



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirement for an abbreviated new drug application (ANDA) applicant to submit data from all bioequivalence (BE) studies the applicant conducts on a drug product formulation submitted for approval.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

## 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 BE studies, including studies that do not meet passing bioequivalence criteria, which are performed on a drug product formulation submitted for approval under an 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 of this document, 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 that 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 ( $[120 \times 0.2] + [60 \times 0.8]$ ).

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

Table 1-- Estimated Annual Reporting Burden<sup>1</sup>

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

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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