (NOX) from the Navajo Generating Station (NGS), located on the Navajo Nation. EPA provided a three-month period for public comments, to close on May 6, 2013. The Navajo Nation, Gila River Indian Community, and other affected stakeholders requested a 90-day extension of the comment period to allow time for stakeholders to develop an alternative to EPA’s proposed BART determination that achieves greater reasonable progress. On March 19, 2013, EPA extended the close of the public comment period to August 5, 2013. EPA is providing notice of our intent to hold five public hearings to accept written and oral comments on the proposed BART determination for NGS.

DATES: EPA will announce dates and locations for the public hearings at a later time in the Federal Register, on our Web site, and in the docket for this proposed rulemaking.1 Comments on the proposed BART determination for NGS must be postmarked no later than August 5, 2013.

ADDRESSES: The public hearings will be held at various locations in Indian country and in the state of Arizona. Please see the section on SUPPLEMENTARY INFORMATION for more details.

FOR FURTHER INFORMATION CONTACT: Anita Lee, EPA Region 9, (415) 972–3958, r9ngsbart@epa.gov.

SUPPLEMENTARY INFORMATION: EPA intends to hold public hearings at one location each on the Navajo Reservation, on the Hopi Reservation, and in Page, Phoenix, and Tucson, Arizona. These hearings will provide interested parties the opportunity to present facts, views, or arguments concerning the proposed rule requiring NGS to meet emission limits for NOX required under the BART provision of the Regional Haze Rule, in order to reduce visibility impairment resulting from NGS at 11 National Parks and Wilderness Areas.

Written statements and supporting information submitted during the comment period will be considered with the same weight as any oral comments and supporting information presented at the public hearing. Written comments must be postmarked on or before the last day of the comment period, August 5, 2013.

If you are unable to attend the hearing but wish to submit comments on the proposed rule, you may submit comments, identified by docket number EPA–R09–OAR–2013–0009, by one of the following methods:

2. Email: r9ngsbart@epa.gov.
3. Mail or deliver: Anita Lee (Air-2), U.S. Environmental Protection Agency Region 9, 75 Hawthorne Street, San Francisco, CA 94105–3901.

For more detailed instructions concerning how to submit comments on this proposed rule, and for more information on our proposed rule, please see the notice of proposed rulemaking, published in the Federal Register on February 5, 2013 (78 FR 8274).

List of Subjects in 40 CFR Part 49

Environmental protection, Air pollution control, Indians, Intergovernmental relations, Nitrogen dioxide.


Dated: June 10, 2013.

Deborah Jordan,

Air Division Director, Region 9.

[FR Doc. 2013–14630 Filed 6–18–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 52


Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Philadelphia County Reasonably Available Control Technology Under the 1997 8-Hour Ozone National Ambient Air Quality Standard; Withdrawal and New Issuance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; withdrawal and new issuance.

SUMMARY: On August 26, 2008, EPA published a proposed rule to approve a revision to the Commonwealth of Pennsylvania (Pennsylvania) State Implementation Plan (SIP) submitted by the Pennsylvania Department of Environmental Protection (PADEP) on behalf of Philadelphia Air Management Services (AMS). The SIP revision, submitted to EPA on September 29, 2006 (the 2006 SIP revision), consists of a demonstration that Philadelphia County is meeting the requirements of reasonably available control technology (RACT) of the Clean Air Act (CAA) for nitrogen oxides (NOX) and volatile organic compounds (VOC) under the 1997 8-hour ozone national ambient air quality standard (NAAQS). EPA has determined that it cannot proceed with the final approval of the 2006 SIP revision. In light of the decision of the United States Court of Appeals for the District of Columbia (the Court) regarding EPA’s Phase 2 Ozone Implementation Rule, EPA cannot approve that compliance with a cap-and-trade program satisfies the NOX RACT requirement for electric generating units (EGUs) in Philadelphia County, as presumed in the 2006 SIP revision. In addition, upon further review, EPA has determined that the 2006 SIP revision does not adequately address the RACT requirements under the 1997 8-hour ozone NAAQS for the major sources of VOC and NOX for which EPA has previously approved source-specific RACT determinations under the 1-hour ozone NAAQS. Therefore, EPA is withdrawing its August 26, 2008 proposed rule to