

shall be accepted by the designated Headquarters official who issued the show cause letter.

§ 172.33 Acceptance of offers in compromise.

An offer in compromise shall be considered accepted only when the offeror is so notified in writing. As a condition to accepting an offer in compromise, the offeror may be required to enter into any collateral agreement or to post any security which is deemed necessary for the protection of the interest of the United States.

Subpart E—Supplemental Petitions for Relief

§ 172.41 Time and place of filing.

If the petitioner is not satisfied with a decision of the deciding official on an original petition for relief, a supplemental petition may be filed with the Fines, Penalties, and Forfeitures Officer having jurisdiction in the port where the violation occurred. Such supplemental petition shall be filed within 60 days from the date of notice to the petitioner of the decision from which further relief is requested unless another time to file such a supplemental petition is prescribed in the decision. A supplemental petition may be filed whether or not the mitigated amount designated in the decision on the original petition is paid.

§ 172.42 Supplemental petition decision authority.

(a) *Decisions of Fines, Penalties, and Forfeitures Officer.* Supplemental petitions filed on cases where the original decision was made by the Fines, Penalties, and Forfeitures Officer, shall be initially reviewed by that official. The Fines, Penalties, and Forfeitures Officer may choose to grant more relief and issue a decision indicating same to the petitioner. If the petitioner is dissatisfied with the further relief granted or if the Fines, Penalties, and Forfeitures Officers decides to grant no further relief, the supplemental petition shall be forwarded to a designated Headquarters official assigned to a field location for review and decision.

(b) *Decisions of Customs Headquarters.* Supplemental petitions filed on cases where the original decision was made by the Chief, Penalties Branch, Office of Regulations and Rulings, Customs Headquarters, shall be forwarded to the Director, International Trade Compliance Division, for review and decision.

(c) *Authority of Assistant Commissioner.* Any authority given to any Headquarters official by this part

may also be exercised by the Assistant Commissioner, Office of Regulations and Rulings, or his designee.

§ 172.43 Waiver of statute of limitations.

The deciding official always reserves the right to require a waiver of the statute of limitations executed by the charged party or parties as a condition precedent before accepting a supplemental petition in any case where the statute will be available as a defense to all or part of that case within one year from the date of decision on the original petition for relief.

Samuel H. Banks,

Acting Commissioner of Customs.

Approved: January 13, 1998.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 98-2250 Filed 1-30-98; 8:45 am]

BILLING CODE 4820-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 601

[Docket No. 98N-0040]

Developing Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "Developing Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring." The purpose of the public meeting is to provide a forum for FDA to gather information for the development of new regulations for the review of radiopharmaceutical applications as required by the Food and Drug Administration Modernization Act of 1997 (the FDAMA).

DATES: Submit written comments by March 4, 1998. The meeting will be held on February 27, 1998, 8 a.m. to 4 p.m.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. The meeting will be held at the Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Dano B. Murphy, Center for Biologics

Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210, FAX 301-443-3874, e-mail

"Murphyd@CBER.FDA.GOV".

SUPPLEMENTARY INFORMATION: Section 122 of the FDAMA (Pub. L. 105-115) requires the Secretary of Health and Human Services to issue proposed rules governing the evaluation and approval of radiopharmaceuticals within 180 days after the date of enactment of the FDAMA after soliciting input from patient advocacy groups, physicians licensed to use radiopharmaceuticals, regulated industry, and interested members of the public. Accordingly, FDA is holding a public meeting to solicit public input.

Comments: If attendance at the meeting is not possible, interested parties may submit written comments to the Dockets Management Branch (address above). 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. FDA will consider all comments received at the meeting and submitted to the docket in drafting proposed rules for the regulation of radiopharmaceuticals. FDA invites interested parties to comment on any aspect of the regulation of radiopharmaceuticals.

