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]

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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]

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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