

application (NDA) 201656 (desmopressin), 0.75 mcg/0.1 mL and 1.5 mcg/0.1 mL nasal spray, submitted by Serenity Pharmaceuticals, LLC, for the proposed treatment of adult onset nocturia.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 4, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 26, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 27, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Kalyani Bhatt at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/>

[ucm111462.htm](#) for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 10, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR must be received no later than August 19, 2016.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 10-29, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Maternal, Infant, and Early Childhood Home Visiting Program Cost Reporting Pilot Study.

*OMB No.:* 0906-xxxx—New.

*Abstract:* The Maternal, Infant, and Early Childhood Home Visiting Program

(Federal Home Visiting Program), administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States, Tribal entities, and certain nonprofit organizations are eligible to receive funding from the Federal Home Visiting Program and have the flexibility to tailor the program to serve the specific needs of their communities. Funding recipients may sub award grant funds to organizations, otherwise known as Local Implementing Agencies (LIAs), in order to provide services to eligible families in at-risk communities.

*Need and Proposed Use of the Information:* This information collection is requested to conduct a pilot study to test the reliability of a standardized cost reporting tool for the provision of evidence-based home visiting services. The information collected will be used to: Test the reliability and feasibility of implementing a proposed set of standardized cost metrics and organizational characteristics across various contexts; estimate preliminary total costs for implementing evidence-based home visiting services, including ranges; and further refine cost metrics and the cost reporting tool based on feedback received through the pilot study. Proposed standard cost metrics have been developed based on a review of the existing literature for measures of home visiting costs, as well as from ongoing discussions with developers of evidence-based home visiting models.

*Likely Respondents:* Organizations including LIAs providing evidence-based home visiting services through the Federal Home Visiting Program.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. 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. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Cost Elements Table .....	90	1	90	4	360
Organizational Characteristics Table .....	90	1	90	0.5	45
<b>Total</b> .....	<b>90</b>	<b>.....</b>	<b>90</b>	<b>.....</b>	<b>405</b>

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Jason E. Bennett,**  
 Director, Division of the Executive Secretariat.  
 [FR Doc. 2016-14417 Filed 6-17-16; 8:45 am]  
**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**[30-Day notice]**

**Agency Information Collection Request. 30-Day Public Comment Request, Grants.gov**

**AGENCY:** Office of the Secretary, HHS.  
 Agency Information Collection Request; 30-Day Public Comment Request; *Grants.gov*.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, *Grants.gov* (EGOV), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, email your request, including your address, phone number, OMB number, to *Ed.Calimag@hhs.gov*, or call the Reports Clearance Office on

(202) 690-6162. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the *Grants.gov* OMB Desk Officer; faxed to OMB at 202-395-6974.

**Proposed Project**

Application for Federal Assistance Research and Related SF424 OMB No. 4040-0001.

3 Year Extension and assignment as a Common Form.

*Office: Grants.gov.*

*Abstract:* The Application for Federal Assistance SF-424 Research and Related is an OMB-approved collection (4040-0001). This information collection is used by more than 26 Federal grant-making entities for research and related projects. This IC originally was to expire on June 30, 2016. The expiration date has been extended to July 31, 2016. We are requesting a three-year clearance of this collection and that it be designated as a Common Form.

*Estimated Annualized Burden Table:*

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
SF-424 Application for Federal Assistance—Research and Related .....	137,407	1	1	137,407
Research and Related Budget 5 Year .....	121,416	1	1	121,416
Research and Related Budget 10 Year .....	1,118	1	1	1,118
SF-424 Research and Related Multi-Project Cover .....	1,570	1	1	1,570
Research & Related Multi-Project 10 Year Budget .....	1,570	1	1	1,570
R & R Multi-Project Subaward Budget Attachment(s) Form 10YR 30ATT ....	1,570	.....	.....	1,570
R & R Subaward Budget Attachment(s) Form .....	217	.....	.....	217
R & R Subaward Budget Attachment(s) Form 5 YR 30 ATT .....	121,088	1	1	121,088
R & R Subaward Budget Attachment(s) Form 10 YR 30 ATT .....	1,118	1	1	1,118
Research & Related Senior/Key Person Profile .....	218	1	1	218
Research and Related Senior/Key Person Profile (Expanded) .....	136,940	1	1	136,940
Research And Related Other Project Information .....	137,699	1	1	137,699
SBIR/STTR Information .....	21,289	1	1	21,289
<b>Total</b> .....	<b>683,220</b>	<b>.....</b>	<b>.....</b>	<b>683,220</b>