

prior to marketing irradiated blood components in interstate commerce.

FDA intends the pilot program to span approximately 1 year, but the actual length of the program depends on the number of manufacturers participating in the program. FDA intends to begin the pilot program 30 days after a final notice announcing the initiation of the program and the availability of the final guidance document is published in the **Federal Register**. At the end of the pilot program, FDA will evaluate the program for efficiency and effectiveness. FDA will make this analysis available to the public upon its completion. If the program proves to be efficient and effective, FDA will consider extending the program to other blood products.

FDA also is announcing the availability of a draft guidance document entitled "Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing." This draft guidance document is intended to help manufacturers of irradiated blood components comply with the regulations in Title 21 of the Code of Federal Regulations and to provide criteria acceptable for the manufacture of irradiated blood components. At this time, the draft guidance document is being made available for comment purposes only and is not intended for use by the industry. The agency has adopted good guidance practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This document is being issued as a draft level 1 guidance document consistent with GGP's.

This draft guidance document represents the agency's current thinking with regard to gamma irradiation of blood and blood components intended for transfusion. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

FDA is soliciting the following from the public: (1) Comments on the draft guidance document, (2) comments concerning the public's interest in a

pilot program that would allow licensure by self-certification, a written request for exception to filing a detailed supplement, and an inspection in lieu of a complete application review, and (3) letters of interest from manufacturers who would consider participating in the pilot program.

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document and the pilot program, including those comments expressing interest in participating in the pilot program. Written comments may be submitted at any time, however, comments should be submitted by April 27, 1999, to ensure adequate consideration in preparation of the final document and the pilot program. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document by using the World Wide Web (WWW). For WWW access, connect to CBER at "http://www.fda.gov/cber/guidelines.htm".

Dated: January 20, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99-1794 Filed 1-26-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Dental Research Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign

language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Dental Research Council, NADCRC January Meeting.

Date: January 25-26, 1999.

Open: January 25, 1999, 8:30 am to 5:00 pm.

Agenda: Director's Report, Division Updates, Presentations.

Place: Natcher Building, 45 Center Drive, Conference Rooms E1/E2, Bethesda, MD 20892.

Closed: January 26, 1999, 9:00 am to 2:00 pm.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Natcher Building, 45 Center Drive, Conference Rooms E1/E2, Bethesda, MD 20892.

Contact Person: Dushanka V. Kleinman, Deputy Director, National Institute of Dental Research, National Institutes of Health, 9000 Rockville Pike, 31/2C39, Bethesda, MD 20892.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: January 21, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-1825 Filed 1-26-99; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4441-N-06]

Submission for OMB Review: Comment Request

AGENCY: Office of the Assistant Secretary for Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of