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]

BILLING CODE 4164–01–P