submitted a GRAS notice for a substance intended for use in animal food, convened a GRAS panel. We therefore estimate that, on an annual basis, 57 proponents will convene a GRAS panel and submit a GRAS notice to FDA for substances intended for use in human food (57 percent × 100 proponents), and 14 proponents will convene a GRAS panel and submit a GRAS notice to FDA for substances intended for use in animal food (55 percent × 25 proponents). We calculate that the total number of proponents who will convene a GRAS panel and submit a GRAS notice to FDA is 71 proponents (57 human food proponents + 14 animal food proponents). We also assume that all proponents will document the application of a written GRAS panel policy to each member of the GRAS panel.

We have very little information about the percentage of proponents who convene a GRAS panel for a documented GRAS conclusion but do not report their documented GRAS conclusions to FDA in a GRAS notice. For the purpose of this analysis, we make the conservative assumption that all 23 proponents who annually document GRAS conclusions without reporting them to FDA will convene a GRAS panel. Taking into account the estimated number of proponents who convene a GRAS panel and submit a GRAS notice to FDA, and the estimated number of proponents who convene a GRAS panel but do not submit a GRAS notice to FDA, we calculate that the total number of proponents who will convene a GRAS panel and document the application of the written GRAS panel policy to each member of a GRAS panel on an annual basis is 94 proponents (71 proponents who submit GRAS notices to FDA + 23 proponents who do not submit GRAS notices).

Based on the recommendations in the guidance, we assume that all GRAS panels will include at least 3 panel members and that some GRAS panels will include as many as 6 panel members. We assume that a GRAS panel will include 5 panel members on average. We also assume that the proponent will reject at least one individual with applicable expertise due to a conflict of interest and, thus, that 94 proponents will document the application of the written GRAS panel policy to 6 individual GRAS panel members, for a total of 564 documentations of the application of the written GRAS panel policy (94 proponents × 6 panel members). As shown in table 2, we estimate that it will take the proponent 16 hours to document the application of the written GRAS policy to each panel member, for a total of 9,024 hours (564 documentations × 16 hours).

Burden Estimate for Disclosures by GRAS Panel Members to Proponents of GRAS Conclusions

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 (in hours)	Total hours
GRAS panel members provide information to the proponents of GRAS conclusions	564	1	564	4	2,256

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

As shown in table 3, we assume that all 564 individuals who are being considered as members of a GRAS panel will each need 4 hours to provide information related to the panel selection and vetting process to the proponent, as detailed in the written GRAS panel policy, for a total of 2,256 hours (564 individuals × 4 hours).

FDA plans to consolidate this collection with OMB control number 0910–0342, ''Substances Generally Recognized as Safe: Notification Procedure'' which contains the regulatory procedures under which a person may notify FDA about a conclusion that a substance is GRAS under the conditions of its intended use in human and/or animal food and includes a standard format for the submission of a GRAS notice. The revision will add 39,120 burden hours and 1,260 respondents.

This guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR parts 170 and 570 have been approved under OMB control number 0910–0342.

II. References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA (2020). GRAS Notices. Available at *https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices.*
2. FDA (2020). Current Animal Food GRAS Notices Inventory. Available at *https://www.fda.gov/animal-veterinary/generally-recognized-safe-gras-notification-program/current-animal-food-gras-notices-inventory.*
3. AIBMR Life Sciences, Inc. (2020). Independent GRAS (Generally Recognized As Safe) Conclusion Inventory Database. Available at *http://aibmr.com/natural-products-industry-compliance-consultation/gras-generally-recognized-as-safe-safety-studies/.*

Dated: October 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23378 Filed 10–26–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2480]

Rare Disease Endpoint Advancement Pilot Meeting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The seventh iteration of the Prescription Drug User Fee Amendments (PDUFA VII) included as part of the FDA User Fee Reauthorization Act of 2022 highlights the goal of advancing and facilitating the development and timely approval of drugs and biological products for rare diseases, including rare diseases in children. The Food and Drug Administration (FDA or Agency) is announcing the Rare Disease Endpoint Advancement Pilot Meeting Program (RDEA Pilot Program) established under the seventh iteration of PDUFA that affords sponsors who are admitted into the RDEA Pilot Program additional engagement opportunities with the Agency to discuss efficacy endpoint development in rare disease drug and

biological product development programs. Meetings under the program will be conducted by FDA's Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) during fiscal years (FYs) 2023 to 2027. For each sponsor whose RDEA program proposal (RDEA proposal or proposal) is admitted into the program, up to four meetings that will provide an opportunity for medical product developers to discuss rare disease endpoint development will be held between the sponsor and CDER or CBER. To promote innovation and evolving science, novel endpoints developed through the RDEA Pilot Program may be presented by FDA (*e.g.,* in a guidance or public workshop or on a public-facing website) as case studies, including novel endpoints for drugs that have not yet been approved or biological products that have not yet been licensed by FDA for a given indication.

