under different circumstances, with a small number requiring more hours (*e.g.,* as many as 5,000 hours for early applications that involve complex products and for which the company has no experience conducting studies or preparing analysis of public health impacts, or for which reliance on master files is not possible) as well as many requiring fewer hours (*e.g.,* as few as 50 hours for applications for products that are very similar to other new products). A PMTA may require one or more types of studies including chemical analysis, nonclinical studies, and clinical studies. FDA also estimates the number of PMTAs that FDA expects to receive annually will be 750 (642 electronic nicotine delivery systems (ENDS) Liquids and 108 ENDS Delivery Systems).

FDA anticipates that the 27 potential respondents to this collection may need to meet with CTP's Office of Science to discuss their investigational plans. This number has been reduced based on the average number of meeting requests received over the past 3 years. To request this meeting, applicants should compile and submit information to FDA for meeting approval. FDA estimates that it will take approximately 270 hours to compile and request a meeting with OS. We have revised the hours per response to be consistent with the meetings information collection for originally regulated products (OMB control number 0910–0731).

Based on the September 2020 order vacating the health warning requirements for cigars and pipe tobacco (set forth in §§ 1143.3 and 1143.5) and remanding the Final Deeming Rule's warning requirements for cigars and pipe tobacco, we have removed the burden associated with this activity. We have included one token hour of burden associated with the requirements in § 1143 to acknowledge the requirement remains in the regulations.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. The total estimated burden for this information collection is 1,285,021 reporting hours, and 778 annual responses. Our estimated burden for the information collection reflects an overall decrease of 2,779 hours and a corresponding decrease of 262 responses. We attribute this adjustment to updated information in the number of meeting requests with CTP's Office of Science to discuss investigational plans, the removal of burden for the cigar warning plans, the removal of the small-scale manufacturer reporting, and have therefore revised the estimated burden and number of respondents to the information collection.

Dated: April 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09072 Filed 4–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3758]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Expanded Access to Investigational Drugs for Treatment Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 May 31, 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 0910–0814. 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.

Expanded Access to Investigational Drugs for Treatment Use

OMB Control Number 0910–0814—Revision

This information collection supports Agency regulations in 21 CFR part 312, subpart I, Expanded Access to Investigational Drugs for Treatment Use; associated guidance; and Form FDA 3926, Individual Patient Expanded Access Investigational New Drug Application (IND). The regulations govern the use of investigational new drugs, biologics, and approved drugs if availability is limited by a risk evaluation and mitigation strategy, when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. The goal of the expanded access program is to facilitate the availability of such products to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition. The regulations provide that certain criteria be met, establish content and format requirements for associated reporting, and require that submissions include a cover sheet.

Although we continue to account for burden associated with the submission of expanded access requests for individual patients, we are revising the information collection to also account for burden attendant to other expanded access submissions, including commercial investigational new drug applications (INDs) that involve large groups of patients enrolled for treatment use of the investigational drug (§§ 312.300 through 312.320 (21 CFR 312.300 through 312.320)), currently approved under OMB control number 0910–0014. Because of FDA's long history of facilitating expanded access to investigational drugs for treatment use for patients with serious or immediately life-threatening diseases or conditions, our efforts in this regard are ongoing.

Form FDA 3926 was developed to assist respondents to the information collection. Form FDA 3926 requires the completion of data fields that enable us to uniformly collect the minimum information necessary from licensed physicians who want to request expanded access as prescribed in the applicable regulations. To supplement the form instructions, we issued guidance, most recently updated in October 2017, entitled ''Individual Patient Expanded Access Applications: Form FDA 3926,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/*

individual-patient-expanded-access-applications-form-fda-3926. As discussed in the guidance, § 312.310(b) contains additional submission requirements for individual patient expanded access requests. These respondents may continue to use either Form FDA 3926 or Form FDA 1571, Investigational New Drug Application (IND), for all types of IND submissions to satisfy requirements in 21 CFR 312.23(a) (approved under OMB control number 0910–0014). FDA considers a completed Form FDA 3926 signed by the physician and checked in the box in Field 10.a (Request for Authorization to use Form FDA 3926) to be a waiver request in accordance with 21 CFR 312.10.

We are proposing the following revisions to data elements in Form FDA 3926 and will make corresponding revisions to the form instructions:

- Reorder Field 8, ''Physician Name, Address, and Contact Information'' to Field 1, and renumber remaining data fields accordingly;
- Add ''Race and Ethnicity'' as an optional item under the ''Clinical Information/Brief Clinical History'' field;
- Add ''Request for Withdrawal'' under the ''Contents of Submission'' field;
- Add technological enhancements to the electronic version of Form FDA 3926 that utilize user-based selections to prompt required data field entries. Currently, certain fields become grayed out if not required for the submission type selected.

Data elements in §§ 312.315 and 312.320 continue to be reported in Forms FDA 1571 and 1572, Statement of Investigator, (approved under OMB control number 0910–0014).

