ongoing study by an IEC, and obtaining and documenting the freely given informed consent of the subject (or a subject's legally authorized representative, if the subject is unable to provide informed consent) before initiating a study. GCP does not require informed consent in life-threatening situations when the IEC reviewing the study finds that the conditions present are consistent with those described in §§ 50.23 or 50.24(a) of this chapter, or when the measures described in the study protocol or elsewhere will protect the rights, safety, and well-being of subjects and ensure compliance with applicable regulatory requirements; and

(ii) FDA is able to validate the data from the study through an onsite inspection if the agency deems it necessary.

(2) Although FDA will not accept as support for an IND, NDA, or BLA a study that does not meet the conditions of paragraph (a)(1) of this section, FDA will examine data from such a study.

(3) Marketing approval of a new drug based solely on foreign clinical data is governed by § 314.106 of this chapter.

(b) *Supporting information.* A sponsor or applicant who submits data from a foreign clinical study not conducted under an IND as support for an IND, NDA, or BLA must submit to FDA, in addition to information required elsewhere in parts 312, 314, or 601 of this chapter, respectively, a description of the actions the sponsor or applicant took to ensure that the research conformed to GCP as described in paragraph (a)(1)(i) of this section. The description must include the following:

(1) The investigator's qualifications;

(2) A description of the research facilities;

(3) A detailed summary of the protocol and results of the study and, should FDA request, case records maintained by the investigator or additional background data such as hospital or other institutional records;

(4) A description of the drug substance and drug product used in the study, including a description of the components, formulation, specifications, and, if available, bioavailability of the specific drug product used in the clinical study;

(5) If the study is intended to support the effectiveness of a drug product, information showing that the study is adequate and well-controlled under § 314.126 of this chapter;

(6) The names and qualifications for the members of the IEC that reviewed the study;

(7) A summary of the IEC's decision to approve or modify and approve the study, or to provide a favorable opinion;

(8) A description of how informed consent was obtained;

(9) A description of what incentives, if any, were provided to subjects to participate in the study;

(10) A description of how the sponsor(s) monitored the study and ensured that the study was carried out consistent with the study protocol; and

(11) A description of how investigators were trained to comply with GCP (as described in paragraph (a)(1)(i) of this section) and to conduct the study in accordance with the study protocol, and copies of written commitments, if any, by investigators to comply with GCP and the protocol.

(c) *Waivers.* (1) A sponsor or applicant may request FDA to waive any applicable requirements under paragraphs (a)(1) and (b) of this section. A waiver request may be submitted in an IND or in an information amendment to an IND, or in an application or in an amendment or supplement to an application submitted under part 314 or 601 of this chapter. A waiver request is required to contain at least one of the following:

(i) An explanation why the sponsor's or applicant's compliance with the requirement is unnecessary or cannot be achieved;

(ii) A description of an alternative submission or course of action that satisfies the purpose of the requirement; or

(iii) Other information justifying a waiver.

(2) FDA may grant a waiver if it finds that doing so would be in the interest of the public health.

Dated: February 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–13063 Filed 6–9–04; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TX–70–2–7347b; FRL–7672–6]

Approval and Promulgation of Implementation Plans for Texas; Approval of Section 179B Demonstration of Attainment, Volatile Organic Compound and Nitrogen Oxide Motor Vehicle Emissions Budgets for Conformity for the El Paso Ozone Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve, through direct final action, a revision to the Texas State Implementation Plan, submitted to show attainment of the one-hour ozone National Ambient Air Quality Standard in the El Paso ozone nonattainment area, but for emissions emanating from outside of the United States. The EPA is also proposing to approve the El Paso area's volatile organic compounds and nitrogen oxides emissions budgets. The State submitted the revisions to satisfy sections 179B and other part D requirements of the Federal Clean Air Act.

DATES: EPA is accepting adverse comment until July 12, 2004. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the direct final rule will not take effect.

ADDRESSES: Submit your comments, identified by File ID No. TX–70–2–7347, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the online instructions for submitting comments.
- U.S. EPA Region 6 ''Contact Us'' Web site: *http://epa.gov/region6/r6coment.htm*. Please click on ''6PD'' (Multimedia) and select ''Air'' before submitting comments.
- E-mail: Mr. Thomas Diggs at *diggs.thomas@epa.gov*. Please also cc the person listed in the **FOR FURTHER INFORMATION CONTACT** section below.
- Fax: Mr. Thomas Diggs, Chief, Air Planning Section (6PD–L), at (214) 665–7263.
- Mail: Mr. Thomas Diggs, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.
- Hand or Courier Delivery: Mr. Thomas Diggs, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Such deliveries are accepted only between the hours of 8 a.m. and 4 p.m. weekdays except for legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Please include the text ''Public comment on File ID No. TX–70–2–7347'' in the subject line of the first page of your comments. EPA's policy is that all comments received will be included in the public file without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do

not submit information that you consider to be CBI or otherwise protected through regulations.gov, or e-mail. The Federal regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public file and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Official File: Copies of the documents relevant to this action are in the official file which is available at the Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. The file will be made available by appointment for public inspection in the Region 6 FOIA Review Room between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below or Mr. Bill Deese at (214) 665–7253 to make an appointment. If possible, please make the appointment at least two working days in advance of your visit. There will be a 15 cent per page fee for making photocopies of documents. On the day of the visit, please check in at the EPA Region 6 reception area at 1445 Ross Avenue, Suite 700, Dallas, Texas.

Copies of any State submittals and EPA's technical support document are also available for public inspection at the State Air Agency listed below during official business hours by appointment:

Texas Commission on Environmental Quality, Office of Air Quality, 12124 Park 35 Circle, Austin, Texas 78753.

FOR FURTHER INFORMATION CONTACT: Joe Kordzi, Air Planning Section (6PD–L), EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 665–7186; fax number (214) 665–7263; e-mail address *kordzi.joe@epa.gov*.

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule which is located in the ''Rules and Regulations'' section of this **Federal Register**.

Dated: May 27, 2004.

Richard E. Greene,

Regional Administrator, Region 6.

[FR Doc. 04–13176 Filed 6–9–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R07–OAR–2004–IA–0001; FRL–7672–2]

Approval and Promulgation of Implementation Plans; State of Iowa

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the state of Iowa. This revision pertains to the order and permits issued by the state to control particulate matter (PM_{10}) emissions from Blackhawk Foundry and Machine Company in Davenport (Scott County), Iowa. This approval would make the order and permits Federally enforceable.

DATES: Comments on this proposed action must be received in writing by July 12, 2004.

ADDRESSES: Comments may be mailed to Harriett Jones, Environmental Protection Agency, Air Permitting and Compliance Branch, 901 North 5th Street, Kansas City, Kansas 66101. Comments may also be submitted electronically or through hand delivery/courier; please follow the detailed instructions in the Addresses section of the direct final rule which is located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Harriett Jones at (913) 551–7730, or at *jones.harriett@epa.gov*.

SUPPLEMENTARY INFORMATION: In the final rules section of the **Federal Register**, EPA is approving the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no relevant adverse comments to this action. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated in relation to this action. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

Dated: June 3, 2004.

James B. Gulliford,

Regional Administrator, Region 7.

[FR Doc. 04–13178 Filed 6–9–04; 8:45 am]

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