• A statement of either the quantity or volume of the repackaged drug product, whichever is appropriate.
• The date the drug product was repackaged.
• The beyond-use-date of the repackaged drug product.
• Storage and handling instructions for the repackaged drug product.
• The National Drug Code (NDC) number of the repackaged drug product, if available.[1]
• The statement ''Not for resale,'' and, if the drug is distributed by an outsourcing facility other than pursuant to a prescription for an individual identified patient, the statement ''Office Use Only.''
• If included on the label of the FDA-approved drug product from which the drug product is being repackaged, a list of the active and inactive ingredients, unless such information is included on the label for the container from which the individual units are removed, as described in this document.

In addition, a condition in the draft guidance is that the label on the container from which the individual units are removed for administration (secondary packaging, *e.g.,* the bag, box, or other package in which the repackaged products are distributed) includes the active and inactive ingredients, if the immediate product label is too small to include this information, and directions for use, including, as appropriate, dosage and administration, and the following information to facilitate adverse event reporting: *http://www.fda.gov/medwatch* and 1–800–FDA–1088.

Another condition in the draft guidance is that each repackaged drug product is accompanied by a copy of the prescribing information that accompanied the original drug product that was repackaged.

We estimate that annually a total of approximately 10 outsourcing facilities (''Number of Respondents'' in table 1, row 1) will each design, test, and produce approximately 10 different labels (''Frequency per Disclosure'' in table 1, row 1) for a total of 100 labels that include the information set forth in section III.A.11 of the draft guidance (including directions for use) (''Total Disclosures'' in table 1, row 1). We also estimate that designing, testing, and producing each label will take approximately 0.5 hours for each repackaged drug product (''Hours per Disclosure'' in table 1, row 1). The provision to add the statement *http://www.fda.gov/medwatch* and 1–800–FDA–1088 is not included in this burden estimate because it is not considered a collection of information under the PRA because the information is ''originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

We also estimate that annually a total of approximately 10 outsourcing facilities (''Number of Respondents'' in table 1, row 2) will each produce a copy of prescribing information as set forth in section III.A.11 of the draft guidance for approximately 10 repackaged drug products (''Frequency per Disclosure'' in table 1, row 1) for a total of 100 disclosures (''total disclosures'' in table 1, row 2). We also estimate that providing prescribing information labeling will take approximately 1 hour for each repackaged drug product (''Hours per Disclosure'' in table 1, row 2). The provision to add *http://www.fda.gov/medwatch* and 1–800–FDA–1088 is not included in this burden estimate because it is not considered a collection of information under the PRA because the information is ''originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

The total estimated third-party disclosure burden resulting from the draft guidance is as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

Repackaging by outsourcing facilities	Number of respondents	Frequency per disclosure	Total disclosures	Hours per disclosure	Total hours
Designing, testing, and producing each label on immediate containers, packages and/or outer containers	10	10	100	.5	50
Prescribing information labeling produced for each repackaged drug product	10	10	100	1	100
Total					150

There are no capital costs or operating and maintenance costs associated with this collection of information.
*(30 minutes)

The draft guidance also references registration, product reporting, and CGMP requirements for outsourcing facilities. In the **Federal Register** of December 4, 2013 (78 FR 72899), FDA estimated the burden resulting from outsourcing facility registration. In the **Federal Register** of December 4, 2013 (78 FR 72897), FDA estimated the burden resulting from outsourcing facility interim product reporting. In the **Federal Register** of July 2, 2014 (79 FR 37743), FDA estimated the burden resulting from outsourcing facility compliance with CGMP requirements.

V. Electronic Access

Persons with access to the Internet can obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: February 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03417 Filed 2–18–15; 8:45 am]

BILLING CODE 4164–01–P

[1] The NDC number of the original approved drug product should not be placed on the repackaged drug product.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Health Information National Trends Survey (HINTS) (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection

listed below. This proposed information collection was previously published in the **Federal Register** on December 4, 2014 (Vol. 79, No. 233, pages 72003—4) and allowed 60 days for public comment. A total of five public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), 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 currently valid OMB control number.

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, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

DATES: *Comment 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.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Bradford W. Hesse, Ph.D., Health Communication and Informatics Research Branch, 9609 Medical Center Drive, MSC 9761, Room 3E610, Rockville, MD 20850 or call non-toll free number 240–276–6721 or Email your request, including your address, to *hesseb@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Health Information National Trends Survey (HINTS) 0925–0538, Reinstatement with Change, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This partnership between NCI and FDA will include assessing the public's knowledge of medical devices, communications related to product recalls, nutritional supplement labeling, and topics to inform FDA's regulatory authority over tobacco, such as risk perceptions about new tobacco products, product pack color gradations, perceptions of product harm, and tobacco product claims and labels. This HINTS survey will couple knowledge-related questions with inquiries into the communication channels through which understanding is being obtained, and assessment of FDA-regulated material. This survey will extend the information collected and priorities from HINTS which have been to provide a comprehensive assessment of the American public's current access to, and use of, information about cancer across the cancer care continuum from cancer prevention, early detection, diagnosis, treatment, and survivorship.

OMB approval is requested for 1 year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,159.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Individuals	4,318	1	30/60	2,159

Dated: February 9, 2015.

Karla Bailey,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2015–03382 Filed 2–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood 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 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Short-term Educational Experiences in Hematology.

Date: March 11, 2015.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda; One Bethesda Metro Center; 7400 Wisconsin Avenue; Bethesda, MD 20814.

Contact Person: Melissa E Nagelin, Ph.D.; Scientific Review Officer; Office of Scientific Review/DERA; National Heart, Lung, and Blood Institute; 6701 Rockledge Drive; Room 7202; Bethesda, MD 20892; 301–435–0297; *nagelinmh2@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; International Strategic Timing of Antiretroviral Therapy.

Date: March 13, 2015.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health; 6705 Rockledge Drive, Room 7188; Bethesda, MD 20817; (Telephone Conference Call).

Contact Person: Chang Sook Kim, Ph.D.; Scientific Review Officer; Office of Scientific Review/DERA; National Heart, Lung, and Blood Institute; 6701 Rockledge Drive; Room 7188; Bethesda, MD 20892–7924; 301–435–0287; *carolko@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS).

Dated: *February 12, 2015.*

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–03344 Filed 2–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections