DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0809]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements for Submission of Bioequivalence Data

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 [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 0910-0630. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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.

Requirements for Submission of In Vivo Bioequivalence Data--21 CFR Parts 314 and 320; OMB Control Number 0910-0630--Extension

In the Federal Register of January 16, 2009 (74 FR 2849), the Agency published a final rule revising FDA regulations to require applicants to submit data on all bioequivalence (BE) studies, including studies that do not meet passing bioequivalence criteria, which are performed on a drug product formulation submitted for approval under an abbreviated new drug application (ANDA), or in an amendment or supplement to an ANDA that contains BE studies. In the final rule, FDA amended 314.94(a)(7)(i), 314.96(a)(1), 320.21(b)(1), and 314.97 (21 CFR 314.94(a)(7)(i), 314.96(a)(1), 320.21(b)(1), and 314.97) to require an ANDA applicant to submit information from all BE studies, both passing and nonpassing, conducted by the applicant on the same drug product formulation as that submitted for approval under an ANDA, amendment, or supplement.

In table 1, FDA has estimated the reporting burden associated with each section of this requirement. FDA believes that the majority of additional BE studies will be reported in ANDAs (submitted under 314.94), rather than supplements (reported in 314.97) because it is unlikely than an ANDA holder will conduct BE studies with a drug after the drug has been approved. With respect to the reporting of additional BE studies in amendments (submitted under 314.96), this should also account for a small number of reports because most BE studies will be conducted on a drug prior to the submission of the ANDA and will be reported in the ANDA itself.

FDA estimates applicants will require approximately 120 hours of staff time to prepare and submit each additional complete BE study report and approximately 60 hours of staff time for each additional BE summary report. The Agency believes that a complete report will be

required approximately 20 percent of the time, while a summary will suffice approximately 80 percent of the time. Based on a weighted-average calculation using the information presented previously in this document, the submission of each additional BE study is expected to take 72 hours of staff time ([120 × 0.2] + [60 × 0.8]).

In the Federal Register of June 26, 2014 (79 FR 36320), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1-- Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
314.94(a)(7)	84	1	84	72	6,048
314.96(a)(1)	1	1	1	72	72
314.97	1	1	1	72	72
Total					6,192

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

Dated: December 10, 2014.

Leslie Kux,

Associate Commissioner for Policy.

4164-01-P

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