In the **Federal Register** of December 14, 2021 (86 FR 71069), 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—CENTER FOR DRUG EVALUATION AND RESEARCH [1]

Part 312, subpart I; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 312.310(b) and 312.305(b); submissions related to expanded access and treatment of an individual patient: Form FDA 3926.	1,204	2.4958	3,005	0.75 (45 minutes)	2,254
§ 312.310(d); submissions related to emergency use of an investigational new drug: Form FDA 3926.	1,265	2.843	3,596	16	57,536
§§ 312.315(c) and 312.305(b); submissions related to expanded access and treatment of an intermediate-size patient population [2].	88	3.64	320	120	38,400
§ 312.320(b); submissions related to a treatment IND or treatment protocol [2].	20	7	140	300	42,000
Total			7,061		140,190

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Data elements are reported in Forms FDA 1571 and 1572, approved under OMB control number 0910–0014.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN—CENTER FOR BIOLOGICS EVALUATION AND RESEARCH [1]

Part 312, subpart I; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 312.310(b) and 312.305(b); number of submissions related to expanded access and treatment of an individual patient: Form FDA 3926	118	1.305	154	8	1,232
§ 312.310(d); number of submissions related to emergency use of an investigational new drug: Form FDA 3926	1,591	4.2137	6,704	16	107,264
§§ 312.315(c) and 312.305(b); number of submissions related to expanded access and treatment of an intermediate-size patient population [2]	28	1	28	120	3,360
§ 312.320(b); number of submissions related to a treatment IND or treatment protocol [2]	15	1	15	300	4,500
Total			6,901		116,356

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Data elements are reported in Forms FDA 1571 and 1572, approved under OMB control number 0910–0014.

The information collection reflects an increase in 254,750 burden hours and 11,568 responses annually since the last OMB review and approval of the information collection. We attribute this to an increase in the number of submissions.

Dated: April 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09070 Filed 4–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[OMB No. 0917–0041]

Request for Public Comment: 30-Day Information Collection: Indian Health Service Information Security Ticketing and Incident Reporting.

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to take this opportunity to comment on the information collection Office of Management and Budget (OMB) Control Number 0917–0041, titled, Information Security Ticketing and Incident Reporting. The purpose of this notice is to allow 30 days for public comment submitted directly to OMB. A copy of the draft supporting statement is available at *www.regulations.gov* (see Docket ID IHS_FRDOC_001).

DATES: *Comment Due Date:* May 31, 2022. Your comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

ADDRESSES: *Direct Your Comments to OMB:* Send your comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Evonne Bennett, Information Collection Clearance Officer at: *Evonne.Bennett@ihs.gov* or 301–443–4750.

SUPPLEMENTARY INFORMATION: This previously approved information collection project was last published in the **Federal Register** on February 17, 2022 (87 FR 9071), and allowed 60 days for public comment. No public comment was received in response to the notice. This notice announces our intent to submit this collection, which expires April 30, 2022, to OMB for approval of an extension, and to solicit comments on specific aspects for the proposed information collection.

Title: 0917–0041, ''Information Security Ticketing and Incident Reporting.''

Form(s) and Form number(s): Incident Reporting Form, Form F07–02b.

OMB Control Number: 0917–0041.

Need and Use of Information Collection: This information collection activity provides a means for federal employees, Tribal employees, contractors, and other non-federal employees to report IHS information technology (IT) security and privacy incidents. This information collection has three purposes: To notify the CSIRT of an incident, provide updates about an open incident, and indicate resolution of an existing incident. The information collection furthers the IHS's ability to use secure IT, to enhance response time to IT incidents, and to maintain the agency's healthcare information security posture. This information collection also allows IHS to process privacy incidents and breaches within the IHS, in keeping with internal and external requirements.

Members of Affected Public: Federal employees, Tribal employees, contractors, and other non-federal employees accessing IHS IT systems.

Status of the Proposed Information Collection: Extension request.

Type of Respondents: Individuals.

The table below provides: Types of data collection instruments, estimation of the number of respondents, number of responses per respondent, annual number of responses, average burden hour per response, and total annual burden hours.

Data collection instrument(s)	Estimated number of respondents	Responses per respondent	Annual number of responses	Average burden hour per response *	Total annual burden hours
IHS Federal and Non-Federal Staff	1700	1	1700	15/60	425
Total	1700	1	1700	15/60	425

*For ease of understanding, the average burden per response is 15 minutes. There are no direct costs to respondents to report.

Requests for Comments: Your written comments and/or suggestions are invited on one or more of the following points:

(a) whether the information collection activity is necessary to carry out an agency function;

(b) whether the agency processes the information collected in a useful and timely fashion;

(c) the accuracy of the public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information);

(d) whether the methodology and assumptions used to determine the estimates are logical;

(e) ways to enhance the quality, utility, and clarity of the information being collected; and

(f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Elizabeth A. Fowler,

Acting Director, Indian Health Service.

[FR Doc. 2022–09055 Filed 4–27–22; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and