

the public health with respect to a compound, mixture, or preparation containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams that also includes one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by codeine alone.

#### PART 310—NEW DRUGS

20. The authority citation for 21 CFR part 310 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

##### § 310.103 [Amended]

21. Section 310.103 *New drug substances intended for hypersensitivity testing* is amended in paragraph (a)(3)(i) by removing the phrase “ ‘Caution: Federal law prohibits dispensing without a prescription’ ” and adding in its place the phrase “ ‘Rx only’ ”.

#### PART 329—HABIT-FORMING DRUGS

22. Part 329 is removed.

#### PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTI-ASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

23. The authority citation for 21 CFR part 341 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

##### § 341.14 [Amended]

24. Section 341.14 *Antitussive active ingredients* is amended in paragraph (a)(2) by removing “§§ 329.20(a) and 341.40” and adding in its place “§ 290.2”.

#### PART 361—PRESCRIPTION DRUGS FOR HUMAN USE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED: DRUGS USED IN RESEARCH

25. The authority citation for 21 CFR part 361 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 371; 42 U.S.C. 262.

##### § 361.1 [Amended]

26. Section 361.1 *Radioactive drugs for certain research uses* is amended in paragraph (f)(1) by removing the phrase “ ‘Caution: Federal law prohibits dispensing without prescription’ ” and adding in its place the phrase “ ‘Rx only’ ”.

#### PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

27. The authority citation for 21 CFR part 369 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 371.

##### § 369.22 [Removed]

28. Section 369.22 is removed.

#### PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

29. The authority citation for 21 CFR part 606 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

30. Section 606.121 is amended by revising paragraph (c)(8)(i) to read as follows:

##### § 606.121 Container label.

\* \* \* \* \*

(c) \* \* \*

(8) \* \* \*

(i) “Rx only.”

\* \* \* \* \*

#### PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

31. The authority citation for 21 CFR part 610 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

##### § 610.60 [Amended]

32. Section 610.60 *Container label* is amended in paragraph (a)(6) by removing the phrase “ ‘Caution: Federal law prohibits dispensing without prescription,’ ” and adding in its place the phrase “ ‘Rx only’ ”.

##### § 610.61 [Amended]

33. Section 610.61 *Package label* is amended in paragraph (s) by removing the phrase “ ‘Caution: Federal law prohibits dispensing without prescription,’ ” and adding in its place the phrase “ ‘Rx only’ ”.

Dated: March 31, 2000.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 00-8737 Filed 4-7-00; 8:45 am]

**BILLING CODE 4160-01-F**

**Editorial Note:** FR Doc. 00-8737 which was originally published in the issue of Monday, April 10, 2000, at page 18934 is being republished in its entirety in the issue of April, 2000, because of typesetting errors. [FR Doc. 00-8737 Filed 4-20-00; 8:45 am]

**BILLING CODE 1505-01-F**

#### ENVIRONMENTAL PROTECTION AGENCY

##### 40 CFR Part 52

[VA084/101-5045b; FRL-6563-1]

#### Approval and Promulgation of Air Quality Implementation Plans; Virginia; Proposed Revised Format for Materials Being Incorporated by Reference; Proposed Approval of Recodification of the Virginia Administrative Code

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the Virginia Department of Environmental Quality. These submittals include miscellaneous revisions and recodification of Virginia's air pollution control regulations. This proposed recodification reorganizes and rennumbers the Virginia SIP to match the numbering system set forth in the Virginia Administrative Code. EPA also proposes to revise the format of regulations for materials submitted by Virginia that are incorporated by reference (IBR) into their respective State implementation plans (SIPs). The regulations affected by this format change have all been previously submitted by the respective State agency and approved by EPA.

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 and a Technical Support Document (TSD) prepared in support of this rulemaking action. A copy of the TSD is available, upon request, from the EPA Regional Office listed in the **ADDRESSES** section of this document. 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.

**DATES:** Comments must be received in writing by May 22, 2000.

**ADDRESSES:** Written comments should be addressed to Marcia L. Spink, Mailcode 3AP20, U.S. Environmental

Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia, 23219.

**FOR FURTHER INFORMATION CONTACT:** Harold A. Frankford, (215) 814-2108 at the EPA Region III address above, or by e-mail at fankford.harold@epa.gov.

**SUPPLEMENTARY INFORMATION:** For further information, please see the information provided in the direct final action, with the same title, that is located in the "Rules and Regulations" section of this **Federal Register** publication.

Dated: March 6, 2000.

**Bradley M. Campbell,**

*Regional Administrator, Region III.*

[FR Doc. 00-9536 Filed 4-20-00; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[CA 031-0174b; FRL-6580-4]

#### Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, Lake County Air Quality Management District and San Joaquin Valley Unified Air Pollution Control District

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is approving revisions to the California State Implementation Plan. The revisions concern rules from the following: Lake County Air Quality Management District (LCAQMD) and San Joaquin Valley Unified Air Pollution Control District (SVUAPCD). The rules control particulate matter (PM) emissions from open burning or processes identified by a weight rate throughput.

The intended effect of this action is to regulate emissions of PM in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). In the Final Rules section of this **Federal Register**, the 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 and anticipates no adverse

comments. A detailed rationale for this approval is set forth in the direct final rule. If no relevant adverse comments are received, no further activity is contemplated in relation to this rule. If EPA receives relevant adverse comments, the direct final rule will not take effect 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 on this rule. Any parties interested in commenting on this rule should do so at this time.

**DATES:** Comments must be received in writing by May 22, 2000.

**ADDRESSES:** Comments should be addressed in writing to: Andrew Steckel, Rulemaking Office (AIR-4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Copies of the rule revisions and EPA's evaluation report of each rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule revisions are also available for inspection at the following locations:

Rulemaking Office (AIR-4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Environmental Protection Agency, Air Docket (6102), Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington, D.C. 20460.

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

Lake County Air Quality Management District, 883 Lakeport Boulevard, Lakeport, CA 95453.

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

**FOR FURTHER INFORMATION CONTACT:** Al Petersen, Rulemaking Office, (AIR-4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744-1135.

**SUPPLEMENTARY INFORMATION:** This document concerns the following rules: LCAQMD Section (Rule) 226.5, Fire Season—Burn Ban; LCAQMD Section (Rule) 431.5, [Non-Agricultural Burning]; LCAQMD Section (Rule) 433, [Exemption—Residential]; Lake County Section (Rule) 1150, Wildland Vegetation Management Burning; and SVUAPCD Rule 4202, Particulate Matter—Emission Rate. These rules were adopted on September 13, 1988, June 13, 1989, July 15, 1997, December 6, 1988, and December 17, 1992,

respectively, and were submitted by the California Air Resources Board (CARB) to EPA on July 23, 1999, March 26, 1990, March 10, 1998, February 7, 1989, and September 28, 1994, respectively. For further information, see the direct final action that is located in the Rules section of this **Federal Register**.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: March 30, 2000.

**Laura Yoshii,**

*Acting Regional Administrator, Region IX.*

[FR Doc. 00-9651 Filed 4-20-00; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[IN99-1b; FRL-6573-6]

#### Approval and Promulgation of Implementation Plan; Indiana

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve revisions to particulate matter (PM) emissions regulations for Dubois County, Indiana, which the Indiana Department of Environmental Management (IDEM) submitted to EPA on February 3, 1999, as amendments to its State Implementation Plan (SIP). The revisions include relaxation of some PM limits, elimination of limits for boilers which are no longer operating, updating facility names, and changing some boiler fuel types. Air quality dispersion modeling provided by IDEM shows that this SIP revision will not have an adverse effect on PM air quality.

**DATES:** EPA must receive written comments on this proposed rule by May 22, 2000.

**ADDRESSES:** You should mail written comments to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

You may inspect copies of the State submittal and EPA's analysis of it at: Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

**FOR FURTHER INFORMATION CONTACT:** David Pohlman, Environmental Scientist, Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency,