

- Cancer industry is predicted to expand to \$85.3 billion by 2010.

*Inventors:* Hui Han and John E. Niederhuber (NCI).

*Patent Status:* U.S. Provisional Application No. 61/253,617 filed 21 Oct 2009 (HHS Reference No. E-303-2009/0-US-01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Jennifer Wong; 301-435-4633; [wongje@mail.nih.gov](mailto:wongje@mail.nih.gov).

Dated: May 20, 2010.

**Richard U. Rodriguez,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-1997-D-0008] (formerly Docket No. 1997D-0318)

#### **Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products” dated May 2010. The guidance announced in this notice provides blood collecting establishments and manufacturers of plasma derivatives with comprehensive FDA recommendations intended to minimize the possible risk of transmission of CJD and vCJD from blood and blood products. This guidance document amends the January 2002 guidance document of the same title by: Incorporating donor deferral recommendations for donors who have received a transfusion of blood or blood components in France since 1980, providing updated scientific information on CJD and vCJD, revising labeling recommendations for Whole Blood and blood components intended for transfusion, and recognizing AABB’s full Donor History Questionnaire

Version 1.3 as an acceptable mechanism for collection of donor history information. The guidance announced in this notice supersedes the guidance document entitled “Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products” dated January 2002 (2002 guidance), and the draft guidance document entitled “Draft Guidance for Industry: Amendment (Donor Deferral for Transfusion in France Since 1980) to “Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products” dated August 2006 (2006 draft guidance).

**DATES:** Submit electronic or written comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic or written comments on the guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Denise Sánchez, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a document entitled “Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products” dated May 2010. This guidance amends the 2002 FDA guidance of the same title by

incorporating donor deferral recommendations as to donors in France (as announced in the 2006 draft guidance), providing updated scientific information on CJD and vCJD, revising labeling recommendations for Whole Blood and blood components intended for transfusion, and recognizing the use of AABB’s full Donor History Questionnaire Version 1.3 as an acceptable mechanism that is consistent with FDA requirements and recommendations for collecting donor history information.

In the **Federal Register** of January 16, 2002 (67 FR 2226), FDA announced the availability of a guidance entitled “Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products” dated January 2002 (the 2002 guidance). The 2002 guidance finalized recommendations to all blood collecting establishments and manufacturers of plasma derivatives for deferral of donors with possible exposure to the CJD and vCJD agents. In the **Federal Register** of August 14, 2006 (71 FR 46484), FDA announced the availability of a draft guidance entitled “Draft Guidance for Industry: Amendment (Donor Deferral for Transfusion in France Since 1980) to ‘Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products’” (the 2006 draft guidance). The 2006 draft guidance was intended to amend the 2002 guidance by adding a donor deferral recommendation for donors who have received a transfusion of blood or blood components in France since 1980. Specifically, in the 2006 draft guidance, we stated that we intended to incorporate the new donor deferral recommendation after receiving comments on the draft guidance and reissue the revised 2002 guidance as a level 2 guidance document for immediate implementation (71 FR 46484, August 14, 2006). Upon further consideration, however, we believe it appropriate to issue the guidance announced in this notice as a level 1 guidance document.

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents FDA’s current thinking on this topic. 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. Paperwork Reduction Act of 1995

This 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 in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.100 have been approved under OMB control number 0910–0116; and the collections of information in 21 CFR Part 600.14 and 606.171 have been approved under OMB control number 0910–0458.

## III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding the guidance. 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. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: May 18, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–12696 Filed 5–26–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Notice of Meetings

In accordance with section 10(d) of the Federal Advisory Committee Act as amended (5 U.S.C., Appendix 2), the Agency for Healthcare Research and Quality (AHRQ) announces meetings of scientific peer review groups. The subcommittees listed below are part of

the Agency's Health Services Research Initial Review Group Committee.

The subcommittee meetings will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications are to be reviewed and discussed at these meetings. These discussions are likely to involve information concerning individuals associated with the applications, including assessments of their personal qualifications to conduct their proposed projects. This information is exempt from mandatory disclosure under the above-cited statutes.

1. *Name of Subcommittee:* Health Care Technology and Decision Sciences.

*Date:* June 15–17, 2010 (Open from 8 a.m. to 8:15 a.m. on June 15 and closed for remainder of the meeting)

*Place:* Crowne Plaza Hotel, 3 Research Court, Conference Room TBD, Rockville, MD 20852.

2. *Name of Subcommittee:* Health Systems Research.

*Date:* June 16–18, 2010 (Open from 8 a.m. to 8:15 a.m. on June 16 and closed for remainder of the meeting)

*Place:* Sheraton Rockville Hotel, 920 King Farm Boulevard, Conference Room TBD, Rockville, MD 20852.

3. *Name of Subcommittee:* Health Care Research Training.

*Date:* June 17–18, 2010 (Open from 8 a.m. to 8:15 a.m. on June 17 and closed for remainder of the meeting)

*Place:* Hyatt Regency Hotel, 7400 Wisconsin Avenue, 1 Bethesda Metro Center, Conference Room TBD, Bethesda, Maryland 20814.

4. *Name of Subcommittee:* Health Care Quality and Effectiveness Research.

*Date:* June 22–24, 2010 (Open from 8:30 a.m. to 8:45 a.m. on June 22 and closed for remainder of the meeting)

*Place:* Hilton Rockville Executive Meeting Center, 1750 Rockville Pike, Conference Room TBD, Rockville, Maryland 20850.

*Contact Person:* Anyone wishing to obtain a roster of members, agenda or minutes of the nonconfidential portions of the meetings should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Suite 2000, Rockville, Maryland 20850, Telephone (301) 427–1554.

Agenda items for these meetings are subject to change as priorities dictate.

Dated: May 13, 2010.

**Carolyn M. Clancy,**

*Director.*

[FR Doc. 2010–12547 Filed 5–26–10; 8:45 am]

**BILLING CODE 4160–90–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Integrating Patient-Reported Outcomes in Hospice and Palliative Care Practices.

*Date:* June 1, 2010.

*Time:* 11 a.m. to 2 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Cancer Institute, 6116 Executive Blvd., Room 8018, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Shamala K. Srinivas, PhD, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8123, Bethesda, MD 20892, 301–594–1224, [ss537t@nih.gov](mailto:ss537t@nih.gov).

This notice is being published less than 30 days prior to the meeting due to scheduling conflicts.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Development of Anticancer Agents.

*Date:* June 2, 2010.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, 6116 Executive Boulevard, Room 8018, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Joyce C. Pegues, B.S., B.A., PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 7149, Bethesda, MD 20892–8329, 301–594–1286, [peguesj@mail.nih.gov](mailto:peguesj@mail.nih.gov).

This notice is being published less than 30 days prior to the meeting due to scheduling conflicts.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer