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

experiences and case studies that highlight the opportunities and limitations in the development and application of disease progression models including models for natural history of disease and clinical trial simulations; and discuss the knowledge gaps and research needed to advance the development and use of disease progression models.

DATES: To ensure that the Agency considers your input, submit either electronic or written comments by March 26, 2021.

ADDRESSES: FDA is establishing a docket for public comment on this workshop. The docket number is FDA–2021–N–0031. The docket will close on March 26, 2021. Submit either electronic or written comments on this public workshop by March 26, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 26, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 26, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0031 for ''Best Practices for Development and Application of Disease Progression Models; Public Workshop; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Maryanne Dingman, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8777, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Under FDARA, FDA agreed, in accordance with section I of the PDUFA VI Performance Goals, ''Ensuring the Effectiveness of the Human Drug Review, part J, Enhancing Regulatory Decision Tools to Support Drug Development and Review,'' to hold several workshops to identify best practices for MIDD. The workshop entitled ''Best Practices for Development and Application of Disease Progression Models,'' to be held in 2021, fulfills FDA's performance commitment under PDUFA VI. FDA is requesting comments from the public to help identify areas of interest to be discussed during the workshop given the wide range of approaches to data collection, aggregation modeling, model development, verification and validation, and potential applications in drug development and regulatory review. The outcome will help the Agency inform the public on current experience, emerging techniques, and limitations to streamline the drug model development and facilitate the decision-making process.

II. Request for Information and Comments

Interested persons are invited to provide detailed information and comments on areas of interest to discuss during the upcoming ''Best Practices for Development and Application of Disease Progression Models '' workshop. FDA is interested in responses about best practice considerations including, but not limited to, the following:

1. The development and application of different types of disease progression models (*e.g.,* empirical, semi-mechanistic, and fully mechanistic or systems modeling).

2. Modeling natural history of disease, specifically methodological considerations and challenges in characterizing the natural relationship between pharmacodynamic markers and clinical outcomes.

3. Clinical trial simulations based on disease progression/natural history models to support drug development and regulatory decisions.

Dated: February 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03727 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–4951]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Humanitarian Use Devices

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: 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 0910–0332. 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.

Medical Devices; Humanitarian Use Devices—21 CFR Part 814

OMB Control Number 0910–0332—Extension

This collection of information implements the humanitarian use devices (HUDs) provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(m)) and part 814, subpart H (21 CFR part 814, subpart H). Under section 520(m) of the FD&C Act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is designed to treat or diagnose a disease or condition that affects no more than 8,000 individuals in the United States; (2) would not be available to a person with a disease or condition unless an exemption is granted and there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose such disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

Respondents may submit a humanitarian device exemption (HDE) application seeking exemption from the effectiveness requirements of sections 514 and 515 of the FD&C Act as authorized by section 520(m)(2) of the FD&C Act. The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) whether to exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

In the **Federal Register** of August 13, 2020 (85 FR 49379), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, they were not responsive to the four collection of information topics solicited.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for HUD designation—814.102	20	1	20	40	800
HDE Application—814.104	4	1	4	328	1,312
HDE Amendments and resubmitted HDEs—814.106	20	5	100	50	5,000
HDE Supplements—814.108	116	1	116	80	9,280
Notification of withdrawal of an HDE—814.116(e)(3)	2	1	2	1	2
Notification of withdrawal of institutional review board approval—814.124(b)	1	1	1	2	2
Periodic reports—814.126(b)(1)	50	1	50	120	6,000
Total					22,396

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