In general, comments should address how FDA should cover the safety and effectiveness of radiopharmaceuticals in its regulations, as well as any identifiable characteristics that might distinguish them from other articles intended for use in the diagnosis and monitoring of diseases, or manifestations of diseases, in humans. Also, because the FDAMA requires that certain factors be included in a rule governing the evaluation and approval of radiopharmaceuticals, FDA invites comments on the following topics: (1) How should the proposed use of a radiopharmaceutical in the practice of medicine determine the nature and extent of safety and effectiveness evaluations; (2) what general characteristics of a radiopharmaceutical should be considered in the preclinical and clinical pharmacological and toxicological evaluations of a radiopharmaceutical (including the radionuclide as well as the ligand and carrier components, i.e., nonradioactive components); (3) how should the estimated absorbed radiation dose in

humans be determined and considered; and (4) under what circumstances might an approved indication for marketing refer to manifestations of disease (biochemical, physiological, anatomic, or pathological processes) common to, or present in, one or more disease states?

Interested parties may want to review section 122 of the FDAMA and a draft regulation for radiopharmaceuticals submitted by the Council on Radionuclides and Radiopharmaceuticals (CORAR). Both the FDAMA and the CORAR proposal have been filed under the docket number found in the heading of this document, and they are available on the Internet.

Electronic Access: Persons with access to the Internet may obtain the FDAMA and the CORAR proposal using the World Wide Web (www) by connecting to "www.fda.gov/cber/misc.htm".

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number) and written material and requests to make oral presentations, by February 18, 1998, to Gloria S. Blankenship, Center for Biologics Evaluation and Research (HFM-43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-1310, FAX 301-827-3079, e-mail "Blankenship@CBER.FDA.GOV". Registration at the site will be done on a space available basis on the day of the public meeting beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Gloria Blankenship (address above) at least 7 days before the meeting.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: January 26, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-2322 Filed 1-30-98; 8:45 am]

BILLING CODE 4160-01-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IA-037-1037b; FRL-5955-3]

Approval and Promulgation of Implementation Plans; State of Iowa

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the state of Iowa for the purpose of updating regulations of the state's two local air pollution control agencies. These agencies are the Polk County Public Works Department and Linn County Health Department.

In the final rules section of the **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 amendment and anticipates no adverse comments. The general rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If the 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. 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: Comments on this proposed rule must be received in writing by March 4, 1998.

ADDRESSES: Comments may be mailed to Christopher D. Hess, Environmental Protection Agency, Air Planning and Development Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101.

FOR FURTHER INFORMATION CONTACT: Christopher D. Hess at (913) 551-7213.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final rule which is located in the rules section of the **Federal Register**.

Dated: December 30, 1997.

Diane Callier,

Acting Regional Administrator, Region VII.

[FR Doc. 98-2487 Filed 1-30-98; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 192, 195

[Docket No. RSPA-98-3347; Notice 1]

Pipeline Safety: Plastic Pipeline Safety Standards

AGENCY: Research and Special Programs Administration, DOT.

ACTION: Notice of public meeting.

SUMMARY: The Research and Special Programs Administration, Office of Pipeline Safety (OPS) invites representatives of the pipeline industry, state and local government, and the public to an open meeting on the Federal gas pipeline safety regulations on plastic pipe system design, construction, maintenance, and rehabilitation in transmission, distribution, and service line applications. The meeting is scheduled to coincide with meetings of the American Gas Association (AGA) Plastic Materials Committee scheduled for the week of March 4, 1998, in Phoenix, Arizona. The purpose of this meeting is to gather information on experience with the current Federal pipeline safety regulations on plastic pipe design, construction, and maintenance and to solicit comments and suggestions to improve these regulations. In particular, OPS seeks comment on whether current regulations should be revised, supplemented, or replaced by references to applicable industry standards and recommended practices.

DATES: The meeting will be held on Wednesday, March 4, 1998, at the Hyatt Regency Phoenix Hotel in Phoenix, Arizona, from 9:00 a.m. until all interested persons have been afforded an opportunity to speak. Interested persons are invited to attend the meeting and present oral or written statements. Persons wishing to speak at the meeting should notify Jenny Donohue at (202) 366-4046 by the close of business on Friday, February 27, 1998. Please estimate the time that will be required for your presentation. RSPA reserves the right to limit the time of each speaker to ensure that everyone is allowed sufficient time. Other speakers may present statements as time allows.

ADDRESSES: This meeting will be held at the Hyatt Regency Phoenix Hotel, 122 North Second Street, Phoenix, Arizona. The telephone number of the hotel is (602) 252-1234.