(1) The nature, circumstances, extent, and gravity of the violation or violations;

(2) The violator's ability to pay;

(3) Its effect on the person's ability to do business;

(4) Any history of prior violations;

(5) The degree of culpability; and

(6) Such other matters as justice may require.

(b) The Hearing Officer shall serve all parties with the initial decision by certified mail, return receipt requested. The initial decision shall include notice that it constitutes a final order of DOE, unless within 15 days of receipt of notification a request for review by the Secretary is filed with the Director.

§ 824.13 Final order.

(a) Upon receipt of a request for review of the initial decision, the Director shall forward the request, along with the entire record, to the Secretary.

(b) The Secretary shall issue a final order as soon as practicable after completing his review. The Secretary may, at his discretion, order additional proceedings, remand the matter or modify the amount of the civil fines assessed in the initial determination. The person shall be notified of the Secretary's final order in writing by certified mail, return receipt requested.

§ 824.14 Special procedures.

A person receiving a notice of violation under § 824.5 may elect in writing within 30 days of receipt of such notice, the application of special procedures regarding payment of the penalty that are set forth in section 234A.c.(3) of the Atomic Energy Act, 42 U.S.C. 2282a.c.(3). The Deputy Secretary, based upon a recommendation of the Director, shall promptly assess a civil penalty, by order, after the date of such election. If the civil penalty has not been paid within sixty calendar days after the assessment has been issued, the Deputy Secretary shall institute an action in the appropriate district court of the United States for an order affirming the assessment of the civil penalty.

§ 824.15 Collection of civil fines.

If any person fails to pay an assessment of a civil penalty after it has become a final order or after the appropriate district court has entered final judgment for DOE under § 824.14, the Deputy Secretary shall institute an action to recover the amount of such penalty in an appropriate district court of the United States. In such action, the validity and appropriateness of such final order or judgment shall not be subject to review.

[FR Doc. 02–7764 Filed 3–29–02; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 212

[Docket No. 99N–4063]

Current Good Manufacturing Practice for Positron Emission Tomography Drug Products; Preliminary Draft Proposed Rule; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability of preliminary draft proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a preliminary draft proposed rule on current good manufacturing practice (CGMP) for positron emission tomography (PET) drug products. We are developing CGMP regulations for PET drug products in accordance with the Food and Drug Administration Modernization Act of 1997 (Modernization Act). We are making a preliminary draft of a proposed rule available to allow full discussion of its contents at an upcoming public meeting on CGMP requirements for PET drug products. We are announcing the availability of a companion draft guidance on CGMP for PET drug products elsewhere in this issue of the **Federal Register**.

DATES: A public meeting on the preliminary draft proposed rule will be held on May 21, 2002. Submit written or electronic comments on the preliminary draft proposed rule by June 5, 2002.

ADDRESSES: A copy of the preliminary draft proposed rule will be on display at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the preliminary draft proposed rule to the Division of Drug Information (HFD–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the preliminary draft proposed rule. Submit written comments to the Dockets Management Branch (address above). Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Brenda Uratani, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–0098.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, the President signed the Modernization Act (Public Law 105–115) into law. Section 121(c)(1)(A) of the Modernization Act directs us to establish appropriate approval procedures and CGMP requirements for PET drugs. Section 121(c)(1)(B) states that, in adopting such requirements, we must take due account of any relevant differences between not-for-profit institutions that compound PET drugs for their patients and commercial manufacturers of such drugs. Section 121(c)(1)(B) also directs us to consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists who make or use PET drugs as we develop PET drug CGMP requirements and approval procedures.

We presented our initial tentative approach to PET drug CGMP requirements and responded to numerous questions and comments about that approach at a public meeting on February 19, 1999. In the **Federal Register** of September 22, 1999 (64 FR 51274), we published a notice of availability of preliminary draft regulations on PET drug CGMP. Those preliminary draft regulations were discussed at a public meeting on September 28, 1999.

