Program Offices that will participate in the consultation include:

- Office of Head Start
- Office of Child Care
- Office of Community Services
- Office of Family Assistance
- Office of Child Support Enforcement
- Administration on Children, Youth and Families:
  - Children's Bureau
  - Family and Youth Services Bureau

To help both you and the ACF principals prepare for this consultation, planning teleconference calls will be held on:

Wednesday, June 5, 2013, 3:00 p.m.—4:00 p.m. (EST).

Wednesday, June 12, 2013, 3:00 p.m.—4:00 p.m. (EST).

Wednesday, June 19, 2013, 3:00 p.m.—4:00 p.m. (EST).

The call-in number and passcode are: 866–763–4038, 354503#.

Testimonies are to be submitted no later than July 2, 2013, to: Lillian Sparks, Commissioner, Administration for Native Americans, 370 L'Enfant Promenade SW., Washington, DC 20447, *anacommissioner@acf.hhs.gov.*

ACF will provide audio and video conferencing of this session for those tribal leaders unable to attend in person. To register for the consultation and obtain information about the audio/video conference, please follow this link: *http://www.regonline.com/tribalconsult2013.*

Dated: April 30, 2013.

George H. Sheldon,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2013–10860 Filed 5–7–13; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Comment Request; State Program Report

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by June 7, 2013.

ADDRESSES: Submit written comments on the collection of information by fax 202.395.5806 or by email to *OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Elena Fazio at 202–357–3583 or email: *elena.fazio@acl.hhs.gov.*

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

The Older Americans Act (OAA) requires annual program performance reports from States. In compliance with this OAA provision, ACL developed a State Program Report (SPR) in 1996 as part of its National Aging Program Information System (NAPIS).

The SPR collects information about how State Units on Aging expend their OAA funds as well as funding from other sources for OAA authorized supportive services. The SPR also collects information on the demographic and functional status of the recipients, and is a key source for AoA performance measurement. This collection includes minor revisions of the format from the 2010 approved version. The proposed revised version will be in effect for the FY 2014 reporting year and thereafter, while the current reporting, OMB Approval Number 0985–0008, will be extended to the end of the FY 2013 reporting cycle. The proposed FY 2014 version may be found on the ACL Web site link entitled Proposed SPR for Review available at *http://www.aoa.gov/AoARoot/Program_Results/OAA_Performance.aspx#national* ACL estimates the burden of this collection of information as follows: 2,600 hours.

Dated: May 3, 2013.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2013–10921 Filed 5–7–13; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0093]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request: Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Act

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 June 7, 2013.

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-New and title Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Act. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@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.

Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Act—(OMB Control Number 0910-New)

As part of its commitments in PDUFA V. FDA has established a new review Program to promote greater transparency and increased communication between the FDA review team and the applicant on the most innovative products reviewed by the Agency. The Program applies to all New Molecular Entities (NMEs), New Drug Applications (NDAs), and original Biologics License Applications (BLAs) that are received from October 1, 2012, through September 30, 2017. The Program is described in detail in section II.B of the document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017'' (the ''Commitment Letter'') (available at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.*

The goals of the Program are to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval so that patients have timely access to safe, effective, and high-quality new drugs and biologics. A key aspect of the Program is an interim and final assessment that will evaluate how well the parameters of the Program have achieved the intended goals. The PDUFA V Commitment Letter specifies that the assessments be conducted by an independent contractor and that they include interviews of pharmaceutical manufacturers who submit NMEs, NDAs, and original BLAs to the Program in PDUFA V. The contractor for the assessments of the Program is Eastern Research Group, Inc. (ERG), and the statement of work for the assessments is available at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM304793.pdf.*

Therefore, in accordance with the PDUFA V Commitment Letter, FDA proposes to have ERG conduct independent interviews of applicants after FDA issues a first-cycle action for applications reviewed under the Program. The purpose of these interviews is to collect feedback from applicants on the success of the Program in increasing review transparency and communication during the review process. ERG will anonymize and aggregate sponsor responses prior to inclusion in the assessments and any presentation materials at public meetings. FDA will publish ERG's assessments (with interview results and findings) in the **Federal Register** for public comment.

In the **Federal Register** of February 19, 2013 (78 FR 11652), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA typically reviews approximately 40 to 45 NMEs, NDAs, and original BLAs per year. ERG will interview one to three sponsor representatives at a time for each application that receives a first-cycle action from FDA up to 135 sponsor representatives per year. Thus, FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest	5	1	5	1.5	7.5
Interviews	135	1	135	1.5	202.5
Total					210

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

ERG will conduct a pretest of the interview protocol with five respondents. FDA estimates that it will take 1.0 to 1.5 hours to complete the pretest, for a total of a maximum of 7.5 hours. We estimate that up to 135 respondents will take part in the post-action interviews each year, with each interview lasting 1.0 to 1.5 hours, for a total of a maximum of 202.5 hours. Thus, the total estimated annual burden is 210 hours. FDA's burden estimate is based on prior experience with similar interviews with the regulated community.

Dated: May 3, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–10898 Filed 5–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0559]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Public Health Service Guideline on Infectious Disease Issues on Xenotransplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Public Health Service Guideline on Infectious Disease Issues on Xenotransplantation'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 20, 2013, the Agency submitted a proposed collection of information entitled ''Public Health Service Guideline on Infectious Disease Issues on Xenotransplantation'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0456. The approval expires on March 31, 2016. A copy of the supporting statement for this information collection is available on