

*Estimated Total Annual Burden Hours: 125.*

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto: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, email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2017-26061 Filed 12-1-17; 8:45 am]

BILLING CODE 4184-29-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Community Living**

**Agency Information Collection Activities; Proposed Collection; Public Comment Request; Revision of a Currently Approved Information Collection (OMB Approval Number 0985-0048); State Grants for Assistive Technology Program State Plan for Assistive Technology**

**AGENCY:** Administration for Community Living, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The Administration for Community Living (ACL) 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 (the PRA). This 30-day notice requests comments on the information collection requirements related to a proposed Revision of a Currently Approved Information Collection (ICR-Rev). The revision will allow ACL to continue to

collect information necessary to determine grantee compliance with Section 4 of the Assistive Technology Act of 1998, as Amended (AT Act).

**DATES:** Submit written or electronic comments on the collection of information by January 3, 2018.

**ADDRESSES:** Submit written comments on the collection of information: by fax at (202) 395-5806 or by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov), Attn: OMB Desk Officer for ACL.

**FOR FURTHER INFORMATION CONTACT:**

Robert Groenendaal at (202) 795-7356 or [Robert.Groenendaal@acl.hhs.gov](mailto:Robert.Groenendaal@acl.hhs.gov).

**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 or update of an existing collection of information, before submitting the collection to OMB for approval. The proposed data collection represents a revision of a currently approved collection (ICR-Rev). In order to comply with the above requirement, ACL is requesting approval of a revision of a previously approved collection, the State Grants for Assistive Technology Program State Plan for AT, formerly known as the 664 report (0985-0048).

The State Plan for AT is submitted every three years and updated annually by all State Grants for AT programs receiving formula funds under Section 4 of the Assistive Technology Act of 1998, as Amended (AT Act). The State Plan for AT is used by ACL to assess grantees' compliance with Section 4 of the AT Act and enables ACL to analyze qualitative and quantitative information to track performance outcomes and efficiency measures of the State Grants for AT programs; support budget requests; comply with the GPRA Modernization Act of 2010 (GPRAMA) reporting requirements; provide national benchmark information; and inform program development and management activities. The burden table below identifies the data collection activities for the instrument as well as the estimates for record keeping and entry of aggregate data. In addition to

submitting a State Plan every three years, states and outlying areas are required to submit annual progress reports on their activities. The data required for these progress reports is specified in Section 4(f) of the AT Act. The State Grants for AT program conduct the following state-level and state leadership activities: device demonstration, device loans, device reutilization, state financing, training and technical assistance, public awareness, and information and referral.

**Comments in Response to the 60-Day Federal Register Notice**

A 60-day notice was published in the **Federal Register** in Vol. 82, No. 178, pg. 43379 on September 15th, 2017. ACL received one comment from the Association of Assistive Technology Act Programs (ATAP), which represents 54 State Grant for AT programs. The comment noted that the proposed changes to the currently approved information collection were developed with extensive input of those it directly impacts, the State AT Program grantees. The revision process began almost two years ago and grantees had multiple opportunities to discuss and make recommendations on the proposed changes, which were reviewed during numerous meetings with ATAP membership at national conferences and during online events. There is uniform support within the ATAP membership for the revisions.

**Burden Estimates**

The proposed State Plan for Assistive Technology Information Collection Program may be found on the ACL Web site at: <https://www.acl.gov/about-acl/public-input>.

The total estimated hour burden per respondent for the proposed State Plan for AT will decrease from the 74 hours per respondent estimated in FY 2015 to 73 hours estimated for FY 2018, an estimated reduction of one hour per respondent or 56 hours in total. The proposed State Plan for AT changes focus on a streamline of drop down choice lists in the current instrument. Actual expenditure data elements for state-level and state leadership tracking replaces the budget projections to provide more accurate fiscal data to ACL and to ensure compliance with AT Act requirements for expenditures. The proposed instrument simplifies the coordination and collaboration items to focus on activities conducted through a formal written agreement to ensure consistency and usefulness of data reported. The revised instrument aligns demographic data elements with the AT Annual Performance Report (APR), so

that the data will be: Entered once, then only updated from that point on; used for both the State Plan and APR; updated quarterly with reminders; and used to populate the online State AT Program listing to ensure currency and

accuracy. The reduction in burden is a result of a data collection workgroup composed of State AT program staff that met to suggest revisions to the current instrument. The workgroup solicited feedback from all of the grantees

through face-to-face meetings and webinar presentations. The number of hours is multiplied by 56 AT State Grants programs, resulting in a total estimated hour burden of 4,088 hours.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
State Plan for AT Annual Progress Report (AT APR) .....	56	1	73.0	4,088

Dated: November 24, 2017.

