305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the document number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

For general information on the PDP process, or to comment on this guidance, please contact: Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20857, 301–594–2186.

For information concerning the design control and GMP aspects of this guidance, please contact: Sandy Weininger, Center for Devices and Radiological Health (HFZ–141), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20857, 301–443–2536, ext. 34.

SUPPLEMENTARY INFORMATION:

I. Background

Section 515(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(f)) provides an alternative to the investigational device exemption (IDE) and PMA processes for class III devices subject to premarket approval. This alternative process, PDP, was not implemented during the early years of FDA's medical device program because it was considered potentially complex and there was a need to focus attention on implementing the core provisions of the Medical Device Amendments of 1976, such as the IDE, premarket approval, 510(k), good manufacturing practices, and problem reporting requirements.

This document provides guidance on the content of PDP applications, expected actions and timeframes in the development of a product under a PDP, and how changes during the course of product development under a PDP should be handled. This draft guidance also provides a framework for interaction between FDA and the applicant; but, because of the wide range of devices that may be developed under the PDP authority, it is unlikely that every element addressed in the guidance will apply to any given device.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the PDP process and the relative duties and responsibilities of the agency and the applicant. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

''CDRH Guidance for Industry—Contents of a Product Development Protocol; Draft'' is available by fax from CDRH's Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt, press 1 to access DSMA Facts, at the second voice prompt, press 2, and then enter the document number 473 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH Home Page includes ''Guidance for Industry—Contents of a Product Development Protocol; Draft'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. The ''Guidance for Industry—Contents of a Product Development Protocol; Draft'' will be available at ''http://www.fda.gov/cdrh/pdp/.html''.

A text-only version of the CDRH Web site is also available from a computer or VT-100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

IV. Comments

Interested persons may, on or before October 26, 1998, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. 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 document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 9, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–19899 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0545]

Draft Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods; 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: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods.'' The draft guidance document describes the recommended donor suitability criteria and the licensing provisions for the collection of red blood cells using automated methods. The draft guidance document provides recommendations to blood establishments for the use of FDA cleared automated blood cell separators for the collection of both single and double units of red blood cells.

DATE: Written comments may be submitted at any time, however, comments should be submitted by September 25, 1998, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods'' 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 draft 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 draft guidance.

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

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, 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: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods.'' The draft guidance document is intended to provide specific recommendations on donor suitability criteria for allogenic and autologous red blood cell donations, on standard operating procedures, and recordkeeping, and describes registration and licensing procedures for the manufacture of double units of red blood cells or single units of red blood cells plus up to two units of fresh frozen plasma.

This draft guidance document represents the agency's current thinking with regard to collecting red blood cells by automated apheresis methods. 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. This draft guidance 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. Written comments may be submitted at any time, however, comments should be submitted by September 25, 1998, to ensure adequate consideration in preparation of the final document. 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 brackets in the heading of this document. A copy of this draft 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 draft guidance document using the World Wide Web (WWW) by connecting to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–19897 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4356–N–14]

Notice of Proposed Information Collection: Comment Request

AGENCY: Office of the Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: September 25, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Oliver Walker, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW, Room 9116, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: John J. Coonts, Director, Office of Insured Single Family Housing, telephone number (202) 708–3046 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Requirements for Single Family Mortgage Instruments.

OMB Control Number, if applicable: 2502–0404.

Description of the need for the information and proposed use: The Single Family Mortgage Instruments are the documents used to record the mortgage (or deed of trust) and the mortgage note (or deed of trust note). These are public documents used to protect both the interest of the mortgage borrower as well as the mortgage lender.

Estimation of total number of hours needed to prepare the information. The estimated number of respondents are 8,300, the frequency of responses is variable depending on business activity, with 0.25 hours per response.

Agency form numbers, if applicable: n/a.

Status of the proposed information collection: Extension of currently approved collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: July 20, 1998.

Ira G. Peppercorn,

General Deputy Assistant Secretary for Housing.

[FR Doc. 98–19913 Filed 7–24–98; 8:45 am]

BILLING CODE 4210–27–M