I. Background

FDA is announcing the availability of a draft information sheet guidance for sponsors, clinical investigators, and IRBs entitled ''Frequently Asked Questions—Statement of Investigator (Form FDA 1572).'' This guidance is intended to assist IRBs, clinical investigators, and sponsors involved in clinical investigations of investigational drugs and biologics in complying with the requirement that each investigator complete and sign a Form FDA 1572 before participating in an investigation. It describes how to complete the Statement of Investigator form (Form FDA 1572).

FDA developed this draft information sheet guidance in response to numerous questions from the research community regarding Form FDA 1572. In this draft guidance, we provide answers to frequently asked questions concerning the purpose of this form, when this form needs to be completed and signed by the investigator, how to best complete the various blocks within the form, and when the form might need to be updated. In addition, we clarify questions related to the use of Form FDA 1572 by clinical investigators participating in studies conducted outside the United States that may or may not be under an investigational new drug application.

This information sheet guidance is part of the Information Sheet Guidance Initiative announced in the **Federal Register** of February 3, 2006 (71 FR 5861), which describes FDA's intention to update the process for developing, issuing, and making available guidances intended for IRBs, clinical investigators, and sponsors. Known as ''Information Sheets,'' these guidances have provided recommendations to IRBs, clinical investigators, and sponsors to help them fulfill their responsibilities to protect human subjects who participate in research regulated by the FDA since the early 1980s. The Information Sheet Guidance Initiative is intended to ensure that the Information Sheets are consistent with the FDA's good guidance practices (GGPs). As part of the initiative, which will be ongoing, the agency plans to rescind Information Sheets that are obsolete, revise and reissue Information Sheet Guidances that address current issues, and develop new Information Sheet Guidances as needed.

This draft information sheet guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The draft information sheet guidance, when finalized, will represent the agency's current thinking on completing Form FDA 1572. 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 statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information for Form FDA 1572 have been approved under OMB Control No. 0910–0014.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/oc/gcp/draft.html* or *http://www.regulations.gov*.

Dated: July 21, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–17305 Filed 7–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 10, 2008, from 8 a.m. to 5:45 p.m. and on September 11, 2008, from 8 a.m. to 3 p.m.

Location: Hilton Hotel, Washington, DC/Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Donald W. Jehn or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (CBER) (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On the morning of September 10, 2008, the Committee will hear an update on the May 29 to 30, 2008, meeting of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability. Following this update, the Committee will discuss strategies to enhance bacterial safety of 7 day platelets for transfusion. In the afternoon, the Committee will discuss iron status in blood donors. On September 11, 2008, the Committee will hear updates on the following topics: (1)

April 29 to 30, 2008, workshop on hemoglobin based oxygen carriers; (2) July 10 to 11, 2008, blood establishment computer software conference; (3) the development of an automated Biologics License Application submission system; and (4) Draft Guidance for Industry: Re-qualification Method for Re-entry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc). Following these updates, the Committee will discuss options for blood donor screening and re-entry for malaria. FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: 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 on or before September 2, 2008. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:30 a.m. and between approximately 4 p.m. and 4:30 p.m. on September 10, 2008, and between approximately 9:15 a.m. and 9:45 a.m. and between approximately 1:30 p.m. and 2 p.m. on September 11, 2008. Those desiring to make formal oral presentations should notify the contact person 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 on or before August 22, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 25, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald W. Jehn or Pearline K. Muckelvene at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: July 17, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–17359 Filed 7–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Risk Communication Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public. All attendees should bring some form of government-issued photo identification, such as a driver's license.

Name of Committee: Risk Communication Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on effective risk communication.

Date and Time: The meeting will be held on August 14, 2008, from 8 a.m. to 5 p.m. and August 15, 2008, from 8 a.m. to 2 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Lee L. Zwanziger, Office of the Commissioner, Office of Policy, Planning and Preparedness, Office of Planning (HFP–60), Food and Drug Administration, 5600 Fishers Lane (for express delivery: rm 15–22), Rockville, MD 20857, 301–827–2895, FAX: 301–827–3285, Food and Drug Administration, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732112560. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On August 14 and 15, 2008, the committee will meet for presentations and discussion of the scientific basis for translating principles of risk communication into practice in situations of emerging and uncertain risk.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is or will be available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: 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 on or before August 11, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on August 14th and 10:30 to 11:30 on August 15th. Those desiring to make formal oral presentations should notify the contact person and should 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 on or before August 7, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will