B. Candidate Prioritization

The Agencies intend to review Parallel Review requests and respond within 30 days after receipt of the email. The Agencies intend to prioritize innovative medical devices that will benefit from the efficiencies of the Parallel Review. Priority will also be given to medical devices expected to have the most impact on the Medicare population. An FDA marketing approval does not guarantee a favorable coverage decision.

III. Paperwork Reduction Act of 1995

As stated in previous **Federal Register** notices related to the Parallel Review pilot, due to FDA and CMS resource issues, the permanent program will follow the same capacity limit by accepting no more than five candidates per year. As such, like the pilot program, this collection of information does not meet the definition of an information collection, as defined under 44 U.S.C. 3501–3520.

IV. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 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 Guidance, ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff.'' Available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf.*

Dated: October 18, 2016.

Leslie Kux,

Associate Commissioner for Policy, Food and Drug Administration.

Dated: October 5, 2016.

Andy Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–25659 Filed 10–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0663]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 (the PRA).

DATES: Fax written comments on the collection of information by November 23, 2016.

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 0910–0672. Also include the FDA docket number found in brackets in the heading of this document.

Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans; OMB Control Number 0910–0672—Extension

In the **Federal Register** of October 31, 2013 (78 FR 65338), FDA published a document entitled ''Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans.'' The document clarified the Agency's expectations for timely review, evaluation, and submission of relevant and useful safety information and implemented internationally harmonized definitions and reporting standards for IND safety reports. The document also required safety reporting for bioavailability and bioequivalence studies. The document was intended to improve the utility of Investigational New Drug (IND) safety reports, expedite FDA's review of critical safety information, better protect human subjects enrolled in clinical trials, and harmonize safety reporting requirements internationally.

The rulemaking included the following information collection under the PRA that was not already included in 21 CFR 312.32 and approved under OMB control number 0910–0014.

Section 312.32(c)(1)(ii) and (c)(1)(iii) requires reporting to FDA, in an IND safety report, of potential serious risks from clinical trials within 15 calendar days for findings from epidemiological studies, pooled analyses of multiple studies, or other clinical studies that suggest a significant risk in humans exposed to the drug.

Section 312.32(c)(1)(iii) specifies the requirements for reporting to FDA in an IND safety report potential serious risks from clinical trials within 15 calendar days for findings from in vitro testing that suggest a significant risk to humans.

Section 312.32(c)(1)(iv) requires reporting to FDA in an IND safety report within 15 calendar days of any clinically important increase in the rate of occurrence of serious suspected adverse reactions over that listed in the protocol or investigator brochure.

The rulemaking also included new information collection under the PRA by requiring safety reporting for bioavailability and bioequivalence studies (21 CFR 320.31(d)).

In tables 1 and 2 of this document, the estimates for ''No. of Respondents,'' ''No. of Responses per Respondent,'' and ''Total Annual Responses'' were obtained from the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) reports and data management systems for submissions received in 2013, 2014, and 2015, and from other sources familiar with the number of submissions received under the noted 21 CFR section. The estimates the ''Hours per Response'' are unchanged based on information from CDER and CBER individuals familiar with the burden associated with these reports and from prior estimates received from the pharmaceutical industry.

In the **Federal Register** of March 18, 2016 (81 FR 14860), we published a 60-day notice requesting public comment on the proposed extension of this

collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

[CDER] [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
320.31(d) Bioavailability and Bioequivalence Safety Reports	13	15	195	14	2,730
312.32(c)(1)(ii) and (c)(1)(iii) IND Safety Reports	100	6	600	12	7,200
312.32(c)(1)(iv) IND Safety Reports	10	1	10	12	120
Total (CDER)					10,050

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN

[CBER] [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
320.31(d) Bioavailability and Bioequivalence Safety Reports	1	1	1	14	14
312.32(c)(1)(ii) and (c)(1)(iii) IND Safety Reports	137	4	548	12	6,576
312.32(c)(1)(iv) IND Safety Reports	5	1.4	7	12	84
Total (CBER)					6,674

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

Dated: October 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25606 Filed 10–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0882]

Generic Drug User Fees; Notice of Public Meeting; Request for Comments; Extension of Comment Period; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period; correction.

SUMMARY: The Food and Drug Administration (FDA) is announcing the extension of the comment period and correcting a notice that appeared in the **Federal Register** of Monday, September 26, 2016 (81 FR 66035). The document announced a public meeting entitled ''Generic Drug User Fees; Public Meeting; Request for Comments.'' In that **Federal Register** notice, FDA requested comments on the draft recommendations related to the reauthorization of the Generic Drug User Fee Amendments of 2012 (GDUFA). The Agency is taking this action to allow interested persons the statutorily required 30 days to submit comments. Also, the document was published with an error in the **SUPPLEMENTARY INFORMATION** section. This document corrects that error.

DATES: FDA is extending the comment period on the Generic Drug User Fee recommendations published September 26, 2016 (81 FR 66035). Submit either electronic or written comments by November 16, 2016.

FOR FURTHER INFORMATION CONTACT: Derek Griffing, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1673, Silver Spring, MD 20993, 240–402–6980, email: *GenericDrugPolicy@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 26, 2016, FDA published a request for comments on GDUFA reauthorization draft recommendations. The comment period ends on November 7, 2016.

Because the Agency posted the draft recommendations on October 14, 2016, and the statute requires a period of 30 days be provided for the public to provide comments on the draft recommendations, FDA is extending the comment period for the GDUFA reauthorization draft recommendations until November 16, 2016.

In addition, in FR Doc. 2016–23111, appearing on page 66035 in the **Federal Register** of Monday, September 26, 2016, the following correction is made:

On page 66038, in the final paragraph of the first column, the second sentence is corrected to read: ''Specifically, FDA would issue product-specific guidance identifying the methodology for developing drugs and generating evidence needed to support ANDA approval, for 90 percent of new chemical entity new drug applications that are approved on or after October 1, 2017, at least 2 years prior to the earliest lawful filing date.''

Dated: October 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25603 Filed 10–21–16; 8:45 am]

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