

and may include a telephone non-response follow-up. Telephone non-response follow-up for mailed surveys is not counted as a telephone survey in Exhibit 1. About 200 people will participate in telephone surveys that will take about 40 minutes. Web-based surveys will be conducted with about 1,000 people and will require about 10 minutes to complete. About 500 people

will participate in focus groups which may last about two hours, while in-person interviews will be conducted with about 200 people and will take about 1 hour to complete. Automated data collection will be conducted for about 500 people and could take about 1 hour. Cognitive testing will be conducted with about 200 persons and is estimated to take 1½ hours to

complete. The total annual burden hours is 2,967.

Exhibit 2 shows the estimated annual cost burden associated with respondent's time to participate in these research activities. The adjusted annual cost burden is estimated to be \$310,111.

Exhibit 1—Estimated Annualized Burden Hours

Type of information collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Mail/email *	2,000	1	20/60	667
Telephone	200	1	40/60	133
Web-based	1,000	1	10/60	167
Focus Groups	500	1	2.0	1000
In-person	200	1	1.0	200
Automated **	500	1	1.0	500
Cognitive Testing ***	200	1	1.5	300
Totals	4,600	N/A	N/A	2,967

* May include telephone non-response follow-up in which case the burden will not change.

** May include testing of database software, CAPI software or other automated technologies.

*** May include cognitive interviews for questionnaire or toolkit development, or "think aloud" testing of prototype websites.

Exhibit 2—Estimated Annualized Burden Costs

Type of information collection	Total burden hours	Average hourly wage rate *	Adjusted hourly wage rate **	Total adjusted cost burden
Mail/email	667	\$52.26	\$104.52	\$69,715
Telephone	133	52.26	104.52	13,901
Web-based	167	52.26	104.52	17,455
Focus Groups	1000	52.26	104.52	104,520
In-person	200	52.26	104.52	20,904
Automated	500	52.26	104.52	52,260
Cognitive Testing	300	52.26	104.52	31,356
Total	2,967	N/A	N/A	310,111

* U.S. Bureau of Labor & Statistics "Occupational Employment and Wages, May 2025" found at the following URL—<https://data.bls.gov/oes/#/area/0000000/2025>. Occupation series "Healthcare practitioners and technical occupations" (29-0000) was used for estimated average hourly wages in these calculations.

** Adjusted Average Hourly Rate is 200% of the average hourly rate. It is a fully loaded rate that includes the benefit costs of respondents.

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the

respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: October 23, 2026.

Jeffrey Toven,
Executive Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–12178]

Notice of Approval of Product Under Voucher: Material Threat Medical Countermeasure (MCM) Priority Review Voucher; Bixlenvo (Bictegravir and Lenacapavir)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the approval of a product redeeming a material threat MCM priority review voucher. The Federal Food, Drug, and

Cosmetic Act (the FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the issuance of material threat MCM priority review vouchers as well as the approval of products redeeming a voucher. FDA has determined that Bixlenvo (bictegravir and lenacapavir), tablets, approved August 27, 2026, meet the redemption criteria.

FOR FURTHER INFORMATION CONTACT:

Andrea Gormley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3751, email: Andrea.Vincent@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under section 565A of the FD&C Act (21 U.S.C. 360bbb-4a), which was added by section 3086 of the Cures Act (Pub. L. 114-255), FDA will report the issuance of material threat MCM priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the application for, Bixlenvo (bictegravir and lenacapavir), tablets approved August 27, 2026, meets the redemption criteria.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions#prv>. For further information about Bixlenvo (bictegravir and lenacapavir), tablets go to the “Drugs@FDA” website at <http://www.accessdata.fda.gov/scripts/cder/daf/>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-3743]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Records; Electronic Signatures

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, 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 information collection applicable to the electronic record signature provisions found in Agency regulations.

DATES: Either electronic or written comments on the collection of information must be submitted by December 28, 2026.

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 December 28, 2026. 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-2023-N-3743 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Good Laboratory Practice Requirements for Nonclinical Laboratory 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>.