

Proposed Rules

Federal Register

Vol. 60, No. 5

Monday, January 9, 1995

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 Parts 600, 601, 606, 607, 610, 640, and 660

[Docket Nos. 94N-0066 and 94N-0080]

Review of Regulations for General Biologics and Licensing and for Blood Establishments and Blood Products; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting for interested persons to express their comments regarding the biologics regulations that the agency intends to review (21 CFR parts 600, 601, 606, 607, 610, 640, and 660). In the **Federal Register** of June 3, 1994 (59 FR 28821 and 28822, respectively), FDA issued two documents, "Review of General Biologics and Licensing Regulations" (Docket No. 94N-0066) and "Review of Regulations for Blood Establishments and Blood Products" (Docket No. 94N-0080), that announced that FDA was intending to review certain biologics regulations and requested public comments regarding those regulations. The comment periods have been extended twice and will close on February 13, 1995. The purpose of the public meeting is to allow additional opportunity for public comment concerning the biologics regulations that the agency is reviewing.

DATES: The public meeting will be held on January 26, 1995, from 1:30 p.m. to 5:30 p.m. Submit written notices of participation and written copies or summaries of oral presentations and the approximate amount of time needed for the presentation by January 19, 1995. Submit written comments regarding the biologics regulations under review by February 13, 1995.

ADDRESSES: The public meeting will be held at the Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD 20857. Submit written notices of participation and written copies or summaries of oral presentations and the approximate amount of time needed for the presentation to Timothy W. Beth, Center for Biologics Evaluation and Research (HFM-635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448 or FAX at 301-443-3874. Submit written comments regarding the review of general biologics and licensing regulations identified with docket number 94N-0066 and written comments regarding the review of regulations for blood establishments and blood products identified with docket number 94N-0080 to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Timothy W. Beth or Jean M. Olson, Center for Biologics Evaluation and Research (HFM-635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 3, 1994 (59 FR 28821 and 28822 respectively), FDA issued two documents, "Review of General Biologics and Licensing Regulations" (Docket No. 94N-0066) and "Review of Regulations for Blood Establishments and Blood Products" (Docket No. 94N-0080). The documents announced the agency's intent to review biologics regulations, 21 CFR parts 600, 601, 606, 607, 610, 640, and 660, and requested written comments from the public. Interested persons were given until August 17, 1994, to respond to the documents. In the **Federal Register** of August 17, 1994 (59 FR 42193), FDA extended the comment periods to November 15, 1994, in response to requests to allow for additional time for public comment. In the **Federal Register** of November 14, 1994 (59 FR 56448), FDA extended the comment periods to February 13, 1995, based on requests to hold a public meeting regarding the biologics regulations under review.

The Biotechnology Industry Organization and the Pharmaceutical Research and Manufacturers of America

requested a public meeting to allow for the presentation of comments regarding the agency's intent to review the biologics regulations. FDA agrees that a public meeting would be useful, and therefore, is holding a public meeting to allow all interested persons to present their comments. Representatives from the Center for Biologics Evaluation and Research (CBER) will chair the public meeting.

Every effort will be made to accommodate each person who wants to participate in the public meeting. However, each person who wants to ensure his or her participation in the meeting is encouraged, by close of business on January 19, 1995, to: (1) File a written notice of participation containing the name, address, phone number, facsimile number, affiliation, if any, of the participant, topic of the presentation, and approximate amount of time requested for the presentation; and (2) submit a copy or summary of their presentation. The requested information, including the written notice of participation, may be submitted to the contact person (address above).

Before the meeting, CBER will determine the amount of time assigned to each person and the approximate scheduled time for each presentation. A schedule showing the persons making presentations will be filed with the Dockets Management Branch (address above) and mailed or FAX'ed to each participant before the meeting. Interested persons attending the meeting who did not request an opportunity to make a presentation will be given the opportunity to make an oral presentation at the conclusion of the meeting, as time permits.

All public comments received at the public meeting and all written comments submitted to the Dockets Management Branch by February 13, 1995, will be considered in the review of the regulations to determine whether they should be revised, rescinded, or continued without change. After careful review of the public comments, FDA intends to publish a proposed rule to amend those regulations that FDA deems appropriate.

Interested persons may, on or before February 13, 1995, submit written comments regarding the biologics regulations the agency intends to review (21 CFR parts 600, 601, 606, 607, 610,