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