

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.

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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]

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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