to October 1, 1990, applicants were to submit separate ANDA's for each dosage form of a drug product and also for each variation (e.g., strength, color, shape) within a dosage form. Separate applications were requested for ease of review since having information on a number of variations within one application could make review more difficult. On October 1, 1990, the OGD Interim Policy and Procedure Guide (PPG) 20–90 was issued. This guide permitted certain variations of solid oral dosage forms and injectables to be submitted within a single abbreviated application. On June 7, 1995, PPG 20–90 was amended to allow certain variations to be filed as supplements.

This guidance incorporates the policies and procedures in PPG 20–90 and clarifies the practice of permitting variations of products in a single application.

This guidance is being issued as a level 1 guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It is being implemented immediately without prior public comment because it is intended to reduce the burden on industry. However, the agency wishes to solicit comments from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance represents the agency's current thinking on variations in drug products that may be included in a single abbreviated application. 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.

Interested persons may, at any time, submit written comments on the guidance 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. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 20, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–1850 Filed 1–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1218]

Blood Standards; Pilot Program for Gamma Irradiated Blood and Blood Components and Draft ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intent to establish a pilot program for licensed blood product manufacturers seeking to market irradiated blood components in interstate commerce. FDA is also announcing the availability for public comment of a draft guidance document entitled ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing.'' FDA is proposing a pilot program that would allow a manufacturer to self-certify conformance to specific criteria as a substitute for the Center for Biologics Evaluation and Research (CBER) review of information submitted in a biologics license application (BLA) supplement filing. Instead of submitting a BLA supplement with supporting operating procedures and data derived from validation and quality control testing, the manufacturer would submit an application form (FDA Form 356h), a self-certification statement that provides that the manufacturer is in compliance with all applicable FDA regulations and meets the criteria for gamma irradiated blood and blood components set forth in the draft guidance document entitled ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing,'' as well as written request to the CBER Director for an exception to filing a detailed supplement. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments on the proposed pilot program and draft guidance document may be submitted at any time, however, comments should be submitted by April 27, 1999, to ensure their adequate consideration in preparation of the final document and for the initiation of the pilot program.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments and letters of interest on the proposed pilot program and the draft guidance document to the Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Steven F. Falter, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing its intent to launch a pilot program for licensed blood product manufacturers seeking to market irradiated blood components in interstate commerce. The pilot program provides that FDA will review for completeness FDA Form 356h, the self-certification, and written request for an exception to filing a detailed supplement and at FDA discretion will schedule a prelicense inspection within 90 days of receipt of the self-certification to confirm conformance with applicable Federal regulations and the recommended criteria contained in the draft guidance document.

To participate in the program a manufacturer must already be licensed for nonirradiated blood components and should be ready for a prelicense inspection at the time it forwards FDA Form 356h, self-certification, and request for exception to FDA. If, during the prelicense inspection, FDA finds significant deficiencies in quality assurance, manufacturing facilities, or product safety, purity, potency, or effectiveness, FDA may withdraw the manufacturer from the pilot program and the manufacturer will be required to submit a BLA supplement with complete supporting documentation

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]

BILLING CODE 4160–01–F

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]

BILLING CODE 4140–01–M

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