**Mary Lazare,**

*Principal Deputy Administrator.*

[FR Doc. 2017-26018 Filed 12-1-17; 8:45 am]

**BILLING CODE 4154-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-4853]

#### Receipt of Notice That a Patent Infringement Complaint Was Filed Against a Biosimilar Applicant

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing notice that an applicant for a proposed biosimilar product notified FDA that a patent infringement action was filed in connection with the applicant's biologics license application (BLA). Under the Public Health Service Act (PHS Act), an applicant for a proposed biosimilar product or interchangeable product must notify FDA within 30 days after the applicant was served with a complaint in a patent infringement action described under the PHS Act. FDA is required to publish notice of the complaint in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Daniel Orr, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6246, Silver Spring, MD 20993-0002, 240-402-0979, [daniel.orr@fda.hhs.gov](mailto:daniel.orr@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111-148) on March 23, 2010. The BPCI Act amended the PHS Act and created an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. Section 351(k) of the PHS Act

(42 U.S.C. 262(k)), added by the BPCI Act, describes the requirements for a BLA for a proposed biosimilar product or a proposed interchangeable product (351(k) BLA). Section 351(l) of the PHS Act, also added by the BPCI Act, describes certain procedures for exchanging patent information and resolving patent disputes between a 351(k) BLA applicant and the holder of the BLA reference product. If a 351(k) applicant is served with a complaint for a patent infringement described in section 351(l)(6) of the PHS Act, the applicant is required to provide FDA with notice and a copy of the complaint within 30 days of service. FDA is required to publish notice of a complaint received under section 351(l)(6)(C) of the PHS Act in the **Federal Register**.

FDA received notice of the following complaint under section 351(l)(6)(C) of the PHS Act:

*AbbVie, Inc., et al. v. Boehringer Ingelheim Intl. GmbH., et al.*, 17-cv-01065 (D. Del., filed August 2, 2017).

This complaint involves the product Humira.

FDA has only a ministerial role in publishing notice of a complaint received under section 351(l)(6)(C) of the PHS Act, and does not perform a substantive review of the complaint.

Dated: November 28, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-26013 Filed 12-1-17; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-6475]

#### Food and Drug Administration Fiscal Year 2017 Performance Review Board Members

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the names of the members who will serve on its Performance Review Board (PRB). The purpose of the PRB is to provide fair and impartial review of senior executive service (SES), senior professional and Title 42(f) SES Equivalents performance appraisals, bonus recommendations, and pay adjustments.

**DATES:** Effective October 30, 2017.

**FOR FURTHER INFORMATION CONTACT:** Abu Sesay, Office of Human Resources Executive and Resources Management Staff, Food and Drug Administration, Three White Flint North, 05C68, 11601 Landsdown St., North Bethesda, MD 20852, 240-402-0440 (not a toll free number).

**SUPPLEMENTARY INFORMATION:** This action is being taken pursuant to 5 U.S.C. 4314(c)(4), which requires that members of performance review boards be appointed in a manner to ensure consistency, stability, and objectivity in performance appraisals and requires that notice of the appointment of an individual to serve as a member be published in the **Federal Register**.

The following persons will serve on the FDA Performance Review Board, which oversees the evaluation of performance appraisals of FDA's senior executives:

James Sigg, PRB Chair  
Tania Tse, PRB Officiator  
Glenda Barfell  
Janelle Barth  
Vincent Bunning  
Mary Beth Clarke  
Tracey Forfa  
Leslie Kux  
Diane Maloney  
Edward Margerrison  
Lynne Rice  
William Tootle

Dated: November 28, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-26015 Filed 12-1-17; 8:45 am]

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