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 or Agency) 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, 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.

Table 1 of this document shows information that is the basis of the estimated number of respondents in tables 2 through 4.

Table 1.--Estimated Number of Applications, Clinical Trials, and Investigators Subject to the Regulation by Type of Application[1]

Application Type	Total No. of Applications	No. of Applications Affected	No. of Trials	No. of Investigators
Drugs:				
New drug application (NDA), new molecular entity (NME)	35	26	3 to 10	3 to 100
NDA nonNME				
NDA efficacy supplement	173	86	1 to 3	10 to 30
Abbreviated new drug application (ANDA)	1,152	250	1.1	2
ANDA supplement	6,774	383	1	2
Biologics:				
Biologics license application (BLA)	22	19	3 to 10	3 to 100
BLA efficacy supplement	16	14	1 to 3	10 to 30
Medical Devices:				
Premarket approval (PMA)	48	48	1 to 3	10 to 20
PMA supplement	23	23	1 to 3	3 to 10
Reclassification devices	3	1	1	3 to 10
510(k)	4,000	200	1	3 to 10

[1] Source: Agency estimates.

In the *Federal Register* of September 27, 2018 (83 FR 48819), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one

comment, however, it was not responsive to the four collection of information topics solicited and therefore this comment will not be discussed in this document.

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

Reporting Burden:

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).

FDA estimates that almost all applicants submit a certification statement under § 54.4(a)(1) and (a)(2). Preparation of the statement using Form FDA 3454 should require no more than 1 hour per study. The number of respondents is based on the estimated number of affected applications.

When certification is not possible and disclosure is made using Form FDA 3455, the applicant must describe, under § 54.4(a)(3), the financial arrangements or interests and the steps that were taken to minimize the potential for bias in the affected study. As the applicant would be fully aware of those arrangements and the steps taken to address them, describing them will be straightforward. The Agency estimates that it will take about 5 hours to prepare this narrative. Based on our experience with this collection, FDA estimates that approximately 10 percent of the respondents with affected applications will submit disclosure statements.

Table 2.--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	1,050	1	1,050	1	1,050

Table 2.--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
Disclosure--54.4(a)(3)--Form FDA 3455	105	1	105	5	525
Total					1,575

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

Recordkeeping Burden:

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 2 years after the date of approval of the applications. Sponsors of covered studies maintain many records regarding clinical investigators, including protocol agreements and investigator resumes or curriculum vitae. FDA estimates than an average of 15 minutes will be required for each recordkeeper to add this record to the clinical investigator's file.

Table 3.--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[2]
Recordkeeping--54.6	1,050	1	1,050	0.25	263

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Third-Party Disclosure Burden:

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 the time required for this task may

range from 5 to 15 minutes; we used the mean, 10 minutes, for the average burden per disclosure. The number of respondents is the sum of the number of affected applications multiplied by the mean of the estimated number of investigators for each application type (rounded) (see table 1 of this document).

Table 4.--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[2]
54.4(b)--Clinical Investigators	7,894	1	7,894	0.17	1,342

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Our estimated burden for the information collection reflects an overall increase of 222 hours and a corresponding increase of 893 responses/records. We attribute this adjustment to an increase in the number of affected applications and the number of investigators. No program changes were made.

Dated: February 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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