ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State High Performance Bonus System (HPBS) Transmission File Layouts for HPBS Work Measures	25	2	12	600

Estimated Total Annual Burden Hours: 600.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV, Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–29421 Filed 12–15–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Administration on Intellectual and Developmental Disabilities (AIDD); Notice of Meeting

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID).

ACTION: Notice of meeting.

DATES: Tuesday, January 27, 2015 from 9:00 a.m. to 4:30 p.m.; and Wednesday, January 28, 2015 from 9:00 a.m. to 4:00 p.m.

These meetings will be open to the general public.

ADDRESSES: These meetings will be held in the U.S. Department of Health and Human Services/Hubert H. Humphrey Building located at 200 Independence Avenue SW., Conference Room 505A, Washington, DC 20201.

Individuals who would like to participate via conference call may do so by dialing toll-free 888–935–0260, when prompted enter pass code: 3656064. Individuals whose full participation in the meeting will require special accommodations (*e.g.,* sign language interpreting services, assistive listening devices, materials in alternative format such as large print or Braille) should notify Dr. MJ Karimi, PCPID Team Lead, via email at *MJ.Karimie@acl.hhs.gov,* or via telephone at 202–357–3588, no later than Friday, January 16, 2015. The PCPID will attempt to accommodate requests made after that date, but cannot guarantee the ability to grant requests received after this deadline. All meeting sites are barrier free, consistent with the Americans with Disabilities Act (ADA) and the Federal Advisory Committee Act (FACA).

Agenda: The Committee Members will discuss preparation of the PCPID 2015 Report to the President, including its content and format, and related data collection and analysis required to complete the writing of the Report. They will also receive presentations from selected experts in the field of Technology for People with Intellectual and Developmental Disabilities.

Additional Information: For further information, please contact Dr. MJ Karimi, Team Lead, President's Committee for People with Intellectual Disabilities, One Massachusetts Avenue NW., Room 4206, Washington, DC 20201. Telephone: 202–357–3588. Fax: 202–205–8037. Email: *MJ.Karimie@acl.hhs.gov*

SUPPLEMENTARY INFORMATION: The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services, through the Administration on Intellectual and Developmental Disabilities, on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. The PCPID Executive Order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expansion of educational opportunities; (B) promotion of homeownership; (C) assurance of workplace integration; (D) improvement of transportation options; (E) expansion of full access to community living; and (F) increasing access to assistive and universally designed technologies.

Dated: December 3, 2014.

Aaron Bishop,

Commissioner, Administration on Intellectual and Developmental Disabilities (AIDD).

[FR Doc. 2014–29417 Filed 12–15–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0809]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements for Submission of Bioequivalence Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 15, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0630. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Requirements for Submission of In Vivo Bioequivalence Data—21 CFR parts 314 and 320.

OMB Control Number 0910–0630—Extension

In the **Federal Register** of January 16, 2009 (74 FR 2849), the Agency published a final rule revising FDA regulations to require applicants to submit data on all bioequivalence (BE) studies, including studies that do not meet passing bioequivalence criteria, which are performed on a drug product formulation submitted for approval under an abbreviated new drug application (ANDA), or in an amendment or supplement to an ANDA that contains BE studies. In the final rule, FDA amended 314.94(a)(7)(i), 314.96(a)(1), 320.21(b)(1), and 314.97 (21 CFR 314.94(a)(7)(i), 314.96(a)(1), 320.21(b)(1), and 314.97) to require an ANDA applicant to submit information from all BE studies, both passing and nonpassing, conducted by the applicant on the same drug product formulation as that submitted for approval under an ANDA, amendment, or supplement.

In table 1, FDA has estimated the reporting burden associated with each section of this requirement. FDA believes that the majority of additional BE studies will be reported in ANDAs (submitted under 314.94), rather than supplements (reported in 314.97) because it is unlikely than an ANDA holder will conduct BE studies with a drug after the drug has been approved. With respect to the reporting of additional BE studies in amendments (submitted under 314.96), this should also account for a small number of reports because most BE studies will be conducted on a drug prior to the submission of the ANDA and will be reported in the ANDA itself.

FDA estimates applicants will require approximately 120 hours of staff time to prepare and submit each additional complete BE study report and approximately 60 hours of staff time for each additional BE summary report. The Agency believes that a complete report will be required approximately 20 percent of the time, while a summary will suffice approximately 80 percent of the time. Based on a weighted-average calculation using the information presented previously in this document, the submission of each additional BE study is expected to take 72 hours of staff time ($[120 \times 0.2] + [60 \times 0.8]$).

In the **Federal Register** of June 26, 2014 (79 FR 36320), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
314.94(a)(7)	84	1	84	72	6,048
314.96(a)(1)	1	1	1	72	72
314.97	1	1	1	72	72
Total					6,192

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 10, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29425 Filed 12–15–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1409]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Records and Reports Concerning Experiences With Approved New Animal Drugs: Adverse Event Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 15, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0284. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Road; COLE–14526, Silver Spring, MD 20993–0002 *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Records and Reports Concerning Experiences With Approved New Animal Drugs: Adverse Event Reports on Paper Forms FDA 1932, 1932a, and 2301—21 CFR 514.80; OMB Control Number 0910–0284—Extension

Section 512(*l*) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(*l*) and 514.80 (21 CFR 514.80) of FDA regulations require applicants of approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects (see 514.80)(b)). Additionally, section 571(e)(3) of the FD&C Act (21 U.S.C. 360ccc(e)(3)) requires that