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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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	No. of Respondents	No. 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	No. of Respondents	No. 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.

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