associated records until notified by FDA and will make such records available to FDA for inspection upon request. Appropriate local public health authorities will periodically verify and reconcile drug accountability records.

J. USPS will obtain information from participating USPS carriers every six months documenting whether (a) they have stored their kits as instructed; (b) they are able to locate their kits readily; (c) their kits are intact; and (d) the doxycycline hyclate in their kits has not expired. USPS will ascertain the circumstances surrounding non-compliance for USPS participants who report (a) loss of a kit or (b) use of doxycycline hyclate from the emergency kit in the absence of instructions to do so. Depending on its findings, USPS may disqualify an individual from further participation. If the doxycycline hyclate emergency kit will expire before the next 6-month follow-up, a new doxycycline hyclate emergency kit will be prescribed for eligible participants in accordance with paragraph D and the other terms of this letter. In such cases, USPS, in conjunction with local public health authorities, will be responsible for ensuring that such kits are collected, accounted for, and disposed of, as instructed by HHS. Drug accountability records will be maintained. USPS will also ascertain whether there have been any adverse events or medication errors associated with the doxycycline hyclate tablet emergency kit. If any such adverse events or medication errors have not previously been reported to FDA as outlined in paragraph H, they must be reported within 15 days to FDA. FDA has authorized BARDA's Form entitled ''Questions to Determine Status of Your Household Antibiotic Kit (HAK) or Individual Household Antibiotic Kit (iHAK)'' (Kit Status form). Any revision of the Kit Status form is subject to FDA's prior approval. USPS, in conjunction with appropriate local public health authorities, will be responsible for ensuring that completed Kit Status forms are maintained until notified by FDA. A report summarizing the information collected on Kit Status forms under this paragraph will be submitted to FDA within 30 days of gathering such information. Associated records will be made available to FDA for inspection upon request.

K. USPS, in conjunction with appropriate public health authorities, will be responsible for collecting any expired doxycycline hyclate tablet emergency kits. USPS and/or appropriate local public health authorities will be responsible for disposing of expired doxycycline hyclate tablet emergency kits as instructed by HHS at that time. USPS, in conjunction with appropriate local public health authorities, will ensure that drug accountability records are maintained and reconciled. Such records shall be made available to FDA for inspection upon request.

L. USPS, in conjunction with appropriate local public health authorities, will be responsible for ensuring that completed Health Assessment Forms, Healthcare Provider Quality Checklists, and any other records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

M. As a condition of this EUA, all advertising and promotional descriptive printed matter relating to the use of doxycycline hyclate tablet emergency kits authorized under this EUA shall be consistent with the Fact Sheets, home preparation instructions, and placard information, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

N. Upon termination of the declaration of emergency under section 564(b)(2) of the Act or upon revocation of this EUA under section 564(g) of the Act, USPS, in conjunction with appropriate public health authorities, will be responsible for collecting all doxycycline hyclate tablet emergency kits. USPS and/or local public health authorities will dispose of doxycycline hyclate emergency kits as instructed by HHS at that time. USPS, in conjunction with appropriate local public health authorities, will ensure that drug accountability records are maintained and reconciled. Such records will be made available to FDA for inspection upon request.

O. HHS will notify FDA of its decision to add a CRI location and its decision to initiate distribution of doxycycline hyclate tablet emergency kits under this EUA to particular CRI locations.

The emergency use of doxycycline hyclate tablet emergency kits as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,
Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy

Dated: October 15, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–25062 Filed 10–20–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0484]

Preparation for International Conference on Harmonization Meetings in Brussels, Belgium; Public Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the public meeting notice entitled ''Preparation for ICH meetings in Brussels, Belgium.'' This meeting was announced in the **Federal Register** of September 16, 2008 (73 FR 53428). The amendment is being made to reflect changes in the *Location* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Tammie Jo Bell, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by email: *Tammie.Bell2@fda.hhs.gov* or fax: 301–827–0003.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 16, 2008, FDA announced that a preparation meeting for the International Conference on Harmonization will be held on October 21, 2008 from 2:30 p.m. to 5:30 p.m.

On page 53428, in the first column, the *Location* portion of the document is amended to read as follows:

Location: The meeting will be held at the Hilton Washington DC/ Rockville Hotel & Executive Meeting Center, Regency Room, 1750 Rockville Pike, Rockville, MD 20852. For directions please visit *www.washingtondcrockville.hilton.com*.

The agenda for the public meeting will be made available via the internet at *http://www.fda.gov/cder/meeting/ICH_20081021.htm*.

Dated: October 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–25034 Filed 10–20–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Evaluation of Risk Factors Associated With Viral Infections in Chinese Donors: a. Risk Factors Associated With HIV; b. Risk Factors Associated With Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV).

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 31, 2008, pages 44751–44753 and allowed 60 days for public comment. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of

Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a current valid OMB control number.

