meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 1, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–01481 Filed 2–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3404]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Drug User Fee Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 11, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0727. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

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

Generic Drug User Fee Coversheet

OMB Control Number 0910–0727—Extension

On July 9, 2012, the President signed the Generic Drug User Fee Amendments (GDUFA) (Pub. L. 112–144, Title III) into law. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to the industry. Section 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f, *et seq.*), as added by GDUFA, authorized FDA to assess and collect the fees related to generic drugs, beginning fiscal year (FY) 2013 and expiring at the close of FY 2017 on September 30, 2017. GDUFA was reauthorized on August 18, 2017 (GDUFA II), and is effective beginning October 1, 2017, through September 30, 2022. GDUFA II enables FDA to assess industry user fees to bring greater predictability and timeliness to the review of generic drug applications.

Form FDA 3794, the Generic Drug User Fee Cover Sheet available at *https://www.ipqpubs.com/wp-content/uploads/2012/09/GDUFA-cover-sheet.pdf,* requests the minimum necessary information from applicants to account for and track user fees and to determine the amount of the fee required. Applicants complete the cover sheets to accompany payments. While applicants may submit payment through multiple means, all cover sheets are prepared using FDA's web-based electronic User Fee System. Upon submitting the completed cover sheet, the User Fee System generates a user fee identification number, which is provided to applicants at the bottom of the cover sheet. It also notes the correct FY user fee assessment that is due for the submission/program. FDA requests that applicants submit a copy of this completed cover sheet along with the abbreviated new drug application, and other GDUFA fees, so FDA can verify that the applicant has paid the correct user fee.

Respondents to the collection of information are potential or actual generic drug application holders or related Active Pharmaceutical Ingredient and Finished Dosage Form manufacturers. Companies with multiple user fee obligations will submit a cover sheet for each user fee obligation.

In the **Federal Register** of September 25, 2018 (83 FR 48430), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received asking whether the information was ''essential for FDA to conduct its duties,'' and whether ''there is a way to reduce burden'' on respondents. We appreciate this feedback. As discussed in both the 60-day notice and this notice, the information collection implements statutory provisions FDA must fulfill under GDUFA II. The information requested from respondents on Form FDA 3794 represents what we consider to be the minimum necessary for us to efficiently and electronically assess, collect, and track user fees associated with generic drug applications.

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Form FDA 3794	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Generic Drug User Fee Cover Sheet	500	7.616	3,808	0.5 (30 minutes)	1,904

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated burden for the information collection reflects an increase since last OMB approval. This adjustment corresponds with an increase in submissions received by the Agency.

Dated: February 4, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–01477 Filed 2–6–19; 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; Children's Graduate Medical Education Quality Bonus System (QBS) Initiative Response Form, OMB No. 0906–xxxx–New

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

ACTION: Notice.

SUMMARY: In compliance with 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 should be received no later than March 11, 2019.

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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Quality Bonus System Initiative Response Form OMB No. 0906–xxxx [New].

Abstract: The Children's Hospitals Graduate Medical Education (CHGME) Payment Program provides federal funds to the nation's freestanding children's hospitals to help them maintain their graduate medical education programs that train resident physicians and dentists. CHGME Support Reauthorization Act of 2013 states that the Secretary may establish a Quality Bonus System (QBS), whereby the Secretary distributes bonus payments to hospitals participating in the CHGME Payment Program that meet standards specified by the Secretary. In order to qualify for the QBS payment in Fiscal Year (FY) 2019, CHGME award recipients must submit documentation as an attachment in the FY 2019 reconciliation application released in April 2019, describing the hospital's initiatives, resident curriculum, and direct resident involvement in the following areas:

a. Integrated care models (*e.g.,* integrated behavioral and mental health, care coordination across providers and settings);

b. Telehealth and/or Health Information Technology;

c. Population health;

d. Social determinants of health; and

e. Additional initiatives to improve access and quality of care to rural and/or underserved communities.

A 60-day notice was published in the **Federal Register** on October 23, 2018, Vol. 83, No. 205.

Need and Proposed Use of the Information: As specified in the CHGME statute, the QBS payment shall be remitted to qualified hospitals participating in the CHGME program that meet standards set forth by the Secretary of HHS. To demonstrate the fulfillment of such standards, it will be necessary for applicants to complete the QBS Response Initiative form and submit it as an attachment to the FY 2019 reconciliation application released in April of 2019. This form will be used to gather information relating to the hospitals' engagement in quality initiatives.

Likely Respondents: CHGME Program award recipients.

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
QBS Response Initiative Form	58	1	58	32.41	1,880
Total	58		58		1,880