4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0280]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Financial Disclosure by Clinical Investigators

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 0910-0396. 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.

Financial Disclosure by Clinical Investigators

OMB Control Number 0910-0396--Extension

Respondents to this collection are sponsors of marketing applications that contain clinical data from studies covered by the regulations. These sponsors represent pharmaceutical, biologic, and medical device firms. Respondents are also clinical investigators who provide financial information to the sponsors of marketing applications.

Under § 54.4(a) (21 CFR 54.4(a)), applicants submitting an application that relies on clinical studies must submit a complete list of clinical investigators who participated in a covered clinical study, and must either certify to the absence of certain financial arrangements with clinical investigators (Form FDA 3454) or, under § 54.4(a)(3), disclose to FDA the nature of those arrangements and the steps taken by the applicant or sponsor to minimize the potential for bias (Form FDA 3455).

Under § 54.6, the sponsors of covered studies must maintain complete records of compensation agreements with any compensation paid to nonemployee clinical investigators, including information showing any financial interests held by the clinical investigator, for a time period of 2 years after the date of approval of the applications. Sponsors of covered studies maintain many records with regard to clinical investigators, including protocol agreements and investigator résumés or curriculum vitae. FDA estimates than an average of 15 minutes will be required for each recordkeeper to add this record to the clinical investigators' file.

Under § 54.4(b), clinical investigators supply to the sponsor of a covered study financial information sufficient to allow the sponsor to submit complete and accurate certification or

disclosure statements. Clinical investigators are accustomed to supplying such information when applying for research grants. Also, most people know the financial holdings of their immediate family and records of such interests are generally accessible because they are needed for preparing tax records. For these reasons, FDA estimates that it will take clinical investigators 15 minutes to submit such records to the sponsor.

In the Federal Register of April 29, 2015 (80 FR 23803), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, none were responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

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
Certification--54.4(a)(1) and (a)(2)--Form FDA 3454	1,000	1	1,000	1	1,000
Disclosure--54.4(a)(3)--Form FDA 3455	100	1	100	5	500
Total					1,500

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Recordkeeping--54.6	1,000	1	1,000	0.25 (15 minutes)	250

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

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
54.4(b)--Clinical Investigators	7,106	1	7,106	0.17 (10 minutes)	1,208

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

Dated: October 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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