approved plan, any applicable FDA regulations, and any conditions of approval for your plan, such as reporting requirements;

(c) Your approved postmarket surveillance plan, with documentation of the date and reason for any deviation from the plan;

(d) All data collected and analyses conducted in support of your postmarket surveillance plan; and

(e) Any other records that we require to be maintained by regulation or by order.

§ 822.32 What records are the investigators in my surveillance plan required to keep?

Your investigator must keep copies of:

(a) All correspondence with another investigator, FDA, or you, including required reports.

(b) The approved postmarket surveillance plan, with documentation of the date and reason for any deviation from the plan.

(c) All data collected and analyses conducted for postmarket surveillance.

(d) Any other records that we require to be maintained by regulation or by order.

§ 822.33 How long must we keep these records?

You and your investigators must keep all records for a period of 2 years after we have accepted your final report, unless we specify otherwise.

§ 822.34 What must I do with the records if the sponsor of the plan or an investigator in the plan changes?

If the sponsor of the plan or an investigator in the plan changes, you must ensure that all records related to the postmarket surveillance have been transferred to the new sponsor or investigator and notify us within 10 days of the effective date of the change. You must provide the name, address, and telephone number of the new sponsor or investigator, certify that all records have been transferred, and provide the date of transfer.

§ 822.35 Can FDA inspect my manufacturing site or other sites involved in my postmarket surveillance plan?

We can review your postmarket surveillance programs during regularly scheduled inspections, inspections initiated to investigate recalls or other similar actions, and inspections initiated specifically to review your postmarket surveillance plan. We may also inspect any other person or site with postmarket surveillance obligations, such as clinical investigators or contractors. Any person authorized to grant access to a facility must permit authorized FDA employees to enter and inspect any facility where the device is held or where records regarding postmarket surveillance are held.

§ 822.36 Can FDA inspect and copy the records related to my postmarket surveillance plan?

We may, at a reasonable time and in a reasonable manner, inspect and copy any records pertaining to the conduct of postmarket surveillance that are required to be kept by this part. You must be able to produce records and information required by this part that are in the possession of others under contract with you to conduct the postmarket surveillance. We also expect those who have signed agreements or are under contract with you to produce the records and information upon our request. This information must be produced within 72 hours of the initiation of the inspection. We generally will redact information pertaining to individual subjects prior to copying those records, unless there are extenuating circumstances.

§ 822.37 Under what circumstances would FDA inspect records identifying subjects?

We can inspect and copy records identifying subjects under the same circumstances that we can inspect any records relating to postmarket surveillance. The agency is likely to be interested in such records if we have reason to believe that required reports have not been submitted, or are incomplete, inaccurate, false, or misleading.

§ 822.38 What reports must I submit to FDA?

You must submit interim and final reports as specified in your approved postmarket surveillance plan. In addition, we may ask you to submit additional information when we believe that the information is necessary for the protection of the public health and implementation of the act. We will also state the reason or purpose for the request and how we will use the information.

Dated: August 18, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–21827 Filed 8–28–00; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 240–0254b; FRL–6856–5]

Revisions to the California State Implementation Plan, San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a revision to the San Joaquin Valley Unified Air Pollution Control District's (SJVUAPCD) portion of the California State Implementation Plan (SIP). This revision concerns volatile organic compound (VOC) emissions from the use of organic solvents. We are proposing to approve a local rule to regulate this emission source under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: Any comments on this proposal must arrive by September 28, 2000.

ADDRESSES: Mail comments to Andy Steckel, Rulemaking Office Chief (AIR–4), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

You can inspect copies of the submitted SIP revision and EPA's technical support document (TSD) at our Region IX office during normal business hours. You may also see copies of the submitted SIP revision at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812.

San Joaquin Valley Unified Air Pollution Control District, 1999 Tuolumne Street, Suite #200, Fresno, CA 93721.

FOR FURTHER INFORMATION CONTACT: Yvonne Fong, Rulemaking Office (Air–4), U.S. Environmental Protection Agency, Region IX, (415) 744–1199.

SUPPLEMENTARY INFORMATION: This proposal addresses SJVUAPCD Rule 4661. In the Rules and Regulations section of this **Federal Register**, we are approving this local rule in a direct final action without prior proposal because we believe this SIP revision is not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in a subsequent action based on this proposed rule. We do not plan to open a second comment period, so anyone interested in commenting should do so

at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: August 8, 2000.

Laura Yoshii,

Acting Regional Administrator, Region IX.

