Disabilities, Office of Program Support, 330 C Street SW., Washington, DC 20201, 202–795–7449.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document. The Children's Health Act of 2000, 42 U.S.C. Section 300d–53(h), requires the Protection and Advocacy (P&A) System in each State to annually prepare and submit to the Secretary a report that includes documentation of the progress they have made in serving individuals with traumatic brain injury. AIDD will review the program performance report (PPR) for compliance and for program outcomes. AIDD will aggregate the information in the PPRs into a national profile of programmatic activities and accomplishments. Information from these reports is shared with the public through postings to the *ACL.gov* Web site. The information will also allow AIDD to track accomplishments against performance goals and determine areas where technical assistance is needed to comply with Federal requirements or improve performance.

The proposed Protection and or Traumatic Brain Injury (PATBI) Program Performance Report (PPR) form can be found on the AIDD Web site at: *https://acl.gov/Programs/AIDD/Program_Resource_Search/Results_PA.aspx.*

Interested persons are invited to send comments regarding our burden estimates 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.

ACL estimates the burden hours for this collection of information as follows:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
PATBI PPR	57	1	16	912

Dated: January 10, 2017.

Edwin Walker,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2017–00879 Filed 1–13–17; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Community Living

Proposed Information Collection Activity; Submission for OMB Review; Comment Request; Protection and Advocacy Annual Program Performance Report and Statement of Goals and Priorities

AGENCY: Office of Program Support, Administration on Intellectual and Developmental Disabilities, Administration on Disability, Administration on Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration on Disability is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by February 16, 2017.

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: Clare Huerta, Administration on Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program Support, 330 C Street SW., DC, Washington, DC 20201, by email: *Clare.Huerta@acl.hhs.gov* or by phone: (202) 795–7301.

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

This notice seeks to collect comments on revisions to two existing data collections. The first is the Annual Protection and Advocacy Systems Program Performance Report (0985–0027). State Protection and Advocacy (P&A) Systems in each State and Territory provide individual legal advocacy, systemic advocacy, monitoring and investigations to protect and advance the rights of people with developmental disabilities, using funding administered by the Administration on Intellectual and Developmental Disabilities, Administration on Disability, Administration on Community Living, HHS. The Developmental Disabilities and Bill of Rights Act (the Act), 42 U.S.C. 15044 requires each P&A to annually prepare a Program Performance Report (PPR) that describes the activities and accomplishments of the system during the preceding fiscal year.

The Act also requires P&As to submit a Statement of Goals and Priorities (SGP) (0985–0034) for each coming fiscal year. P&As are required to annually report on ''the activities, accomplishments, and expenditures of the system during the preceding fiscal year, including a description of the system's goals, the extent to which the goals were achieved, barriers to their achievement, the process used to obtain public input, the nature of such input, and how such input was used.''

To meet it statutory reporting requirements, P&As have used separate forms for submitting the annual PPR (0985–0027) and the SGP (0985–0034). The Department is proposing that the

two be combined by creating a Protection and Advocacy Annual Program Performance Report and Statement of Goals and Priorities form. By combining the forms, P&As will have a reduced burden because they will only have to submit one annual report. The combined form will also allow federal reviewers to analyze patterns more readily between goals and priority setting and program performance.

The annual PPR and SGP are reviewed by federal staff for compliance and outcomes. Information in the PPRs and SGPs is analyzed to create a national profile of programmatic compliance, outcomes, and goals and priorities for P&A Systems for tracking accomplishments against goals and to formulate areas of technical assistance related to compliance with Federal requirements and program performance. Information collected in the unified report will inform AIDD of trends in P&A advocacy, collaboration with other federally-funded entities, and identify best practices for efficient use of federal funds.

Comments in Response to the 60 Day Federal Register Notice

A notice was published in the **Federal Register** in Vol. 81, No. 57592 on August 23, 2016, announcing that ACL was requesting approval of a data collection (ICR New). ACL received two comments expressing concern that the combination of the SGP and PPR reporting forms would reduce the overall oversight of the P&A program. ACL responds that, while the reporting forms are being combined, the content which the grantees are reporting remains the same, with the addition of more quantitative measures to support the qualitative data that the grantees provide every year. The addition of more quantitative measures will provide a fuller picture of how the programs are functioning. The combined PPR and SGP allow federal staff to review the same information from the programs in a streamlined format that reduces the need to reenter the same information multiple times. ACL does not plan to make any changes in the data collection based on these comments.

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 burden related to the information collection described above. *The form is available at: http://www.acl.gov/Programs/AIDD/Program_Resource_Search/Results_PA.aspx.*

Estimated Burden: The average burden for the 57 Protection and Advocacy Systems [i] was calculated based on consultations with selected States.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Protection and Advocacy Annual Program Performance Report and Statement of Goals and Priorities	57	1	75	4,275

Estimated Total Annual Burden Hours: 4,275.

Dated: January 10, 2017.

Edwin L. Walker,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2017–00880 Filed 1–13–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4412]

Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an Abbreviated New Drug Application; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA.'' This draft guidance is intended to assist potential applicants who plan to develop and submit an abbreviated new drug application (ANDA) to seek approval of a generic combination product that includes both a drug constituent part and a delivery device constituent part.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance March 20, 2017.

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

[i] This number includes the 50 States, District of Columbia, Puerto Rico and three Outlying Areas.