The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the application and constitutes a waiver of any contentions concerning the legal status of the drug product. FDA will then withdraw approval of the application, and the drug product may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

This notice is issued under section 505(e) of the FD&C Act and under the authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA, draft guidance for industry, ''Bioequivalence Recommendations for CONCERTA (Methylphenidate Hydrochloride) Extended-Release Tablets,'' November 2014 (available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM320007.pdf*).
2. FDA, draft guidance for industry, ''Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA,'' December 2013 (available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377465*).
3. Dighe, S. V. and W. P. Adams, ''Bioequivalence: A United States Regulatory Perspective.'' In: Welling, P. G., L. S. Tse, and S. V. Dighe, eds., *Pharmaceutical Bioequivalence.* New York: Marcel Dekker, Inc., pp. 347–380, 1991.
4. Swanson, J. M., S. B. Wigal, T. Wigal, et al., ''A Comparison of Once-Daily Extended-Release Methylphenidate Formulations in Children With Attention-Deficit/Hyperactivity Disorder in the Laboratory School (The Comacs Study),'' *Pediatrics,* vol. 113, pp. 206–216, 2004.
5. Kimko, H., E. Gibiansky, L. Gibiansky, et al., ''Population Pharmacodynamic Modeling of Various Extended-Release Formulations of Methylphenidate in Children With Attention Deficit Hyperactivity Disorder Via Meta-Analysis,'' *Journal of Pharmacokinetics and Pharmacodynamics,* vol. 39(2), pp. 161–176, 2012.
6. Memorandum to Janet Woodcock, Director, Center for Drug Evaluation and Research, in Support of Beginning Approval Withdrawal Proceedings for ANDA 091695 (October 1, 2016, Peters).

Dated: October 12, 2016.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2016–25092 Filed 10–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; National Practitioner Data Bank Attestation of Reports by Hospitals, Medical Malpractice Payers, Health Plans, and Certain Other Health Care Entities

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR must be received no later than November 17, 2016.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: National Practitioner Data Bank (NPDB) Attestation of Reports by Hospitals, Medical Malpractice Payers, Health Plans, and Health Centers OMB No. 0906–xxxx—NEW.

Abstract: The National Practitioner Data Bank (NPDB) plans to collect data from hospitals, medical malpractice payers, health plans, and certain other health care entities [1] that are subject to NPDB reporting requirements to assist these entities in understanding and meeting their reporting requirements to the NPDB. The NPDB currently collects similar data (OMB No. 0915–0126) from state licensing boards on a regular basis and this information collection request would expand beyond current activities to include hospitals, medical malpractice payers, health plans, and certain other health care entities.

NPDB began operation on September 1, 1990. The statutory authorities establishing and governing the NPDB are Title IV of Public Law (Pub. L.) 99–660, the Health Care Quality Improvement Act of 1986, as amended, Section 5 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93, codified as Section 1921 of the Social Security Act, and Section 221(a) of the Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, codified as Section 1128E of

[1] Unless otherwise noted, the term ''certain other health care entities'' refers to health centers whose access and reporting obligations are addressed in the NPDB statutory and regulatory requirements for health care entities. In this document, ''health center'' refers to organizations that receive grants under the HRSA Health Center Program as authorized under section 330 of the Public Health Service Act, as amended (referred to as ''grantees'') and FQHC Look-Alike organizations, which meet all the Health Center Program requirements but do not receive Health Center Program grants. It does not refer to FQHCs that are sponsored by tribal or Urban Indian Health Organizations, except for those that receive Health Center Program grants.

the Social Security Act. Final regulations governing the NPDB are codified at 45 CFR part 60. Responsibility for NPDB implementation and operation resides in the Bureau of Health Workforce, HRSA, HHS.

NPDB acts primarily as a flagging system; its principal purpose is to facilitate comprehensive review of practitioners' professional credentials and background. Information on medical malpractice payments, health-related civil judgments, adverse licensure actions, adverse clinical privileging actions, adverse professional society actions, and Medicare/Medicaid exclusions is collected from, and disseminated to, eligible entities such as licensing boards, hospitals, and certain other health care entities. It is intended that NPDB information should be considered with other relevant information in evaluating a practitioner's credentials.

NPDB outlines specific reporting requirements for hospitals, medical malpractice payers, health plans, and certain other health care entities per 45 CFR 60.7, 60.12, 60.14, 60.15, and 60.16. These reporting requirements are further explained in Chapter E of the NPDB e-Guidebook, which can be found at: *http://www.npdb.hrsa.gov/resources/aboutGuidebooks.jsp.*

Through a process called Attestation, hospitals, medical malpractice payers, health plans, and certain other health care entities will be required to attest that they understand and have met their responsibility to submit all required reports to the NPDB. The Attestation process will be completely automated through the secure NPDB system (*https://www.npdb.hrsa.gov*), using both secure email messaging and system notifications to alert entities registered with the NPDB of their responsibility to attest. All entities with reporting requirements and querying access to the NPDB must register with the NPDB before gaining access to the secure NPDB system for all reporting and querying transactions.

Although the Attestation process and forms are new, the secure NPDB system currently used by hospitals, medical malpractice payers, health plans, and certain other health care entities to conduct reporting and querying will not change, ensuring that these entities are familiar with the interface needed to complete the Attestation process. NPDB will ask these entities to attest their reporting compliance every 2 years. If the organization is responsible for privileging or credentialing individuals who provide services for other sites, those sites will be included in the Attestation process.

The Attestation forms will collect the following information: information regarding sub-sites and entity relationships; contact information for the Attesting Official; and a statement attesting whether or not all required reports have been submitted.

Need and Proposed Use of the Information: The NPDB engages in compliance activities to ensure the accuracy and completeness of the information in the NPDB. Through the Attestation process, the NPDB can better determine which hospitals, medical malpractice payers, health plans, and certain other health care entities are meeting the reporting requirements, and which of these entities may require additional outreach and assistance. The biennial Attestation process will strengthen the robustness of the data in the NPDB, improving the accuracy of query responses for entities with access to NPDB reports.

Likely Respondents: Hospitals medical malpractice payers, health plans, certain other health care entities, and their representatives.

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 ICR 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
Health Center Form	1,500	1	1,500	1	1,500
Generic Form [1]	4,875	1	4,875	1	4,875
• Hospitals. • Medical Malpractice Payers. • Health Plans.					
Total	[2] 6,375		6,375		6,375

[1] Hospitals, medical malpractice payers, and health plans will attest using the generic form.

[2] There are approximately 6,800 hospitals, 575 medical malpractice payers, 1,400 health plans, and 2,200 health centers registered with the NPDB. However, the reporting entities may include multiple sites that are registered independently in the system, thereby increasing the total number of respondents. Therefore, we estimate there will be 7,500 respondents for hospitals, 750 respondents for medical malpractice payers, 1,500 respondents for health plans, and 3,000 respondents for health centers for 12,750 total respondents. Given that entities will only be required to complete attestation biennially, these estimates are divided in half for the annualized burden hours.

Amy McNulty,

Deputy Director, Division of the Executive Secretariat.

[FR Doc. 2016–25074 Filed 10–17–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Performance Review Board Members

Title 5, U.S.C. 4314(c) (4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Members be published in the **Federal Register**.

The following persons may be named to serve on the Performance Review Boards or Panels, which oversee the evaluation of performance appraisals of Senior Executive Service members of