Proposed Collection: Title: Evaluation of Risk Factors Associated with Viral Infections in Chinese Donors: a. Risk factors associated with Human Immunodeficiency Virus (HIV), b. Risk factors associated with Hepatitis B virus (HBV) and Hepatitis C virus (HCV). This collection will cover two protocols as stated in the title. The first protocol will aim to study risk factors associated with HIV in Chinese donors and the second protocol will study risk factors related to HBV and HCV in Chinese donors. *Type of Information Collection Request: NEW. Need and Use of Information Collection:* Understanding the risk factors associated with HIV, HBV and HCV infections in donors is essential for developing donor behavioral screening policies. Injection drug use, sexual transmissions, transfusion history, and medical injections are thought to be major routes of transmission in China but their relative importance in blood donors is unknown.

In the U.S., risk factors have been better characterized, but questions still remain. Risk factors cannot be identified in 33% and 40% of persons with acute hepatitis B and C respectively, and risk factors may differ between the U.S. and China. This study will improve our understanding of potential transfusion transmitted viral risk factors that cannot be optimally studied in the U.S. because of their low prevalence. For example, we may be able to assess whether treatments commonly used in China, such as acupuncture and medical injections, are important routes of HBV and HCV transmission.

The primary objectives of the proposed study are to assess:

- The primary risk factors associated with HIV, HBV and HCV.
- The relative importance of injection drug use, heterosexual transmission, family history, transfusion history, history of previous whole blood or plasma donation, male to male sex, medical injections, acupuncture, and tattoos as routes of transmission for HIV, HBV and HCV.
- Other important routes of transmission for these viruses such as sex with an injection drug user, snorting drugs, living with someone who has HBV and HCV, living with someone who injects drugs, sharing a toothbrush or a razor, having been in jail, occupational history, having surgery, etc.

It is proposed to conduct a large, multi blood center case-control study to meet the study objectives. Cases for the HIV protocol will be donors with confirmed anti-HIV antibody reactivity. Blood centers will select a random group of donors with negative infectious disease test results as Controls for this study. Controls will be enrolled with a 2:1 ratio to Cases and will be matched to the Cases by blood center and donation month. Blood centers will contact potential Controls by phone and/or mail, inviting them to come back to participate in this study. Cases and Controls will be consented and interviewed using the same Risk Factor Questionnaire (RFQ) by Chinese-CDC (C–CDC) or blood center staff, either at the local C–CDC or blood center.

The second protocol assessing risk factors related to HBV and HCV will have three groups of donors: ''HBV Group'': HBV (HBsAg) positive donors either from prescreening (rapid testing) or routine screening testing. Confirmatory testing for HBV will be done for these donors. ''HCV Group'': HCV (anti-HCV) positive donors from routine screening testing (blood centers do not do prescreening rapid testing for anti-HCV). Confirmatory testing for HCV will be done for these donors. The third group will be a ''Control Group'' including donors with negative results for all prescreening and routine screening tests. No additional testing is done for these donors. On a monthly basis, the blood centers will use the confirmatory testing results for HBV and HCV respectively, to generate a list of cases. For that same month, the blood center will generate a list of controls (randomly selected and matched by blood center and month of donation). The same control group will be used for HBV and HCV cases. Donors in all three groups will be mailed a Risk Factor Survey study packet. The packet will include a study information sheet (discussing the purpose and nature of this study), an informed consent document explaining the voluntary nature, the benefits and risks of this study, a RFQ, a small monetary reward for taking the survey and an envelope with paid postage for the donor to mail their completed questionnaire back to the blood center.

Frequency of Response: Once. *Affected Public:* Individuals. *Type of Respondents:* Adult Blood Donors. The annual reporting burden is as follows: *Estimated Number of Respondents:* 3,920; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* 0.33; and *Estimated Total Annual Burden Hours Requested:* 1,293.5. The annualized cost to respondents is estimated at: $1,940.25 (based on $1.50 per hour). According to China's National Bureau of Statistics in 2006, the average annual wage in China is 21,001 Chinese Yuan (or $2,958 U.S. dollars based on current exchange rate of 1 U.S. dollar = 7.1). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Estimated No. of respondents	Estimated No. of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
HIV Risk factor:			
Case	350	0.33	115.5
Control	700	0.33	231
HBV and HCV Risk factor:			
Case	1700	0.33	561
Control	1170	0.33	386
Total	3920	0.33	1293.5

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information,

including the validity of the methodology and the assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Room 9144, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892–7950, or call 301–435–0065, or E-mail your request to *nemog@nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received *within 30 days* of the date of this publication.

Dated: October 8, 2008.

Dr. George Nemo,

Project Officer, NHLBI, National Institutes of Health.

[FR Doc. E8–24947 Filed 10–20–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting 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 the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Developmental Genetics.

Date: November 13, 2008.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Peter Zelazowski, PhD., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Rm. 5B01, Bethesda, MD 20892–7510, 301–435–6902, *peter.zelazowski@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 14, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–24948 Filed 10–20–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting 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 the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Initial Review Group; Genome Research Review Committee.

Date: November 18, 2008.

Time: 2 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Room 4076, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Rudy Pozzatti, PhD., Scientific Review Officer, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892, 301 402–0838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: October 14, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–24950 Filed 10–20–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting 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 the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel Developing and Advanced Centers.

Date: November 17, 2008.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Arlington Gateway, 801 North Glebe Road, Arlington, VA.

Contact Person: Marina Broitman, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892–9608, 301–402–8152, *mbroitma@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)