Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. 95N–0138]

Disqualification of a Clinical Investigator

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the investigational new drug regulation that provides for disqualification of clinical investigators for submitting false information. It has come to the agency's attention that, as written, the regulation may be unclear. The proposed amendment would clarify the agency's authority to reach sponsor-investigators under the existing regulation.

DATES: Written comments by May 16, 1996. FDA proposes that any final rule based on this proposal become effective 60 days after its date of publication in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Howard P. Muller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is proposing to amend the regulations governing disqualification of clinical investigators to clarify that existing § 312.70 (21 CFR 312.70) reaches sponsor-investigators. Although the proposed amendment would not signify a change in policy, it has come to the agency's attention that, as written, the regulation may be unclear.

Generally, clinical investigators who conduct clinical trials to investigate new drugs submit their data to individual or corporate sponsors. Part 312 (21 CFR part 312) requires sponsors to monitor the progress of clinical investigations and to submit clinical investigation reports to the agency. Thus, data generated by the clinical investigator become the subject of reports that are submitted to the agency.

Sponsor-investigators both directly conduct investigations and report data to the agency. Section 312.3(b) defines ''sponsor-investigator'' as ''an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed.'' The definition specifically states that ''[t]he requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.'' Therefore, existing § 312.70 covers the disqualification of sponsor-investigators. However, the language of § 312.70, as it applies to sponsor-investigators, may be confusing.

Under existing § 312.70(b), the agency may disqualify an investigator who has ''deliberately or repeatedly submitted false information to the sponsor in any required report.'' However, unlike investigators, sponsor-investigators submit information directly to FDA and not to a separate sponsor. Although FDA believes that § 312.70 encompasses the disqualification of sponsor-investigators, because a sponsor-investigator does not submit information to a sponsor, the existing regulatory language may be ambiguous. Therefore, the agency is proposing to amend § 312.70 for clarity.

The proposed rule, if finalized, would clarify that the agency can disqualify clinical investigators and sponsor-investigators for submitting to sponsors, or to FDA, false information in any required report.

II. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed regulation does not impose paperwork or recordkeeping burdens, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

IV. Effective Date

FDA proposes that any final rule based on this proposal become effective 60 days after its date of publication in the Federal Register.

V. Request for Comments

Interested persons may, on or before May 16, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

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