Our estimated burden for the information collection reflects an increase of 52 hours. We attribute this adjustment to an increase in the number of establishments and reprocessed SUDs.

Dated: February 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03748 Filed 2–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–7012]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Use of Public Human Genetic Variant Databases To Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics

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 March 26, 2021.

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 0910–0850. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

Agency Information Collection Activities; Proposed Collection; Comment Request; Use of Public Human Genetic Variant Databases To Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics

OMB Control Number 0910–0850—Extension

Section 2011 of the 21st Century Cures Act of 2016 (Pub. L. 114–255) encourages the FDA to develop new approaches for addressing regulatory science issues as part of the Precision Medicine Initiative (PMI).

In the **Federal Register** of April 13, 2018 (83 FR 16110), FDA announced the availability of a guidance for industry entitled ''Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics; Guidance for Stakeholders and Food and Drug Administration Staff.'' [1] The guidance describes one part of FDA's PMI effort to create a flexible and adaptive regulatory approach to the oversight of next generation sequencing (NGS)-based tests. The goal of this effort is to help ensure patients receive accurate and meaningful test results, while promoting innovation in test development. The guidance describes how publicly accessible databases of human genetic variants can serve as sources of valid scientific evidence to support the clinical validity of genotype-phenotype relationships in FDA's regulatory review of both NGS-based tests and genetic and genomic tests based on other technologies. Publicly accessible genetic databases may be useful to support the clinical validity of NGS tests as well as single gene or panel tests that use other technology.

The guidance describes FDA's considerations in determining whether a genetic variant database is a source of valid scientific evidence that could support the clinical validity of an NGS-based test. The guidance further outlines the process by which administrators [2] of genetic variant databases could voluntarily apply to FDA for recognition, and how FDA would review such applications and periodically reevaluate recognized databases. The guidance also recommends that, at the time of recognition, the database administrator make information regarding policies, procedures, and conflicts of interest publicly available and accessible on the genetic variant database's website.

Respondents are administrators of genetic databases. Our estimate of five respondents per year is based on the current number of databases that may meet FDA recommendations for recognition and seek such recognition.

Based on our experience and the nature of the information, we estimate that it will take an average of 80 hours to complete and submit an application for recognition. We estimate that maintenance of recognition activities will take approximately one-fourth of that time (20 hours) annually. We estimate that it will take approximately 1 hour to post the information on the website.

In the **Federal Register** of September 23, 2020 (85 FR 59801), we published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments. One comment was not relevant to the topic or information collection. A summary of the other comment and our response are as follows:

(Comment) One comment expressed concerns and suggestions regarding the collection, storage, and security of personally identifiable information (PII) and protected health information (PHI).

(Response) The guidance document ''Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics'' describes, among other things, FDA's considerations in determining whether a publicly accessible genetic variant database is a source of valid scientific evidence that could support the clinical validity of genetic and genomic-based tests in a premarket submission and outlines the process by which administrators of publicly accessible genetic variant databases could voluntarily apply to FDA for recognition, and how FDA would assess such applications and periodically reevaluate recognized databases. FDA recommends that genetic database administrators should identify the applicable laws and regulations to assure that any requirements are addressed and transparently documented. Genetic variant database administrators should also put in place adequate security measures to ensure the protection and privacy of PII and PHI and provide

[1] Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-public-human-genetic-variant-databases-support-clinical-validity-genetic-and-genomic-based-vitro.*

[2] FDA acknowledges that many databases may not use the term ''administrator'' or may have a committee of individuals that oversee the database. Therefore, for the purpose of this guidance, a genetic variant database administrator is the entity or entities that oversee database operations.

training for database staff on security and privacy protection. The guidance recommends that, among other considerations, such a genetic variant database would collect, store, and report data and conclusions in compliance with all applicable requirements regarding protected health information, patient privacy, research subject protections, and data security. In section V.A of the guidance, FDA discusses security and privacy of such data, stating that ''[g]enetic variant database operations must be in compliance with all applicable federal laws and regulations (*e.g.,* the Health Insurance Portability and Accountability Act, the Genetic Information Nondiscrimination Act, the Privacy Act, the Federal Policy for the Protection of Human Subjects (''Common Rule''), etc.) regarding protected health information, patient privacy, research involving human subjects, and data security, as applicable.''

However, we believe the comment may misunderstand the subject of the information collection request. We are requesting extension of the OMB approval of the information collection associated with the guidance document, *i.e.,* the application for recognition of a publicly accessible genetic variant database as a source of valid scientific evidence that could support the clinical validity of genetic and genomic-based tests in a premarket submission, as well as record maintenance and public disclosure related to such recognition. The application for recognition does not include submission of PII or PHI that may be contained in a genetic variant database. Rather, the application includes standard operating procedures and other documents related to the database's handling of PII and PHI confidentiality and privacy, among other considerations. The information collected in the application for recognition is used to evaluate the database's oversight and governance procedures to determine that, among other things, they are designed to ensure the protection of PII and PHI and provide appropriate training for database staff.

We have not revised the information collection based on the comment.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Application for recognition of genetic database	5	1	5	80	400

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of recognition activities	5	1	5	20	100

[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]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Public disclosure of policies, procedures, and conflicts of interest	5	1	5	1	5

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: February 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03729 Filed 2–23–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0031]

Best Practices for Development and Application of Disease Progression Models; Public Workshop; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: One of the goals of the Prescription Drug User Fee Act of 2017 (PDUFA VI), part of the FDA Reauthorization Act of 2017 (FDARA), is advancing model-informed drug development (MIDD). The ''Best Practices for Development and Application of Disease Progression Models'' workshop fulfills FDA's performance commitment under PDUFA VI to hold a workshop. The Food and Drug Administration (FDA or Agency) is opening a docket to solicit public input on topics areas for an upcoming disease progression modeling workshop. The purpose of this public workshop is to discuss the best practices for developing disease progression models and their application to support drug development decisions; share