[FR Doc. 00–21910 Filed 8–28–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IN98–1b, IN125–1b; FRL–6854–5]

Approval and Promulgation of Implementation Plans; Indiana Source-Specific Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to limitations for two facilities in Lake County, Indiana. These limitations concern particulate matter from Lever Brothers facility and both particulate matter and sulfur dioxide from NIPSCo's Dean Mitchell Station. Indiana requested these revisions on February 3, 1999, and December 28, 1999, respectively.

In separate action in today's **Federal Register**, EPA is approving the submittals as a direct final rule without prior proposal, because the EPA views this as a noncontroversial action and anticipates no adverse comments. A detailed rationale for this action is set forth in the direct final rule.

If EPA receives no adverse written comments in response to these actions, we contemplate no further activity in relation to this proposed rule. If we receive adverse written comments, we will withdraw the direct final rule and will address all public comments in a subsequent final rule based on this proposed rule. Any parties interested in commenting on this action should do so at this time.

DATES: EPA must receive comments by September 28, 2000.

ADDRESSES: Mail written comments to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch (AR–18J), United States Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

A copy of the State submittal is available for inspection at: Regulation Development Section, Air Programs Branch (AR–18J), United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: John Summerhays, at (312) 886–6067.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule published in the rules section of this **Federal Register**.

Authority: 42 U.S.C. 7401–7671q.

Dated: August 4, 2000.

Francis X. Lyons,

Regional Administrator, Region 5.

[FR Doc. 00–21912 Filed 8–28–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–6858–6]

RIN 2060–AH47

National Emission Standards for Hazardous Air Pollutant Emissions: Group IV Polymers and Resins

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to indefinitely stay the compliance date for the process contact cooling tower (PCCT) provisions for existing affected sources producing poly(ethylene terephthalate) (PET) using the continuous terephthalic acid (TPA) high viscosity multiple end finisher process. We are proposing this stay of the compliance date because the EPA is in the process of responding to a request to reconsider relevant portions of the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Group IV Polymers and Resins which may result in changes to the emission limitation which applys to PCCT in this subcategory.

In the ''Rules and Regulations'' section of this **Federal Register**, we are finalizing this stay without prior proposal because we view this as a noncontroversial action and anticipate no adverse comment. We have explained our reasons for this action in the preamble to the direct final rule. If we receive an adverse comment on this action, we will withdraw the direct final rule and it will not take effect. We will address all public comments in a subsequent final rule based on this proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

DATES: *Comments:* Written comments must be received by September 28, 2000, unless a hearing is requested by September 8, 2000. If a hearing is requested, written comments must be received by October 13, 2000.

Public Hearing. Anyone requesting a public hearing must contact the EPA by September 8, 2000. If requested, a public hearing will be held in Research Triangle Park, North Carolina at 10:30 a.m. on September 12, 2000.

ADDRESSES: *Comments.* Comments should be submitted (in duplicate, if possible) to: Air and Radiation Docket and Information Center (6102), Attention Docket Number A–92–45 (Group IV Polymers and Resins), Room M–1500, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, D.C. 20460. The EPA requests that a separate copy also be sent to the contact person listed below (see **FOR FURTHER INFORMATION CONTACT**).

Public Hearing. If a public hearing is held, it will be held at the EPA's Office of Administration Auditorium, Research Triangle Park, North Carolina.

Docket. Docket number A–92–45, containing information relevant to this proposed rulemaking, is available for public inspection between 8:00 a.m. and 5:30 p.m., Monday through Friday (except for Federal holidays) at the following address: U.S. Environmental Protection Agency, Air and Radiation Docket and Information Center (MC–6102), 401 M Street, SW, Washington, DC 20460, telephone: (202) 260–7548. The docket is located at the above address in Room M–1500, Waterside Mall (ground floor). A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Mr. Robert E. Rosensteel, Organic Chemicals Group, Emission Standards Division (MD–13), Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5608, electronic mail address rosensteel.bob@epa.gov.

SUPPLEMENTARY INFORMATION:

Comments. Comments and data may be submitted by electronic mail (e-mail) to: *a-and-r-docket@epa.gov.* Electronic comments must be submitted as an ASCII file to avoid the use of special characters and encryption problems and will also be accepted on disks in WordPerfect® version 5.1, 6.1 or Corel 8 file format. All comments and data submitted in electronic form must note the docket number A–92–45. No confidential business information (CBI) should be submitted by e-mail. Electronic comments may be filed