Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Healthy Indiana Program (HIP) 2.0 Beneficiaries Survey; *Use:* Approval for testing and developing the survey is vital to adequately inform CMS decision making regarding Section 1115 Waivers, in particular the State's upcoming NEMT waiver due for renewal by December 1, 2016. The NEMT benefit provides transportation for Medicaid beneficiaries who otherwise have no means of transportation to get to and from medical services. The Healthy Indiana Program (HIP) 2.0 demonstration provides authority for the State to not offer NEMT for the new adult group during the first year of the demonstration (except for pregnant women and individuals determined to be medically frail). CMS may extend the State's authority, subject to evaluation of the impact of this policy on access to care. *Form Number:* CMS–10615 (OMB control number: 0938–1300); *Frequency:* Once; *Affected Public:* Individuals and households; *Number of Respondents:* 36; *Total Annual Responses:* 36; *Total Annual Hours:* 36. (For policy questions regarding this collection contact Teresa DeCaro at 202–384–6309).

Written comments and recommendations will be considered from the public if received by the date and address noted above.

Dated: March 22, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–06828 Filed 3–28–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Community Living

Proposed Information Collection Activity; Comment Request; State Developmental Disabilities Council 5-Year State Plan

AGENCY: Administration on Intellectual and Developmental Disabilities, Administration on Community Living, HHS.

ACTION: Notice.

SUMMARY: A plan developed by the State Council on Developmental Disabilities is required by federal statute. Each State Council on Developmental Disabilities must develop the plan, provide for public comments in the State, provide for approval by the State's Governor, and finally submit the plan on a five-year basis. On an annual basis, the Council must review the plan and make any amendments. The State Plan will be used (1) by any amendments. The State Plan will be used (2) by the Council as a planning document; (3) by the citizenry of the State as a mechanism for commenting on the plans of the Council; (4) by the Department as a stewardship tool, for ensuring compliance with the Developmental Disabilities Assistance and Bill of Rights Act, as one basis for providing technical assistance (*e.g.,* during site visits), and as a support for management decision making.

DATES: Submit written comments on the collection of information by May 31, 2016.

ADDRESSES: Submit written comments on the collection of information by email to: *Valerie.Bond@acl.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Valerie Bond, Administration on Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program Support, 330 C Street SW., Room 1139–C, Washington, DC 20201, (202) 795–7311.

SUPPLEMENTARY INFORMATION: In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration on Community Living is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to: Valerie Bond, Administration on Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program Support, 330 C Street NW., Room 1139–C, Washington, DC 20201.

The Department specifically requests comments on: (a) Whether the proposed Collection of information is necessary for the proper performance of the function 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) the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden information to be collected; and (e) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection technique comments and or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Respondents: 56 State Developmental Disabilities Councils.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Developmental Disabilities Council 5-Year State Plan	56	1	367	20,552

Estimated Total Annual Burden Hours: 20,552.

Dated: March 22, 2016.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2016–07065 Filed 3–28–16; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3037]

Pediatric Studies of Lorazepam; Establishment of Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to make available to the public a report of the pediatric studies of Lorazepam that were conducted in accordance with the Public Health Service Act (PHS Act) and submitted to the Director of the National Institutes of Health (NIH) and the Commissioner of Food and Drugs.

DATES: Submit either electronic or written comments by April 28, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/*Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–3037 for ''Pediatric Studies of Lorazepam; Establishment of Public Docket.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori Gorski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6466, Silver Spring, MD 20993–0002, *Lori.Gorski@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under section 409I of the PHS Act (42 U.S.C. 284m), the Secretary of the Department of Health and Human Services (the Secretary) acting through the Director of the NIH, in consultation with FDA and experts in pediatric research, must develop, prioritize, and publish a list of priority needs in pediatric therapeutics, including drugs and indications that require study.[1] For drugs and indications on this list, FDA, acting in consultation with NIH, is authorized to issue a written request to holders of a new drug application or abbreviated new drug application for a drug for which pediatric studies are needed to provide safety and efficacy information for pediatric labeling. If the sponsors receiving the written request decline to conduct the studies or if FDA does not receive a response to the written request within 30 days of the date the written request was issued, the Secretary, acting through the Director of NIH, and in consultation with FDA, must publish a request for proposals to conduct the pediatric studies described in the written request and award funds to an entity with appropriate expertise for the conduct of the pediatric studies described in the written request. Upon completion of the pediatric studies, a study report that includes all data generated in connection with the studies must be submitted to FDA and NIH and placed in a public docket assigned by FDA.

Lorazepam is commonly used in pediatric practice as a first-line agent for the initial treatment of status epilepticus. However, there is limited information available about dosing, pharmacokinetics, effectiveness, and safety in pediatric patients treated with Lorazepam.

A written request for pediatric studies of Lorazepam was issued on July 5, 2002, to Wyeth-Ayerst Research, the holder of the new drug applications for Lorazepam. FDA did not receive a response to the written request. On January 21, 2003, NIH published a **Federal Register** notice (68 FR 2789) announcing the addition of several drugs, including Lorazepam, to the priority list of drugs most in need of study for use by children to ensure their safety and efficacy. Accordingly, NIH issued a request for proposals to conduct the pediatric studies described in the written request and awarded funds to the Children's National Medical Center in September 2004, to complete the studies described in the written request. Upon completion of the pediatric studies, a report of the pediatric studies of Lorazepam was submitted to NIH and FDA. As required under section 409I of the PHS act, FDA opened a public docket and NIH placed in the docket the report of pediatric studies of Lorazepam that was submitted to NIH and FDA. The report includes all data generated in connection with the study, including the written request.

