Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX 301–827–2843.

Registration and Request for Oral Presentations: Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by August 28, 1998. Registration at the site will be done on a space available basis on the day of the workshop beginning at 7:30 a.m. There is no registration fee for the workshop. Requests for oral presentations should be sent to Jaroslav G. Vostal, Division of Hematology (HFM–335), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–496–2577, FAX 301–402–2780, e-mail ''VOSTAL@A1.CBER.FDA.GOV''. Space is limited, therefore interested parties are encouraged to register early.

If you need special accommodations due to disability, please contact Joseph Wilczek at least 7 days in advance.

Agenda: The goals of the workshop include the following: (1) Review current methodology for measuring platelet clinical efficacy; (2) define the clinical efficacy of a platelet transfusion; (3) discuss similarities and differences between intact platelets and platelet substitutes; (4) present animal models used for measuring platelet substitute efficacy; and (5) discuss design of clinical trials to establish clinical efficacy for platelets and platelet substitutes. The information obtained from these presentations will assist FDA in developing standards to evaluate novel platelet products and to assure the safety and effectiveness of these products.I11*Transcripts*: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 days after the workshop at a cost of 10 cents per page.

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–19896 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0497]

Hematopoietic Stem/Progenitor Cell Products: Discussion of Unrelated Allogeneic Placental/Umbilical Cord Blood and Peripheral Blood Cell Banking and Transplantation; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop: Hematopoietic Stem/Progenitor Cell Products: Discussion of Unrelated Allogeneic Placental/Umbilical Cord Blood and Peripheral Blood Cell Banking and Transplantation. This workshop, which is cosponsored by FDA and the National Institutes of Health, will include a discussion of the current status of clinical and nonclinical laboratory data to support the development of standards for unrelated allogeneic peripheral and placental/umbilical cord blood hematopoietic stem/progenitor cell products; studies to obtain data for product safety and effectiveness; and the notice and request for comments entitled ''Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental/Umbilical Cord Blood Hematopoietic Stem/Progenitor Cell Products; Request for Comments'' that published in the **Federal Register** of January 20, 1998 (63 FR 2985).

Date and Time: The public workshop will be held on Thursday, September 10, 1998, 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Jack Masur Auditorium, Bldg. 10, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD.

Contact Person: Joseph Wilczek, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM–350), 1401 Rockville Pike, Rockville, MD 20852, 301–827–6129, FAX 301–827–2843.

SUPPLEMENTARY INFORMATION: The goals of this workshop are to: (1) Discuss the current status of related and unrelated allogeneic peripheral blood hematopoietic stem/progenitor cell collection; (2) discuss the current status of unrelated allogeneic placental/umbilical cord blood banking and transplantation; (3) discuss issues regarding the administration of cytokines to normal donors for the mobilization of peripheral blood hematopoietic stem/progenitor cells and transplantation; and (4) address questions the public may have regarding the notice and request for comments published in the **Federal Register** of January 20, 1998 (63 FR 2985). The information obtained from these presentations will assist FDA and the interested public in developing standards for unrelated allogeneic peripheral blood and placental/umbilical cord blood hematopoietic stem/progenitor cell products.

Registration and Requests for Oral Presentations: Send or fax registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations, to the contact person by Tuesday, August 11, 1998. Registration at the site will be done on a space available basis on the day of the workshop beginning at 7:30 a.m. There is no registration fee for this workshop.

If you need special accommodations due to a disability, please contact Joseph Wilczek at least 7 days in advance.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the workshop at a cost of 10 cents per page.

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–19892 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–0049]

Guidance for Industry on Environmental Assessment of Human Drug and Biologics Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Environmental Assessment of Human Drug and Biologics Applications.'' This guidance is intended to provide information on when an environmental assessment (EA) should be submitted in support of a human drug or biologics application

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–