

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.

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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