and recommendations on how to prepare EA's.

DATES: Written comments may be submitted at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of the guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or 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. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5629, or Daniel C. Kearns, Center for Biologics Evaluation and Research (HFM–206), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3031.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Environmental Assessment of Human Drug and Biologics Applications.'' The National Environmental Policy Act of 1969 (NEPA) requires all Federal agencies to assess the environmental impacts of their actions and to ensure that the interested and affected public is informed of environmental analyses. FDA is required under NEPA to consider the environmental impact of approving drug and biologics applications as an integral part of its regulatory process. Under the President's reinventing Government initiatives announced in April 1995, FDA reevaluated and revised its environmental regulations to reduce the number of EA's required to be submitted by industry and, consequently, the number of findings of no significant impact prepared by the agency under NEPA.

In the **Federal Register** of April 3, 1996 (61 FR 14922) (republished May 1, 1996 (61 FR 19476)), FDA issued for public comment a notice of proposed rulemaking that proposed additional categorical exclusions for those actions the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) have determined normally do not individually or cumulatively have a significant effect on the quality of the human environment. The final rule was published in the **Federal Register** of July 29, 1997 (62 FR 40570), and became effective August 28, 1997. This guidance is based on the final rule and supersedes CDER's ''Guidance for Industry For the Submission of an Environmental Assessment in Human Drug Applications and Supplements,'' which published in November 1995.

In the **Federal Register** of February 12, 1998 (63 FR 7174), FDA announced the availability of a draft version of this guidance. The February 12, 1998, document gave interested persons an opportunity to submit comments through April 13, 1998. All comments received during the comment period have been carefully reviewed and incorporated, where appropriate, in this revised guidance.

FDA's regulations in part 25 (21 CFR part 25) specify that environmental assessments must be submitted as part of certain new drug applications, abbreviated applications, applications for marketing approval of a biologic product, supplements to such applications, investigational new drug applications and for various other actions (see § 25.20), unless the action qualifies for a categorical exclusion.

This guidance provides information on when an EA should be submitted and recommendations on how to prepare EA's for submission to CDER and CBER for these drug or biologics applications. Topics covered include: (1) When categorical exclusions apply, (2) when to submit an EA, (3) the content and format of EA's, (4) specific guidance for the environmental issues that are most likely to be associated with human drugs and biologics, (5) test methods, (6) an applicant's treatment of confidential information submitted in support of an EA, and (7) master files for drugs and biologics.

This guidance is a level 1 guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on environmental assessment of human drug and biologics applications. 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.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the 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 and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–19900 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–0563]

CDRH Draft Guidance For Industry: Contents of a Product Development Protocol; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''CDRH Guidance for Industry—Contents of a Product Development Protocol; Draft''. This draft guidance is not final nor is it in effect at this time. This document provides guidance on the content of product development protocol (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.

DATES: Written comments must be received by October 26, 1998.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the draft guidance document entitled ''CDRH Guidance for Industry—Contents of a Product Development Protocol; Draft'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Written comments concerning this document must be submitted to the Dockets Management Branch (HFA–

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),