Date and Time: The meeting will be held on January 12, 2000, 10 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: David Krause, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 141, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12519. Please call the Information Line or access the Internet address of http://www.fda.gov/cdrh/panelmtg.html for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for an Absorbable Adhesion Barrier Device.

Procedure: On January 12, 2000, from 10:30 a.m. to 5 p.m. the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 29, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m., and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 5, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On January 12, 2000, from 10 a.m. to 10:30 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) relating to pending issues and applications.

FDA regrets that it was unable to publish this notice 15 days prior to the January 12, 2000, General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee meeting were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C., app. 2).

Dated: December 21, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–34068 Filed 12–29–99; 2:12 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5046]

Draft ''Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture.'' The draft guidance document applies to the manufacture of all licensed Whole Blood, blood components, Source Plasma, and Source Leukocytes. The draft guidance document, when finalized, is intended to assist manufacturers in determining which reporting mechanism is appropriate for a change to an approved license application for Whole Blood, blood components, Source Plasma, and Source Leukocytes.

DATES: Submit written comments at any time, however, comments should be submitted by April 3, 2000, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture'' 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, 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 on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, 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 the availability of a draft guidance document entitled ''Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture.'' The draft guidance document is intended to assist licensed manufacturers in determining which reporting mechanism is appropriate for a change to an approved license application for Whole Blood, blood components, Source Plasma, and Source Leukocytes. Recommendations are provided for postapproval changes in product, labeling, production process, quality controls, equipment, and facilities.

In the **Federal Register** of July 24, 1997 (62 FR 39890), FDA published the final rule entitled ''Changes to an Approved Application.'' The final rule amended the biologics regulations in § 601.12 (21 CFR 601.12) to reduce unnecessary reporting burdens on applicants licensed to manufacture biological products under the Public Health Service Act. Under § 601.12, a change to an approved product, labeling, production process, quality controls, equipment, or facilities is required to be reported to FDA in the following manner: (1) A supplement requiring approval prior to distribution; (2) a supplement submitted at least 30 days prior to distribution of the product made using the change; or (3) an annual report, depending on its potential to have an adverse effect on the identity, strength, quality, purity, or potency of the biological product as they may relate to the safety or effectiveness of the product. In addition, FDA made available a guidance document entitled ''Guidance for Industry: Changes to an Approved Application: Biological

Products'' published in the **Federal Register** of July 24, 1997 (62 FR 39904).

On December 2, 1997 (62 FR 56193, October 29, 1997), CBER held a public workshop entitled ''Workshop on the Biologics License Application (BLA) for Blood Products, and Reporting Changes to an Approved Application.'' The workshop was intended for firms that manufacture licensed human blood products, including products for transfusion and source materials for further manufacture. The workshop discussion focused on the application procedures, forms, and documentation needed for the BLA and how changes to an approved application are to be reported to FDA.

In response to comments received from industry requesting guidance specifically for blood and blood components, CBER has developed the draft guidance document for the manufacturers of licensed Whole blood and blood components intended for transfusion and for further manufacture into both injectable and noninjectable products. The draft guidance document, when finalized, will replace the recommendations in the ''Guidance for Industry: Changes to an Approved Application: Biological Products'' for Whole Blood, blood components, Source Plasma, and Source Leukocytes. The ''Guidance for Industry: Changes to an Approved Application: Biological Products'' remains applicable for all other biological products.

This draft guidance document represents the agency's current thinking on changes to an approved application for all licensed human blood and blood components intended for transfusion or for further manufacture. 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 requirement 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

This 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. Submit written comments at any time, however, comments should be submitted by April 3, 2000, to ensure adequate consideration in preparation of the final 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 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 at http://www.fda.gov/cber/guidelines.htm.

Dated: December 22, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–34039 Filed 12–30–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0296]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration; HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. The proposed collections consist of uniform mandatory notices to be given to Medicare home health beneficiaries by home health agencies (HHAs) when the HHA believes that services may not or may no longer be covered. Interested persons are invited to send comments regarding burden or any other aspect of these collections of information requirements. All comments will be considered together, including those comments submitted with respect to the Emergency **Federal Register** notice published on September 22, 1999, with regard to balancing the burden on providers with the provision of sufficient information to beneficiaries. We are particularly interested in receiving input regarding the form of the notices and the order in which the information is presented. We also invite comments on how best to fully inform beneficiaries with regard to services not covered by Medicare. Comments may also be sent regarding the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Additionally, we acknowledge that comments regarding these notices were made by beneficiary advocates in the context of the ongoing litigation in *Healey* v. *Shalala,* Civil Action No.3:98CV00418 (DJS) (D.Conn.). These comments related to: (1) the extent and type of notice that is required in cases in which the physician concurs in the reduction, termination, or denial of services; (2) the incorporation of a statement regarding a requirement that a beneficiary agree to share her medical records with the RHHI in the event that she requests the submission of a demand bill; and (3) general concerns about design and readability. The comments will be considered along with all other comments received in response to this request. However, we consider it most efficient and effective to publish these notices for comment in their present form and to consider all comments in a single comprehensive proceeding.

We also received comments from the National Association of Home Care (''NAHC'') , representing members of the provider community, regarding these notices. These comments related to the time required for implementation and general readability concerns. Among other things, NAHC also stated its belief that the notices misstate, in the boxes regarding the beneficiaries' choices, the standard under which coverage is determined. Similarly, these concerns will be considered with all other comments received in response to this request.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Home Health Advance Beneficiary Notices (HHABNs) and Supporting Regulations in 42 CFR Section 411.404-.406, 484.10, and 484.12(a);

Form No.: HCFA–R–0296 (OMB# 0938–0781);

Use: Beneficiaries must receive timely, accurate, complete, and useful notices which will enable them to make informed consumer decisions, with a proper understanding of their rights to a Medicare initial determination, their appeal rights in the case of payment