After considering the comments on the preliminary draft regulations, FDA has decided to make several revisions to its approach to CGMP for PET drug products. In accordance with 21 CFR 10.40(f)(4) and 10.80(b)(2), we are making revised preliminary draft regulations available for comment. The preliminary draft proposed rule does not include sections on the economic impact of the proposed rule, federalism concerns, and Paperwork Reduction Act issues. We will include these sections when we publish a proposed rule, but we invite comments on these matters at this time.

Elsewhere in this issue of the **Federal Register**, we are announcing the availability of a companion draft guidance entitled ''PET Drug Products—Current Good Manufacturing Practice (CGMP).'' Both the preliminary draft proposed rule and the draft guidance

will be discussed at a public meeting to be held on May 21, 2002, from 9 a.m. to 4:30 p.m., at 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the preliminary draft proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Electronic comments may be submitted to *http://www.fda.gov/dockets/ecomments.* The preliminary draft proposed rule and the comments submitted to this docket may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm or www.fda.gov/cder/fdama* under ''Section 121—PET (Positron Emission Tomography).''

(**Authority:** 21 U.S.C. 321 *et seq.*)

Dated: March 25, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–7728 Filed 3–29–02; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WY–001–0007b, WY–001–0008b, WY–001–0009b; FRL–7166–3]

Approval and Promulgation of Air Quality Implementation Plans; Wyoming; Withdrawal of Proposed Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of proposed rule.

SUMMARY: Due to the State of Wyoming's withdrawal of the August 9, 2000, August 7, 2001 and August 13, 2001 submittals to the EPA that revise the Wyoming State Implementation Plan (SIP), EPA is withdrawing the proposed rule, published concurrently with a direct final rule, to partially approve and partially disapprove these revisions that restructure and modify the State's air quality rules. In the direct final rule, published on February 6, 2002 (67 FR 5485), we stated that if we received adverse comment by March 8, 2002, the rule would be withdrawn and would not take effect. EPA subsequently received a letter from the State of Wyoming (on March 8, 2002) withdrawing the three submittals that EPA is taking action on in our February 6, 2002 direct final rule. EPA also received adverse comments from the Wyoming Outdoor Council (on March 7, 2002). Since, in addition to receiving adverse comments, the State of Wyoming withdrew their submittals, the proposed rule and the direct final rule are withdrawn and will not take effect. In the ''Final Rules'' section of today's **Federal Register** publication, we are withdrawing the direct final rule published on February 6, 2002 (67 FR 5552).

EFFECTIVE DATE: The proposed rule is withdrawn as of April 1, 2002.

FOR FURTHER INFORMATION CONTACT: Megan Williams, EPA Region VIII, (303) 312–6431 or Laurel Dygowski, EPA Region VIII, (303) 312–6144.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final rule located in the Rules and Regulations section of the February 6, 2002 **Federal Register** (67 FR 5485).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen Dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, and Volatile organic compounds.

Dated: March 25, 2002.

Jack W. McGraw,

Acting Regional Administrator, Region VIII.

[FR Doc. 02–7773 Filed 3–29–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 255–0320a; FRL–7164–8]

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 both a conditional approval and a limited approval and limited disapproval of revisions to the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD or District) portion of the California State Implementation Plan (SIP). These revisions concern fugitive dust and particulate matter less than 10 microns in diameter (PM–10). We are proposing action on local rules that regulate these emissions under the Clean Air Act, as amended in 1990 (CAA or the Act). The proposed conditional approval is with respect to enforceability and reasonably available control measures (RACM), and the proposed limited approval and limited disapproval is with respect to best available control measures (BACM). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by May 31, 2002.

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.

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

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 1001 ''I'' Street, Sacramento, CA 95814.

San Joaquin Valley Unified Air Pollution Control District, 1990 East Gettysburg Street, Fresno, CA 93726.

FOR FURTHER INFORMATION CONTACT: Karen Irwin, Planning Office (AIR–2), U.S. Environmental Protection Agency, Region IX; (415) 947–4116.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

Table of Contents

I. The State's Submittal

A. What rules did the State submit?

Table 1 lists the rules we are proposing to approve with the dates that they were adopted by the District and submitted by the California Air Resources Board (CARB) to EPA.