

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Sentinel Family Cohort	Cohort Intake	360	1	10/60	60
Sentinel Family Cohort	Cohort Weekly Illness Reporting	360	12	3/60	216
Total	1,109

Leroy A. Richardson,
*Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.*

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**DEPARTMENT OF HEALTH AND
 HUMAN SERVICES**

**Centers for Disease Control and
 Prevention**

[60Day-14-0740]

**Proposed Data Collections Submitted
 for Public Comment and
 Recommendations**

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404-639-7570 and send comments to Leroy A. Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information

technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Medical Monitoring Project (MMP)—(OMB No. 0920-0740, Expiration: 5/31/2015)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention (DHAP) requests a revision of the currently approved Information Collection Request: “Medical Monitoring Project” expiring May 31, 2015. This data collection addresses the need for national estimates of access to and utilization of HIV-related medical care and services, the quality of HIV-related ambulatory care, and HIV-related behaviors and clinical outcomes.

For the proposed project, the same data collection methods will be used as for the currently approved project. Data would be collected from a probability sample of HIV-diagnosed adults in the U.S. who consent to an interview and abstraction of their medical records. As for the currently approved project, de-identified information would also be extracted from HIV case surveillance records for a dataset, referred to as the

minimum dataset, which is used to assess non-response bias, for quality control, to improve the ability of MMP to monitor ongoing care and treatment of HIV-infected persons, and to make inferences from the MMP sample to HIV-diagnosed persons nationally. No other Federal agency collects such nationally representative population-based information from HIV-diagnosed adults. The data are expected to have significant implications for policy, program development, and resource allocation at the state/local and national levels.

The changes proposed in this request update the data collection system to meet prevailing information needs and enhance the value of MMP data, while remaining within the scope of the currently approved project purpose. The result is a 16% reduction in burden, or a reduction of 1,397 total burden hours annually.

A change in sampling methods accounts for the net reduction in burden. Specifically, sampling from the existing HIV case surveillance database, the National HIV Surveillance System (NHSS, OMB Control No. 0920-0573, Exp. 2/29/2016) would replace the current health care-facility-based sampling. This change in sampling methods would broaden participation in MMP to all HIV-infected persons who have been diagnosed and reported to the NHSS, a population that is more representative of persons living with HIV than are persons receiving HIV medical care. Sampling from NHSS will allow MMP to address key information gaps related to increasing access to care, one of three strategic areas of national focus of the National HIV/AIDS Strategy.

The change in project sampling methods reduces the amount of time health care facility staff will spend on project activities, substantially reducing burden hours and offsetting increases in burden from other changes, listed below.

Restoration of the original sample of 26 geographic primary sampling units is proposed in this request, for more complete coverage of the population of

interest. Three project areas that initially participated in MMP—and were subsequently dropped in 2009 because funding was restricted—will be reinstated as primary sampling units if funding allows.

Increasing the sample size in three areas that were previously allocated comparatively small samples (Georgia, Illinois, and Pennsylvania) is expected to improve the ability to produce representative local estimates in these areas.

Health care facility staff may be asked to look up contact information for sampled persons with incomplete or incorrect contact information in NHSS; this was not necessary in prior MMP cycles because the patient samples were drawn from facility records.

Finally, changes were made that did not affect the burden, listed below:

- The interview instrument was revised to enable the collection of critical information from HIV-infected persons not receiving medical care and to improve question coherence, boost the efficiency of the data collection, and increase the relevance and value of the

information. These changes were based on an evaluation of the currently approved MMP interview instrument involving stakeholders, as well as a pilot which evaluated new questions (Formative Research and Tool Development, OMB Control No. 0920–0840, expiration 2/29/2016). These revisions did not change the average time required to complete the interview.

- Six data elements were removed from the medical record abstraction form and two data elements were added. Because the medical records are abstracted by MMP staff, these changes do not affect the burden of the project on the public.

- Sampled persons may be interviewed wherever they currently reside, conditional on local law and policy, and in a manner specified by a written, project-specific agreement with the HIV surveillance unit at the person's local health department.

- Videoconferencing was added as an optional mode of interview administration. Administering the interview via videoconferencing will provide more flexibility for participating

in the interview and facilitate communication between respondent and interviewer, for example, by allowing interviewers to respond appropriately to a respondent's visual cues. Videoconferencing will also allow the interviewer to ensure that the respondent is using the correct response cards for interview questions. No audio/ audiovisual recordings will be made of the interviews, including interviews administered by videoconferencing.

This proposed data collection would supplement the National HIV Surveillance System (NHSS, OMB Control No. 0920–0573, Exp. 2/29/2016) in 26 selected state and local health departments, which collect information on persons diagnosed with, living with, and dying from HIV infection and AIDS.

The participation of respondents is voluntary. There is no cost to the respondents other than their time. Through their participation, respondents will help to improve programs to prevent HIV infection as well as services for those who already have HIV.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response (in hours)	Total burden hours
Sampled, Eligible HIV-Infected Persons	Interview Questionnaire	8,720	1	45/60	6,540
Facility office staff looking up contact information.	2,180	1	2/60	73
Facility office staff approaching sampled persons for enrollment.	1,090	1	5/60	91
Facility office staff pulling medical records	8,720	1	3/60	436
Total	7,140

Leroy A. Richardson,
*Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1288]

Draft Guidance for Industry: Electronic Submission of Lot Distribution Reports; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled “Draft Guidance for Industry: Electronic Submission of Lot Distribution Reports; Availability” that appeared in the **Federal Register** of August 29, 2014 (79 FR 51576). The document announced the availability of a draft guidance entitled “Guidance for Industry: Electronic Submission of Lot Distribution Reports” dated August 2014. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lori J. Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, August 29,

2014, in FR Doc. 2014–20635, on page 51576, the following correction is made:

1. On page 51576, in the first column, in the Docket No. heading, “[FDA–2014–S–0009]” is corrected to read “[FDA–2014–D–1288]”.

Dated: September 10, 2014.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2014–22015 Filed 9–15–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the Neurotransporters, Receptors, and Calcium Signaling Study