

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 312 be amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

1. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371); sec. 351 of the Public Health Service Act (42 U.S.C. 262).

2. Section 312.70 is amended by revising the first sentences of paragraphs (a) and (b) to read as follows:

§ 312.70 Disqualification of a clinical investigator.

(a) If FDA has information indicating that an investigator (including a sponsor-investigator) has repeatedly or deliberately failed to comply with the requirements of this part, part 50, or part 56 of this chapter, or has submitted to FDA or to the sponsor false information in any required report, the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research will furnish the investigator written notice of the matter complained of and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference.

* * *

(b) After evaluating all available information, including any explanation presented by the investigator, if the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the requirements of this part, part 50, or part 56 of this chapter, or has deliberately or repeatedly submitted false information to FDA or to the sponsor in any required report, the Commissioner will notify the investigator and the sponsor of any investigation in which the investigator has been named as a participant that the investigator is not entitled to receive investigational drugs. * * *

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Dated: February 9, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96-3384 Filed 2-15-96; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD07-95-062]

RIN 2115-AA97

Security Safety Zone Regulations Savannah, GA

AGENCY: Coast Guard, DOT.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Coast Guard will hold a public hearing to receive comments on proposals to establish security and safety zones during the 1996 Centennial Olympic Games to be held in the Savannah, Georgia area. The Coast Guard believes these security and safety zones are necessary to protect both Olympic athletes and the maritime public during a variety of activities associated with the Olympic sailing competitions. The proposed regulations are to establish the security and safety zones as early as July 2, 1996 and disestablish them as late as August 5, 1996.

DATES: The public hearing will be held on February 29, 1996, from 7 p.m. to 9 p.m. at the Juliette Low Federal Building, 100 West Oglethorpe Avenue, Room 1015, Savannah, Georgia 31402.

ADDRESSES: The public hearing will be held at the Juliette Low Federal Building, 100 West Oglethorpe Avenue, Room 1015, Savannah, Georgia 31402. Those wishing to make presentations at this public meeting should contact LT L. Fagan or CPO P. Webber at (912) 652-4353. Written comments may be mailed to CPO P. Webber at 222 West Oglethorpe Avenue, Suite 402, Savannah, Georgia 31401. Comments will become part of this docket and will be available for inspection or copying at 222 West Oglethorpe Avenue, Suite 402, Savannah, Georgia 31401, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LT L. Fagan, Coast Guard Marine Safety Office Savannah at (912) 652-4353.

SUPPLEMENTARY INFORMATION:

The Coast Guard is proposing to establish security and safety zones to protect both the Olympic athletes and the maritime community from the potential hazards associated with the large influx of boaters anticipated during the festivities and sailing venue competitions of the Olympic Games. (January 3, 1996; 61 FR 136) These security and safety zones will affect the

following waterways: Bull River; Savannah River; Wassaw Sound; Wilmington River; Tybee Cut; Turners Creek; and Half Moon River, as early as July 2, 1996 and as late as August 5, 1996.

The Coast Guard will hold a public hearing on February 29, 1996 at 7 p.m. at the Juliette Low Federal Building, 100 West Oglethorpe Avenue, Room 1015, Savannah, Georgia 31402, to receive comments/presentations regarding whether the Coast Guard should establish all or amend some of the proposed security and safety zones.

Attendance is open to the public. With advance notice, and as time permits, members of the public may make oral presentations during the meeting. Persons wishing to make oral presentations should notify the person listed above under the **FOR FURTHER INFORMATION CONTACT** no later than the day before the meeting. Written material may be submitted prior to, during, or after the meeting until March 4, 1996.

Dated: February 12, 1996.

Roger T. Rufe, Jr.,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 96-3602 Filed 2-15-96; 8:45 am]

BILLING CODE 4910-14-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[SC-28-1-7164b; FRL-5316-8]

Approval and Promulgation of Implementation Plans; South Carolina: Approval of Revisions to the South Carolina State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On March 3, 1995, the State of South Carolina, through the South Carolina Department of Environment, Health and Natural Resources, submitted revisions to the South Carolina State Implementation Plan (SIP). These revisions involve R.61-62.5 Standard Number 7. Prevention of Significant Deterioration. 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 EPA views this as a noncontroversial revision amendment 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 that direct final

rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: To be considered, comments must be received by March 18, 1996.

ADDRESSES: Written comments on this action should be addressed to Mr. Randy Terry at the EPA Regional Office listed below.

Copies of the documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 443, 401 M Street SW., Washington, DC 20460.

Environmental Protection Agency, Region 4 Air Programs Branch, 345 Courtland Street NE., Atlanta, Georgia 30365.

South Carolina Department of Environment, Health and Natural Resources, 2600 Bull Street, Columbia, South Carolina 29201.

FOR FURTHER INFORMATION CONTACT: Mr. Randy Terry, Regulatory Planning and Development Section, Air Programs Branch, Air, Pesticides, and Toxics Management Division, Region 4 Environmental Protection Agency, 345 Courtland Street, Atlanta, Georgia 30365. The telephone number is 404/347-3555, ext. 4212.

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

Dated: September 19, 1995.

Patrick M. Tobin,

Acting Regional Administrator.

[FR Doc. 96-2584 Filed 2-15-96; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Parts 52 and 81

[NM28-1-7087; FRL-5423-3]

Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning Purposes; State of New Mexico; Albuquerque/Bernalillo County; Approval of the Vehicle Inspection and Maintenance Program, Emissions Inventory, and Maintenance Plan; Redesignation of the Nonattainment Area to Attainment; and Carbon Monoxide Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On April 14, 1995, the Governor of New Mexico submitted a request for redesignation to attainment for the Albuquerque/Bernalillo County carbon monoxide (CO) nonattainment area. This request included a revision to the State Implementation Plan (SIP) for the administration of a vehicle inspection and maintenance (I/M) program, a 1993 emissions inventory for Albuquerque/Bernalillo County, and an attainment maintenance plan. The submission of the revised I/M program was intended to fulfill previously unfulfilled requirements for an I/M program. In this action, the EPA is proposing approval of the Albuquerque/Bernalillo County I/M program, 1993 periodic emissions inventory, and the request for redesignation, because all meet the requirements set forth in the Clean Air Act (Act).

DATES: All written comments must be received by March 18, 1996.

ADDRESSES: Written comments on this action should be addressed to Mr. Thomas H. Diggs, Chief, Air Planning Section, at the EPA Regional Office listed below. Copies of the documents relevant to this action are available for public inspection during normal business hours at the addresses listed below. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least twenty-four hours before the visiting day.

U.S. Environmental Protection Agency, Region 6, Air Planning Section (6PD-L), 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202-2733.

Albuquerque Environmental Health Department, Air Pollution Control Division, One Civic Plaza Room 3023, Albuquerque, New Mexico 87102

FOR FURTHER INFORMATION CONTACT: Mr. Matthew Witosky, Air Planning Section (6PD-L), Multimedia Planning and Permitting Division, USEPA Region 6,

1445 Ross Avenue, Dallas, Texas 75202-2733, telephone (214) 665-7214.

SUPPLEMENTARY INFORMATION:

I. Background

Albuquerque/Bernalillo County, New Mexico, was designated nonattainment for CO and classified as moderate with a design value below 12.7 parts per million (ppm) (specifically 11.1 ppm), under sections 107(d)(4)(A) and 186(a) of the Act, upon enactment of the Clean Air Act Amendments (CAAA) of 1990 (the Act).¹ Please reference 56 FR 56694 (November 6, 1991) and 57 FR 13498 and 13529 (April 16, 1992). On November 5, 1992, the Governor of New Mexico submitted to the EPA a SIP revision for CO concerning Albuquerque/Bernalillo County that was intended to satisfy the Act's requirements due on November 15, 1992. The Act outlines certain required items to be included in CO SIPs. The required items for the Albuquerque/Bernalillo County CO SIP, due November 15, 1992, included: (1) a comprehensive, accurate, and current inventory of actual emissions from all sources of CO in the nonattainment area (sections 172(c)(3) and 187(a)(1) of the Act); (2) no later than September 30, 1995, and no later than the end of each three year period thereafter, until the area is redesignated to attainment, a revised inventory meeting the requirements of sections 187(a)(1) and 187(a)(5) of the Act; (3) a permit program to be submitted by November 15, 1993, which meets the requirements of section 173 for the construction and operation of new and modified major stationary sources of CO (section 172(c)(5)); (4) contingency measures due November 15, 1993, that are to be implemented if the EPA determines that the area has failed to attain the primary standards by the applicable date (section 172(c)(9)); (5) a commitment to upgrade and submit a SIP revision for the I/M program by November 15, 1993, (section 187(a)(4)); and (6) an oxygenated fuels program (section 211(m)).

The Albuquerque/Bernalillo County Air Quality Control Board has ambient monitoring data showing attainment of the CO National Ambient Air Quality Standards (NAAQS) during the period from 1992 through September of 1995. Therefore, in an effort to comply with

¹ The Clean Air Act as amended (1990 Amendments) made significant changes to the air quality planning requirements for areas that do not meet (or that significantly contribute to ambient air quality in a nearby area that does not meet) the CO NAAQS (see Pub. L. No. 101-549, 104 Stat. 2399). References herein are to the CAAA, 42 U.S.C. sections 7401 *et seq.*