and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive labels to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, 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

We are announcing the availability of a guidance for blood establishments entitled ''Recommendations for Investigational and Licensed COVID–19 Convalescent Plasma; Guidance for Industry.'' We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (see § 10.115(g)(2) and section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C))). We made this determination because the revisions to the guidance reflect the current epidemiology of COVID–19 and provide updated recommendations needed by blood establishments and sponsors. Specifically, we are issuing this guidance to ensure that blood establishments and sponsors are aware of our current recommendations to expedite the timely development of COVID–19 convalescent plasma. Immediate implementation of the guidance is required to facilitate the licensure of COVID–19 convalescent plasma to protect the public health. Although this guidance document is being implemented immediately, it remains subject to comment in accordance with FDA's GGP regulation (§ 10.115(g)(3)(D)).

COVID–19 convalescent plasma is plasma containing antibodies to SARS–CoV–2 intended for transfusion that is collected from individuals who have recovered from COVID–19. FDA first issued an emergency use authorization (EUA) on August 23, 2020, for COVID–19 convalescent plasma for the treatment of hospitalized patients with COVID–19, pursuant to section 564 of the FD&C Act (21 U.S.C. 360bbb–3). FDA has subsequently reissued the EUA with revisions. Most recently, on December 28, 2021, FDA revised the EUA to limit authorization to the use of COVID–19 convalescent plasma with high titers of anti-SARS–CoV–2 antibodies for the treatment of COVID–19 in patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting. The purpose of this guidance is to provide FDA's recommendations on two regulatory pathways for the manufacture of COVID–19 convalescent plasma. Specifically, the guidance provides recommendations to blood establishments for the submission of a BLA for the manufacture of COVID–19 convalescent plasma for transfusion intended to treat patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting. The guidance also provides FDA's recommendations for INDs for investigational COVID–19 convalescent plasma for transfusion.

The guidance represents the current thinking of FDA on investigational and licensed COVID–19 convalescent plasma. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

FDA has also issued a separate guidance entitled ''Investigational COVID–19 Convalescent Plasma,'' which was most recently updated in October 2023 (88 FR 15417). The ''Investigational COVID–19 Convalescent Plasma'' guidance provides recommendations and additional information related to the EUA for COVID–19 convalescent plasma, as well as recommendations for administering COVID–19 convalescent plasma under the IND pathway in accordance with 21 CFR part 312. The recommendations in section III.A.2 of the guidance being announced today pertaining to investigational new drug applications for COVID–19 convalescent plasma supersede the recommendations in section III.C. of the ''Investigational COVID–19 Convalescent Plasma'' guidance. We intend to revise the ''Investigational COVID–19 Convalescent Plasma'' guidance to reflect this change.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 606 have been approved under OMB control number 0910–0116; and the collections of information in 21 CFR part 630 have been approved under OMB control number 0910–0795.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16046 Filed 7–19–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1298]

Agency Information Collection Activities; Proposed Collection; Comment Request; Diversity Action Plans for Clinical Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each

proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collections of information related to Diversity Action Plans for Clinical Studies.

DATES: Either electronic or written comments on the collection of information must be submitted by September 20, 2024.

ADDRESSES: You may submit comments 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 at the end of September 20, 2024. 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–2024–N–1298 for ''Diversity Action Plans To Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies.'' 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.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collections of information as set forth in the draft guidance for industry ''Diversity Action Plans To Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies.''

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use

of automated collection techniques, when appropriate, and other forms of information technology.

Diversity Action Plans (DAPs) for Clinical Studies

OMB Control No. 0910–NEW

This information collection supports the implementation of sections 3601 and 3602 of the Food and Drug Omnibus Reform Act of 2022 (FDORA) included as part of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328). In the **Federal Register** of June 28, 2024 (89 FR 54010), FDA announced the availability of a draft guidance for industry entitled ''Diversity Action Plans To Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies,'' as required under FDORA. The guidance is available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-action-plans-improve-enrollment-participants-underrepresented-populations-clinical-studies.* Statutory requirements in sections 505(z) and 520(g) of the FD&C Act (21 U.S.C. 355(z) and 360j(g)) are discussed in the draft guidance document, including the content of a DAP (guidance Section V), applicable timelines (guidance Section VI), procedures for submitting a DAP and receiving feedback (guidance Section VII), and requesting a DAP waiver (guidance Section VIII).

A DAP must include the sponsor's goals for enrollment in the clinical study disaggregated by race, ethnicity, sex, and age group of clinically relevant study populations, the sponsor's rationale for those goals, including sufficient information and analysis to explain how the goals were determined, and an explanation of how the sponsor intends to meet such goals. The appropriate submission for a medical product type (investigational new drug application (IND) for drugs and biological products, and investigational device exemptions (IDE), premarket notification (510(k)), premarket approval application (PMA), and de novo classification request (De Novo) for devices) should include a cover letter identifying the submission as a DAP and whether the DAP submission is for an initial or a revised plan.

DAP Waiver Requests should be submitted with a cover letter identifying the submission as a Diversity Action Plan—Waiver request. The waiver request should also identify the submission number, applicable clinical study name or identification number, and a justification for the waiver request, including relevant data and information. DAP submission and waiver requests should be submitted electronically.

DAP submissions and waiver requests are processed through FDA's Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and Center for Devices and Radiological Health (CDRH) according to product type.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ONE-TIME RECORDKEEPING BURDEN [1]

Review guidance to comply with FDORA sections 3601/3602	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER (sec. 505(z)(3) of the FD&C Act)	200	1	200	1	200
CBER (sec. 505(z)(3) of the FD&C Act)	40	1	40	1	40
CDRH (sec. 520(g)(9) of the FD&C Act)	488	1	488	1	488
Total			728		728

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

We are expanding the scope of our currently approved collection inventory to acknowledge the establishment of DAP requirements under FDORA and to account for burden that may be attendant to the submission of a DAP or for requesting a waiver. As explained in the draft guidance document Section VII (Procedures for Submitting the Diversity Action Plan and Receiving Feedback), the submission process will vary depending on the medical product type.

As reflected in table 1, we estimate a one-time burden of 728 hours and 728 responses, cumulatively, with regard to reviewing the guidance and to any necessary adjustment respondents may need to make in complying with applicable requirements.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Information collection activity; statutory authority	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER DAP Submission—sec. 505(z)(3) of the FD&C Act	146	1.37	200	100	20,000
CBER DAP Submission—sec. 505(z)(3) of the FD&C Act	35	1.14	40	100	4,000
CDRH—sec. 520(g)(9)(A) of the FD&C Act	488	1	488	40	19,520
Waiver request CDER—sec. 505(z)(4) of the FD&C Act	4	1	4	16	72
Waiver request CBER—sec. 505(z)(4) of the FD&C Act	1	1	1	16	16
Waiver request CDRH—sec. 520(g)(9)(C) of the FD&C Act	5	1	5	16	80
Total			738		43,688

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

As reflected in table 2, we assume recurring activities to include the preparation, submission, and retention of information consistent with statutory requirements and discussed in the draft guidance and, therefore, estimate an

annual recordkeeping burden of 738 responses and 43,688 hours, including the submission of DAPs and waiver requests to FDA. We discuss these revisions and adjustments with regard to drugs and devices, respectively.

A. Section 505(z)(1) of the FD&C Act (21 U.S.C. 355(z)(1))—Drugs and Biological Products

Regulations establishing procedures and requirements governing clinical investigations for investigational new drugs and biological products are found in part 312 (21 CFR part 312). Specifically, regulations in part 312, subpart D, establish responsibilities for sponsors and investigators of new drugs, including requirements applicable to the investigational plans. Relatedly, regulations in 21 CFR 312.2(e) and 312.145 provide for the issuance of Agency guidance to assist respondents who must comply with part 312 and other requirements applicable to the clinical investigation of new drugs and biological products. The intent of the current draft guidance is to increase enrollment of participants who are members of historically underrepresented populations in clinical studies to help improve the strength and generalizability of the evidence for the intended use population. We have developed and issued other guidance documents also intended to enhance the representativeness of clinical trial populations and to improve enrollment of participants from underrepresented populations in clinical trials.[1]

As outlined in Section VII of the guidance, DAPs for drug and biological products must be submitted to the IND under which the applicable clinical study is to be conducted and, for applicable submissions, must be submitted in eCTD format through FDA's Electronic Submissions Gateways (ESG and ESG-NextGen). Based on our experience with current IND submissions, we estimate receipt of 240 DAPs annually, for FDA's drug and biological product programs. We assume an average of 100 hours are necessary to prepare and submit a DAP.

As noted in Section VIII of the guidance, the appropriateness of a DAP waiver is case-specific and depends on factors relevant to a specific development program. Sponsors should submit their DAP waiver requests electronically to the applicable IND for consideration by FDA. We estimate receipt of 5 waiver requests annually for CDER and CBER combined and estimate that each waiver request would require 16 hours to prepare and submit.

Related information collection activities are currently approved under OMB control number 0910–0014. We intend to revise the scope of the information collection to account for DAP submissions and waiver requests and to adjust our estimated burden for the activities in the relevant information collection after evaluating DAP submissions received.

B. Section 520(g)(9) of the FD&C Act (21 U.S.C. 360j(g))—Devices

Regulations that govern the clinical investigation of medical devices are found in part 812 (21 CFR part 812) (investigational device exemptions (IDE)), where regulations in subpart B set forth content elements, and 21 CFR 812.20 specifically requires the submission of an investigational plan. Consistent with Section VII of the draft guidance, a DAP submission should be accompanied by a cover letter and submitted as part of the IDE application for clinical studies of significant risk devices, or for device studies that require development of a Diversity Action Plan but do not require an IDE (see Section III of the guidance), the DAP must be submitted as part of a 510(k), PMA, or De Novo. Currently, CDRH maintains dedicated IT systems intended to facilitate the uniform submission of information by respondents (CDRH Customer Collaboration Portal, *https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal*). Although electronic submission is not mandatory for all device submissions, most forms are completed and submitted electronically.

In estimating the burden per response for a DAP submitted to CDRH, we considered the differences in requirements for the specific development programs (*i.e.,* IDE, IND, PMA, De Novo, and 510(k)) and the content and number of clinical studies that may be included in a submission. The burden to submit a DAP for a device may vary to the extent that submitters have already considered the enrollment of participants from underrepresented populations, as recommended in existing guidance documents related to improving clinical studies.[2] We assume a range of 16 to 40 hours is necessary to prepare and submit a DAP to CDRH. Based on our experience with current submissions, we estimate 488 DAP submissions annually.

Similarly, requests for waivers from any requirement in part 812 are provided for in § 812.10, and requests for waivers from applicable requirements under § 812.28(a)(1) and (b) are provided for in § 812.28(c). As discussed in Section VIII of the draft guidance, requests to waive the requirement to submit a DAP should be submitted electronically as a stand-alone submission for consideration by FDA. Further, the appropriateness of a waiver is case-specific and depends on factors relevant to a specific development program. We assume a range of 8 to 16 hours is necessary to prepare and submit a DAP waiver, and we assume 5 DAP waiver requests annually.

Under section 520(g)(9)(A)(ii) of the FD&C Act, the sponsor of a device for which submission of an application for an IDE is not required must develop a diversity action plan for any clinical study with respect to the device, except for a device being studied as described in § 812.2(c). Such diversity action plan must be submitted in any 510(k), De Novo, or PMA for such device. Regulations that govern 510(k), De Novo, and PMA are found in 21 CFR parts 807 subpart E, 860 subpart D, and 814 subparts A through E, respectively. Related information collection activities are currently approved under OMB control numbers 0910–0078 (IDE), 0910–0231 (PMA), 0910–0844 (De Novo), and 0910–0120 (510(k)), respectively. We intend to revise the scope of the information collections to account for DAP submissions and waiver requests. We will adjust our estimated burden in these information collections after evaluating the DAP submissions we receive.

The draft guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR part 314 relating to new drug marketing applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 relating to biological product development and marketing applications have been

[1] ''Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial.*

[2] See *e.g.,* ''Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies,'' *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-and-reporting-age-race-and-ethnicity-specific-data-medical-device-clinical-studies,* and ''Evaluation of Sex-Specific Data in Medical Device Clinical Studies,'' *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-sex-specific-data-medical-device-clinical-studies-guidance-industry-and-food-and-drug.*

approved under OMB control number 0910–0338. The collections of information pertaining to submission of a biologics license application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) have been approved under OMB control number 0910–0718. The collections of information in 21 CFR part 50 for protection of human subjects have been approved under OMB control number 0910–0130. The collections of information pertaining to the Q-Submission program for medical devices have been approved under OMB control number 0910–0756.

Dated: July 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15988 Filed 7–19–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–3130 and FDA–2023–E–3135]

Determination of Regulatory Review Period for Purposes of Patent Extension; XENPOZYME; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is correcting a notice that appeared in the **Federal Register** of July 2, 2024. The document announced the determination of the regulatory review period for XENPOZYME (olipudase alfa-rpcp) for purposes of patent extension. The document was published with an incorrect patent number. This notice corrects the patent number.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Tuesday, July 2, 2024 (89 FR 54829), appearing on pg. 54830, in the first paragraph of the third column, under Section I. Background of the **SUPPLEMENTARY INFORMATION** section, the patent numbers are corrected to read ''U.S. Patent Nos. 8,349,319 and 8,658,162.''

Dated: July 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15998 Filed 7–19–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal/for the Advisory Commission on Childhood Vaccines

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA), the Department of Health and Human Services is hereby giving notice that the charter for the Advisory Commission on Childhood Vaccines (ACCV) has been renewed. The effective date of the renewed charter is July 21, 2024.

FOR FURTHER INFORMATION CONTACT: Pita Gomez, Principal Staff Liaison, Division of Injury Compensation Programs, HRSA, 5600 Fishers Lane, 8W–25A, Rockville, MD 20857; 800–338–2382; or *ACCV@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACCV provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on policy, program development, and other matters of significance concerning the activities under 2119 of the Public Health Service Act (the Act) (42 U.S.C. 300aa–19), as enacted by Public Law 99–660, and as subsequently amended. ACCV advises the Secretary on issues related to the implementation of the National Vaccine Injury Compensation Program. Other activities of ACCV include: recommending changes in the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 of the Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying federal, state, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b) of the Act; advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; consulting on the development or revision of Vaccine Information Statements; and recommending to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the National Vaccine Injury Compensation Program.

The recharter for ACCV was approved on July 8, 2024. Renewal of the ACCV charter gives authorization for the Commission to operate until July 21, 2026.

A copy of the ACCV charter is available on the ACCV website at *https://www.hrsa.gov/advisory-committees/vaccines/index.html.* A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is *http://www.facadatabase.gov/.*

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–16025 Filed 7–19–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 20, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov,* or call (202) 795–7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of