## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2023–N–0941]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Drug User Fee Program; Controlled Correspondence Related to Generic Drug Development

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on controlled correspondence related to generic drug development.

**DATES:** Either electronic or written comments on the collection of information must be submitted by June 12, 2023.

**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 June 12, 2023. 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–2018–D–1592 for ''Controlled Correspondence Related to Generic Drug Development.'' 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:** 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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

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.

**Generic Drug User Fee Program; Controlled Correspondence**

*OMB Control Number 0910–0727—REVISION*

This information collection supports implementation of FDA's Generic Drug User Fee program. The Generic Drug User Fee Amendments (GDUFA) (Pub. L. 112–144, Title III) were enacted to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA authorizes FDA to assess user fees to fund critical and measurable enhancements to the performance of FDA's generic drugs program, bringing greater predictability and timeliness to the review of generic drug applications. GDUFA is currently authorized through September 30, 2027. For more information regarding GDUFA and ongoing implementation, we invite you to visit our website at *https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments.*

For operational efficiency, we are revising the information collection to include recommendations found in Agency guidance currently approved in OMB control no. 0910–0797. As discussed in the current GDUFA Commitment Letter, found on our website and included in the information collection, FDA has agreed to specific program enhancements and performance goals. Accordingly, we issued the guidance document entitled ''Controlled Correspondence Related to Generic Drug Development'' (December 2022), to communicate instruction regarding the process by which generic drug manufacturers and related industry or their representatives can request information related to generic drug development. The guidance document also identifies necessary content elements to facilitate FDA's prompt consideration of the request, as well as prescribed timeframes. The guidance document is available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/controlled-correspondence-related-generic-drug-development* and was issued consistent with our Good Guidance Practice regulations found in 21 CFR 10.115, which provide for public comment at any time.

We are also revising the information collection to include Covered Product Authorization Requests (CPAs), provided for under the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (CREATES Act). The CREATES Act provides a pathway for eligible product developers to obtain access to the product samples they need to fulfill testing and other regulatory requirements to support their applications. To make use of this pathway, an eligible product developer seeking to develop a product subject to a Risk Evaluation and Mitigation Strategies with elements to assure safe use must obtain from the Agency a Covered Product Authorization (see 21 U.S.C. 355–2(b)(2)). The draft procedural guidance document entitled ''How to Obtain Covered Product Authorization'' (September 2022) explains that CPAs are submitted as controlled correspondence to the CDER NextGen Collaboration Portal and that general questions may be submitted by email to *GenericDrugs@fda.hhs.gov.* The draft guidance is available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-obtain-covered-product-authorization.*

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

| Information collection activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| GDUFA Controlled Correspondence submitted consistent with GFI Section IV | 390 | 12.5 | 4,875 | 5 | 24,375 |
| CPA Requests submitted consistent with Draft GFI Section IV | 10 | 12.5 | 125 | 5 | 625 |
| Total | | | 5,000 | | 25,000 |

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

Our burden estimate reflects an increase of 125 responses and 625 hours annually corresponding with the inclusion of CPAs to the information collection. We have otherwise retained the currently approved burden estimate associated with controlled correspondence for generic drug development

Dated: April 5, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2023–N–1190]**

### Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting; 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:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The committee will discuss the Biologics License Application (BLA) 125781 from Sarepta Therapeutics, Inc. for delandistrogene moxeparvovec with the requested indication for the treatment of ambulatory patients with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held virtually on May 12, 2023, from 9 a.m. to 6 p.m. Eastern Time.

**ADDRESSES:** Please note that due to the impact of COVID–19, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to