DATES: The RDEA Pilot Program will proceed from October 1, 2022, through September 30, 2027. Sponsors may submit RDEA program proposals beginning July 1, 2023, through June 30, 2027. Submit either electronic or written comments about this program by December 27, 2022.

ADDRESSES: You may submit comments about the RDEA Pilot Program as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time December 27, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2022–N–2480 for ''Rare Disease Endpoint Advancement Pilot Program.'' 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: Mary Jo Salerno, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–0420, *RDEA.Meetings@fda.hhs.gov,* with the subject line ''RDEA Pilot Meeting Program for CDER'' or Julienne Vaillancourt, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7252, Silver Spring, MD 20993–0002, 301–796–1827, *RDEA.Meetings@fda.hhs.gov,* with the subject line ''RDEA Pilot Meeting Program for CBER.'' Additional information is available on the RDEA Pilot Program web page: *https://www.fda.gov/drugs/development-resources/rare-disease-endpoint-advancement-pilot-program.*

SUPPLEMENTARY INFORMATION:

I. Background

In connection with the seventh iteration of PDUFA, FDA committed to conduct a pilot program to advance rare disease drug development programs by providing a mechanism for sponsors to collaborate with FDA throughout the efficacy endpoint development process (see ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027,'' section I.K.4.a, *https://www.fda.gov/media/151712/download*).

FDA is announcing this pilot program to satisfy the above-mentioned commitment. The goals of the early meeting discussions granted under this program are to provide advice on how a proposed novel endpoint can be used in a specific rare disease drug development program and to promote innovation by allowing FDA to publicly present the proposed novel endpoints (or natural history studies in which the proposed endpoint is intended to be studied) considered through the program, including novel endpoints for drugs or biological products that have

not yet been approved or licensed by FDA for a given indication. FDA has committed to accepting a limited number of qualified proposals for admission into the RDEA Pilot Program that increases after the first year of PDUFA VII. For FY 2023, sponsors may submit RDEA proposals beginning in the fourth quarter, and FDA will accept a maximum of one proposal. For FYs 2024 through 2027, FDA will accept up to one RDEA proposal per quarter with a maximum of three proposals per year.

Complete RDEA proposals may be submitted throughout the quarter on a rolling basis; however, only those received by the quarterly closing date, which will be the last day of each quarter of the fiscal year (*i.e.,* December 31, March 31, June 30, September 30), will be considered for selection in the following quarter. Within 60 days after the quarterly closing date, FDA will review the RDEA proposals, select a proposal to proceed to disclosure discussions, and notify sponsors of their proposal status. When FDA and the sponsor agree on the information that FDA may share publicly, FDA will notify the sponsor of admission into the program.

Sponsors admitted to the RDEA Pilot Program may participate in up to four focused meetings with relevant FDA staff to discuss endpoint development. FDA's advice provided during and between RDEA meetings does not constitute a regulatory decision and is considered nonbinding. Being admitted into the RDEA Pilot Program and completing four RDEA meetings does not guarantee approval for a regulatory submission that includes efficacy endpoints discussed during RDEA meetings. Likewise, being denied admission into the RDEA Pilot Program does not mean that the proposed novel endpoint is unacceptable for regulatory decision making.

After completion of four RDEA meetings, the sponsor can request additional input on their novel endpoint from FDA, as needed, through other formal meeting mechanisms, such as Type B, Type C, Type C Surrogate Endpoint, or Type D meetings. Sponsors that do not participate in the RDEA Pilot Program will have an opportunity to interact with the Agency through traditional channels.

The listed eligibility and selection factors outlined in this notice reflect the current thinking at the time of publication. Information about the process for applying to and participating in the RDEA pilot meeting program will be communicated on the following web page: *https://www.fda.gov/drugs/development-resources/rare-disease-endpoint-advancement-pilot-program.*

II. General, Eligibility, and Disclosure Information for the RDEA Pilot Program

A. General Information

The RDEA Pilot Program will be jointly administered by the following Centers:

- *CDER:* CDER's Rare Diseases Team, in the Office of New Drugs, Division of Rare Diseases and Medical Genetics, which is the point of contact for RDEA Pilot Program communications for CDER products.
- *CBER:* CBER's Rare Disease Liaison, in the Office of the Director, Policy Staff, which is the point of contact for RDEA Pilot Program communications for CBER products.

B. Eligibility and Selection Information

To be eligible for the RDEA Pilot Program:

- The associated development program should be active and address a rare disease, with an active investigational new drug application (IND) or pre-IND for the rare disease.
  - Sponsors that do not yet have an active development program but have, or are initiating, a natural history study where the proposed endpoint is intended to be studied are also eligible to apply.
  - FDA may also consider accepting a proposal for a development program for a common disease that includes innovative or novel endpoint elements, including the specific endpoint and/or the methodology being developed if there is sufficient justification that the proposal could be applicable to a rare disease.
- The proposed endpoint is a novel efficacy endpoint intended to establish substantial evidence of effectiveness for a rare disease treatment. An endpoint is considered novel if it has never been used to support drug approval or if it has been substantially modified from previous use to support drug approval.

Preference will be given to proposals:

- That have the potential to impact drug development more broadly, such as one that uses a novel approach to develop an efficacy endpoint or an endpoint that could potentially be relevant to other diseases.
- That collectively reflect a range of different types of endpoints.
- That have novel approaches for collecting additional clinical data in the premarket stage to advance validation of the endpoint for a surrogate endpoint proposal. If the sponsor is proposing to develop a surrogate endpoint as part of a rare disease application, participation in a prior Type C Surrogate Endpoint meeting is encouraged.

C. Disclosure

To promote innovation in this area, novel efficacy endpoints developed through the RDEA Pilot Program may be presented by FDA (*e.g.,* in a guidance, at public workshops and conferences, or on FDA's website) as case studies, including while the drug studied in the trial has not yet been approved by FDA. Accordingly, before FDA grants the initial meeting under the program, FDA and the sponsor must agree on the information that FDA may include in these public case studies. The specific information to be disclosed will depend on the content of each novel efficacy endpoint and associated natural history study if applicable. FDA intends to focus on information that is beneficial to advancing efficacy endpoint development for drugs that treat rare diseases and those elements relevant to understanding the novel efficacy endpoint and its potential use in a clinical trial intended to support regulatory approval.

Sponsors wishing to participate in the program should identify aspects of the proposed novel endpoint and associated natural history, if applicable, that they consider nondisclosable and provide a rationale for withholding the information. Participation in the program, including any agreement on information disclosure, will be voluntary and at the discretion of the sponsor. Sponsors that do not wish to make such disclosures may seek regulatory input through other existing channels.

IV. Paperwork Reduction Act of 1995

While this notice contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required for this notice. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 for INDs and clinical trials have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 601 for biologic new drug applications (NDAs) have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 314 for the submission of NDAs and for requesting meetings with FDA about drug development programs have been

approved under OMB control number 0910–0001. The collections of information relating to rare disease drug and biological product development programs have been approved under OMB control number 0910–0765.

Dated: October 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23383 Filed 10–26–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2016–D–2565]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 510(k) Third-Party Review Program

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 November 28, 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 0910–0375. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

510(k) Third-Party Review Program

OMB Control Number 0910–0375—Extension

Section 523 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360m), directs FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s; see 21 U.S.C. 360(k)). Participation in the 510(k) third-party (3P510k) review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation, to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually 3 years.

Respondents to this information collection are businesses or government, and can be for-profit or not-for-profit organizations.

The guidance ''510(k) Third-Party Review Program, Guidance for Industry, Food and Drug Administration Staff and Third Party Review Organizations'' (March 2020) (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program*) is intended to provide a comprehensive look into FDA's current thinking regarding the 3P510k review program. This guidance document also reflects section 523 of the FD&C Act, which directs FDA to issue guidance on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person. The 3P510k review program is intended to allow review of devices by third-party 510k review organizations (3PROs) to provide manufacturers of these devices an alternative review process that allows FDA to best utilize our resources on higher risk devices.

In the **Federal Register** of June 24, 2022 (87 FR 37863), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although four 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; guidance document section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Requests for accreditation (initial); Section VI	1	1	1	24	24
Requests for accreditation (re-recognition); Section VI	3	1	3	24	72
510(k) reviews conducted by accredited third parties; Section VI	9	14	126	40	5,040
Complaints; Section VII	1	1	1	0.25 (15 minutes)	1
Total					5,137

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; guidance document section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
510(k) reviews; Section VII	9	14	126	10	1,260
Records regarding qualifications to receive FDA recognition as a 3PRO; Section VII	9	1	9	1	9
Recordkeeping system regarding complaints; Section VII	9	1	9	2	18