We invite interested parties to review the report and submit comments to the docket. The public docket is available for public review in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

[1] Prior to the 2007 reauthorization of the Best Pharmaceuticals for Children Act (Pub. L. 107–109), the priority list included specific drugs instead of therapeutic areas.

Dated: March 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–07012 Filed 3–28–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Privacy Act of 1974; System of Records Notice

AGENCY: Assistant Secretary for Public Affairs (ASPA), Office of the Secretary (OS), Department of Health and Human Services (HHS).

ACTION: Notice of an altered system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended (5 U.S.C. 552a), HHS is updating a department-wide system of records, System No. 09–90–0058, currently titled ''Freedom of Information Case Files and Correspondence Control Log, HHS/OS/ASPA/FOIA.'' This system of records was established prior to 1979 (see 44 FR 58144) and was previously revised in 1989 and 1994 (see 54 FR 41684 and 59 FR 55845). Due to the length of time since the last revision, the updates published in this Notice affect most sections of the System of Records Notice (SORN). The updates include changing the system name to ''Tracking Records and Case Files for FOIA and Privacy Act Requests and Appeals;'' expanding the scope of the system to include tracking records and case files pertaining to not only FOIA and Privacy Act requests processed in agency FOIA offices, but Privacy Act requests and appeals handled by System Managers for Privacy Act systems and related privacy personnel, when those records are retrieved by personal identifier; adding several new routine uses; and clarifying that some of the records in this system of records may be exempt from certain Privacy Act requirements. The updates are more fully explained in the **SUPPLEMENTARY INFORMATION** section of this Notice.

DATES: This Notice is effective on publication, with the exception of the new and revised routine uses. The new and revised routine uses will be effective 30 days after publication of this Notice, unless comments are received that warrant a revision to this Notice. Written comments on the routine uses should be submitted within 30 days. Until the new and revised routine uses are effective, the routine uses previously published for the system will remain in effect.

ADDRESSES: You may submit comments to Beth Kramer, HHS Privacy Act Officer, FOIA/PA Division, by email to: *HHS.ACFO@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Beth Kramer, HHS Privacy Act Officer, FOIA/PA Division, Hubert H. Humphrey Building—Suite 729H, 200 Independence Avenue SW., Washington, DC 20201. Ms. Kramer can also be reached by telephone at 202–690–7453.

SUPPLEMENTARY INFORMATION:

I. Explanation of Revisions to System No. 09–90–0058

The revised System of Records Notice (SORN) published in this Notice for System No. 09–90–0058 includes the following significant changes, in addition to minor wording changes throughout:

- The system name and scope have been revised to cover not only tracking records and case files used by HHS Freedom of Information Act (FOIA) offices to process FOIA and Privacy Act requests and appeals (which typically involve only ''access'' to agency records), but tracking records and case files used by System Managers of Privacy Act systems and related privacy personnel to process any type of Privacy Act request or appeal (*e.g.,* seeking access, notification, correction and amendment, or an accounting of disclosures), when those tracking records and case files are retrieved by personal identifier.
- The Categories of Individuals section has been revised to omit organizations (because the Privacy Act applies only to individuals, not entities), but not to add any additional categories of individuals besides individual FOIA and Privacy Act requesters and appellants. The result is that only an individual FOIA or Privacy Act requester or appellant may make a Privacy Act request under this SORN for access to, correction of, notification as to, or an accounting of disclosures with respect to tracking records and/or case files used by HHS to process a FOIA and/or Privacy Act request in which that individual was the requester or appellant. Further, because agency records processed in response to a third-party FOIA request are not about the requester or appellant, a provision has been added to make clear that Privacy Act rights are afforded to an individual requester or appellant only to the extent that the information in the tracking record and case file retrieved by that individual's identifier is, in fact, about that individual requester or appellant. The intent is to include in the Categories of Individuals section only individual requesters and appellants (not, for example, individual representatives who requested records under FOIA on behalf of an entity).
  - **Note:** Privacy Act case files and tracking records are about individual requesters and appellants only, because Privacy Act requests can only be made by an individual record subject personally, not by a third party or through a representative (unless the representative is the parent of or court-appointed guardian for a minor or legally-declared incompetent who is the record subject). The agency's position is that FOIA case files and tracking records, likewise, are about requesters and appellants only, not other individuals who may be identified in the agency records sought by FOIA requesters and appellants. This is because HHS' FOIA case files and tracking records are not keyed or indexed to individuals mentioned in records requested under FOIA, but are keyed to requesters and appellants, and because the purpose for which records are processed under FOIA is to release information about the *agency* (not to release information about individuals mentioned in the records to third party FOIA requesters, except as required to shed light on conduct of the *agency*).
- The Categories of Records section has been rewritten, to reflect two distinct categories (tracking records and case files); to describe the contents in more detail; to clarify that any classified records responsive to a FOIA request or appeal are considered part of the case file for that request or appeal, even if the classified records must be maintained in a security office instead of in the FOIA office; and to specifically exclude related categories of records covered by other SORNs, to avoid duplicating other systems of records.
- The Purposes section has been rewritten to provide a broader description of uses and users of the records within HHS. (The prior description mentioned only ''FOIA correspondence and processing,'' ''Freedom of Information staff,'' and ''appeals officials and members of the Office of General Counsel.'')
- An existing routine use authorizing disclosures to contractors (routine use 2) has been revised to be more accurate in reflecting the broad purposes for which contractors may be engaged to assist HHS and require access to records in the system. (The former description was limited to ''collating, aggregating, analyzing, or otherwise refining records in this system.'')