DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1218]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program For Licensing,'' dated February 2000. FDA is also announcing the establishment of a pilot program for licensed blood product manufacturers seeking to market irradiated blood components in interstate commerce. The pilot program is intended to allow self-certification in lieu of the submission of a detailed biologics licence application (BLA) supplement. FDA is initiating the pilot program to determine if streamlining the process of licensing will be more efficient and effective for both the manufacturer and FDA without compromising product safety, purity, and potency.

DATES: Written comments may be submitted at any time. The effective date for implementation of the pilot program is April 14, 2000.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''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 (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance 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 guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit requests for participation in the pilot program to Mary Ann Denham at the address below.

FOR FURTHER INFORMATION CONTACT: About participation in the pilot program:

Mary Ann Denham, Center for Biologics Evaluation and Research (HFM–375), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2861.

About this notice:

Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program For Licensing,'' dated February 2000. This guidance document is intended to assist manufacturers of gamma irradiated blood and blood components to self-certify conformance to specific criteria as part of a pilot program in lieu of the submission of a detailed BLA supplement filing. Instead of submitting a BLA supplement with supporting operating procedures and data derived from validation and quality control testing, the manufacturer may submit an application form (Form FDA 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 guidance document entitled ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program For Licensing,'' dated February 2000, as well as written request to the CBER Director for an exception to filing a detailed supplement. The pilot program provides that FDA will review for completeness Form FDA 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 guidance document.

This guidance document finalizes the draft guidance entitled ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program For Licensing'' that was announced in the **Federal Register** of January 27, 1999 (64 FR 4118).

To participate in the program a manufacturer should already be licensed for nonirradiated blood components and should be ready for a prelicense inspection at the time it forwards Form FDA 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 will begin the pilot program on April 14, 2000. At the end of the pilot program, FDA will evaluate the program for efficiency and effectiveness and will make this evaluation available to the public. If the program proves to be efficient and effective, FDA will consider extending the program to other blood products.

This guidance document represents the agency's current thinking on gamma irradiation of blood and blood components intended for transfusion or for further manufacturing. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. If a manufacturer chooses to participate in this voluntary program, it should conform to the specific criteria set forth in this guidance. Manufacturers who want to use an alternative approach must submit a detailed BLA supplement under 21 CFR 601.12 or otherwise satisfy FDA that an exemption from that requirement is justified under 21 CFR 640.120. As with other guidance documents, FDA does not intend this guidance document to be all-inclusive and cautions that not all information may be applicable to all situations.

II. Comments

Interested persons, may at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be

identified with the docket number found in the brackets in the heading of this guidance document. A copy of the guidance 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 guidance document using the Internet. For Internet access, connect to CBER at http://www.fda.gov/cber/guidelines.htm.

Dated: March 1, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–6283 Filed 3–14–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3032–N]

Medicare Program; Meeting of the Medical and Surgical Procedures Panel of the Medicare Coverage Advisory Committee—April 12 and 13, 2000

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Medical and Surgical Procedures Panel of the Medicare Coverage Advisory Committee (MCAC). The panel provides advice and recommendations to the agency about clinical coverage issues. The panel will hear and discuss presentations from interested persons regarding the treatment of non-neurogenic urinary incontinence in adults. The meeting will focus on two treatment options: biofeedback and pelvic floor electrical stimulation. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES: *The Meeting:* The meeting will be held on April 12, 2000 from 8:00 a.m. until 5:15 p.m. and on April 13, 2000, from 8:00 a.m. until 3:00 p.m. E.S.T.

Deadline for Presentations and Comments: March 22, 2000, 5 p.m.

Special Accommodations: Persons attending the meeting who are hearing impaired and require sign language interpretation, or have a condition that requires other special assistance or accommodations, are asked to notify the Executive Secretary by March 31, 2000.

ADDRESSES:

The Meeting: The meeting will be held at The Baltimore Convention Center, One West Pratt Street, Baltimore, MD 21201.

Presentations and Comments: Submit formal presentations and written comments to Constance A. Conrad, Executive Secretary; Office of Clinical Standards and Quality; Health Care Financing Administration; 7500 Security Boulevard; Mail Stop S3–02–01; Baltimore, MD 21244.

Website: You may access up-to-date information on this meeting at www.hcfa.gov/quality/8b.htm.

Hotline: You may access up-to-date information on this meeting on the HCFA Advisory Committee Information Hotline, 1–877–449–5699 (toll free) or in the Baltimore area (410) 786–9379.

FOR FURTHER INFORMATION CONTACT: Constance A. Conrad, Executive Secretary, 410–786–4631.

SUPPLEMENTARY INFORMATION: On August 13, 1999, we published a notice (64 FR 44231) to describe the MCAC, which provides advice and recommendations to us about clinical issues. This notice announces the following public meeting of the MCAC:

Current Panel Members:

Alan M. Garber, M.D.; Michael D. Maves, M.D.; Angus M. McBryde, M.D.; H. Logan Holtgrewe, M.D.; Kenneth P. Brin, M.D.; Les J. Zendle, M.D.; Bruce Sigsbee, M.D.; Linda D. Bradley, M.D.; James P. Rathmell, M.D.; Arnold M. Epstein, M.D.; Phyllis E. Greenberger, M.S.W.; Marshall S. Stanton, M.D.

Meeting Topic:

The Panel will hear and discuss presentations from interested persons regarding the treatment of non-neurogenic urinary incontinence in adults. The meeting will focus on two treatment options: biofeedback the first day and pelvic floor electrical stimulation the second day.

Procedure and Agenda:

This meeting is open to the public. The panel will hear oral presentations from the public for approximately 2 hours and 30 minutes on each day of the meeting. The Panel may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations you must notify the For Further Information Contact person, and submit the following by the Deadline for Presentations and Comments date listed in the **DATES** section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, the names and addresses of proposed participants, and an estimate of the time required to make the presentation. We will request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public presentation, we will make a presentation to the Panel. After our presentation, the Panel will deliberate openly on the topic. Interested persons may observe the deliberations, but the Panel will not hear further comments during this time except at the request of the chairperson. At the end of the Panel deliberations each day, the Panel will allow approximately a 30-minute open public session for any attendee to address issues specific to the topic. After which, the members will vote and the Panel will make its recommendation.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 29, 2000.

Jeffrey L. Kang,

Director, Office of Clinical Standards and Quality, Health Care Financing Administration.

[FR Doc. 00–6421 Filed 3–14–00; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding the Section 340B Drug Pricing Program—Program Guidance Clarification

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992,'' enacted section 340B of the Public Health Service Act, ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible (covered) entities must sign a pharmaceutical pricing agreement with the Secretary of HHS in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

The purpose of this notice is to clarify section 340B program guidance related to the mechanism to prevent duplicate discounts (i.e., the generation of a