requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The information collected by the Project Impact Assessment Survey is needed for two main reasons: (1) To collect crucial information required to report on the ANA established Government Performance and Results Act measures, and (2) to properly abide by ANA's congressionally mandated statute (42 U.S.C. 2992 *et seq.*) found within the Native American Programs Act of 1974, as amended, which states that ANA will evaluate projects assisted through ANA grant dollars ''including evaluations that describe and measure the impact of such projects, their effectiveness in achieving stated goals, their impact on related programs, and their structure and mechanisms for delivery of services.'' The information collected with this survey will fulfill ANA's statutory requirement and will also serve as an important planning and performance tool for ANA.

Updates to this information collection address the Indian Community Economic Enhancement Act of 2020 (Pub. L. 116–261). It also addresses the flexibilities and assistance offered under COVID–19 recovery assistance.

Respondents: Tribal Governments, Native American nonprofit organizations, and Tribal Colleges and Universities.

BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ANA Project Outcome Assessment Survey	85	1	6	510

Estimated Total Burden Hours: 510.

Authority: 42 U.S.C. 2992.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–06652 Filed 3–29–22; 8:45 am]

BILLING CODE 4184–34–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, Agency, 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.

DATES: Submit written comments (including recommendations) on the collection of information by April 29, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 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.

In the **Federal Register** of December 2, 2021 (86 FR 68500), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

Table 1 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 number of applications	Number of applications affected	Number of trials	Number of investigators
Drugs:				
New drug application (NDA), new molecular entity (NME)	55	55	3 to 10	3 to 100.
NDA non-NME	78	37	3 to 10	3 to 100.
NDA efficacy supplement	196	119	1 to 3	10 to 30.
Abbreviated new drug application (ANDA)	821	1	1.1	2.
ANDA supplement	10,894	1	1	2.
CBER Biologics:				
Biologics license application (BLA)	10	10	3 to 10	3 to 100.
BLA efficacy supplement	30	30	1 to 3	10 to 30.
CDER Biologics:				

TABLE 1—ESTIMATED NUMBER OF APPLICATIONS, CLINICAL TRIALS, AND INVESTIGATORS SUBJECT TO THE REGULATION BY TYPE OF APPLICATION [1]—Continued

Application type	Total number of applications	Number of applications affected	Number of trials	Number of investigators
BLAs	25	25	3 to 10	3 to 100.
BLA efficacy supplements	102	65	1 to 3	10 to 30.
Medical Devices:				
Premarket approval (PMA)	39	39	1 to 31	10 to 20.
PMA supplement	29	29	1 to 3	3 to 10.
Reclassification devices	0	0	0	0.
510(k)	3,947	247	1	3 to 10.
De Novo requests	63	57	1 to 3	10 to 20.

[1] Source: Agency estimates.

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 (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	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Certification—54.4(a)(1) and (2)—Form FDA 3454	715	1	715	1	715
Disclosure—54.4(a)(3)—Form FDA 3455	72	1	72	5	360
Total					1,075

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

Recordkeeping Burden

Under § 54.6 (21 CFR 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 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.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
Recordkeeping—54.6	715	1	715	0.25	179

[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 median, 10 minutes, for the average burden per disclosure (see table 1).

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN[1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours[2]
54.4(b)—Clinical Investigators	13,082	1	13,082	0.17	2,224

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

The burden for this information collection request has changed since the last OMB approval. Our estimated burden for the information collection reflects a 298 hour increase. We have adjusted our estimated burden for the information collection to reflect the number of submissions we received in the last few years. Additionally, for products regulated by the Center for Devices and Radiological Health, we now include De Novo requests as a type of application that may rely on clinical studies. Upon review, we have corrected an inadvertent omission regarding the number of BLAs and BLA efficacy supplements received by our Center for Drug Evaluation and Research and used, in part, as a basis for calculating the cumulative burden estimate. We have corrected that error here, as reflected in table 1.

Dated: March 24, 2022.

Andi Lipstein Fristedt,

Deputy Commissioner for Policy, Legislation, and International Affairs, U.S. Food and Drug Administration.

[FR Doc. 2022–06661 Filed 3–29–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Application for Health Center Program Recipients for Deemed Public Health Service Employment With Liability Protections Under the Federal Tort Claims Act, 0906–0035, Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than April 29, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the acting HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Application for Health Center Program Recipients for Deemed Public Health Service Employment with Liability Protections Under the Federal Tort Claims Act (FTCA), OMB No. 0906–0035—Revision.

Abstract: Section 224(g)–(n) of the Public Health Service (PHS) Act (42 U.S.C. 233(g)–(n)), as amended, authorizes the ''deeming'' of entities receiving funds under section 330 of the PHS Act as PHS employees for the purposes of receiving FTCA coverage. The Health Center Program is administered by HRSA's Bureau of Primary Health Care (BPHC). Health centers submit deeming applications annually to BPHC in the prescribed form and manner in order to obtain deemed PHS employee status for this purpose.

The FTCA Program has a web-based application system, the Electronic Handbooks. These electronic application forms decrease the time and effort required to complete the older, paper-based OMB approved FTCA application forms. The application includes: Contact Information; Section 1: Review of Risk Management Systems; Section 2: Quality Improvement/Quality Assurance; Section 3: Credentialing and Privileging; Section 4: Claims Management; and Section 5: Additional Information, Certification, and Signatures.

HRSA is proposing several changes to the Application for Health Center Program Award Recipients for Deemed PHS Employment with Liability Protections under the FTCA, to be used for health center deeming applications for calendar year 2022 and thereafter, to clarify questions posed and required documentation. Specifically, the Application includes the following proposed changes:

- *Updated application language:* Throughout the application, alternate terminology was utilized to provide greater clarity and specificity. These changes were based on stakeholder feedback and information received from the HRSA Health Center Program Support. These changes are not substantive in nature.
- Some questions were removed from Quality Improvement/Quality Assurance Section, as these questions are similar to information that is also collected in the Risk Management Section. This change is intended to reduce duplicative information collection.
- For the Credentialing and Privileging Section, in this cycle, the application will return to the previous process of submitting a Credentialing List with providers' credentialing and privileging information.

A 60-day notice published in the **Federal Register**, 86 Fed Reg. 72250 (December 21, 2021). There were no public comments.