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 Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document titled ''Recommendations for Reducing the Risk of Transfusion-Transmitted Hepatitis B Virus.'' The guidance provides blood establishments that collect blood and blood components, including Source Plasma, with FDA's recommendations for testing blood and blood components for HBV to reduce adequately and appropriately the risk of transfusion-transmitted HBV. The recommendations contained in the guidance apply to the collection of Whole Blood and blood components, including Source Plasma. Specifically, the guidance provides recommendations on donation testing, donor deferral and requalification of deferred donors. The guidance also provides recommendations for product management, retrieval and quarantine.

In the **Federal Register** of July 16, 2025 (90 FR 32013), FDA announced the availability of the draft guidance titled ''Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen'' dated July 2025. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to improve clarity. The guidance announced in this notice finalizes the recommendations in the draft guidance dated July 16, 2025.

As such, the guidance recommends the discontinuation of testing certain donations for HBsAg and conforming changes for donor requalification and labeling. Namely, we recommend that when donations are tested for HBV deoxyribonucleic acid (DNA) by nucleic acid tests (NAT) and for anti-HBc using screening tests that FDA has licensed, approved, or cleared for such use, in accordance with the manufacturer's instructions, testing for HBsAg is not necessary to reduce adequately and appropriately the risk of transmission of HBV. For Source Plasma donations, we continue to recommend that testing for HBsAg and HBV DNA by NAT is necessary to reduce adequately and appropriately the risk of transmission of HBV.

In addition, the guidance consolidates FDA's recommendations for testing blood and blood components for HBV that have been issued previously in various memoranda and guidance documents. In consolidating the previous recommendations, minor changes were made to reflect advances in the tests used to screen blood donation for HBV and for consistency and alignment with current practices. As such, this final guidance supersedes the prior memoranda and guidance documents containing recommendations on donation testing, donor deferral and requalification of deferred donors, and blood product management, retrieval and quarantine related to HBV listed in the Summary above.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Recommendations for Reducing the Risk of Transfusion-Transmitted Hepatitis B Virus.'' 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.

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 601.12 pertaining to licensed blood establishments reporting changes to an approved biologics license application have been approved under OMB control number 0910–0338. The collections of information in 21 CFR parts 610, 630, and 606 pertaining to current good manufacturing practices for blood, blood components, donor notification, and requirements for donor testing have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the internet may obtain the draft 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.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22369 Filed 11–2–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–4299]

Potency Assurance for Cellular and Gene Therapy Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance titled ''Potency Assurance for Cellular and Gene Therapy Products.'' The guidance document provides recommendations to help assure the potency of human cellular therapy or gene therapy (CGT) products at all stages of the product lifecycle. FDA is recommending a comprehensive approach to potency assurance of CGT products that is grounded in quality risk management. For investigational products, we describe how to progressively implement a strategy for potency assurance during product development and provide additional considerations to help assure the potency of products that are undergoing rapid clinical development. For licensed products, we describe requirements for potency assurance, including testing required for lot release assays. The guidance announced in this notice finalizes the draft guidance of the same title issued on December 28, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on November 3, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–2023–D–4299 for ''Potency Assurance for Cellular and Gene Therapy Products.'' Received comments 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.

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 Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the 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: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document titled ''Potency Assurance for Cellular and Gene Therapy Products.'' This guidance provides recommendations to help assure the potency of human CGT products that are regulated as biological products under section 351 of the Public Health Service Act (42 U.S.C. 262).

This final guidance provides recommendations for developing a science- and risk-based strategy to help assure the potency of human CGT products. A potency assurance strategy is a multifaceted approach that reduces risks to the potency of a product through: (1) manufacturing process design, (2) manufacturing process control, (3) material control, (4) in-process testing, and (5) potency lot release assays. The goal of a potency assurance strategy is to ensure that every lot of a product released will have the specific ability or capacity to achieve the intended therapeutic effect.

The guidance emphasizes that potency assays and their corresponding acceptance criteria should be designed to make meaningful contributions to potency assurance by reducing risks to product potency. We provide illustrative examples of approaches to potency assay development that are grounded in quality risk management. Due to the diversity of CGT products and the product-specific nature of potency assays, the recommendations in this final guidance regarding the selection and design of potency assays are necessarily general.

In the **Federal Register** of December 28, 2023 (88 FR 89707), FDA announced the availability of the draft guidance of the same title dated December 28, 2023. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes: advice on integration of potency assurance into existing quality systems, expanded risk assessment guidance, advice on regulatory engagement pathways, and additional practical examples with refined terminology throughout. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated December 28, 2023.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Potency Assurance for Cellular and Gene Therapy Products.'' 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.

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 parts 210 and 211 pertaining to manufacturing, processing, packing, and holding of finished pharmaceuticals and biological products for human use have been approved under OMB control number 0910–0139. The collections of information in 21 CFR 312.23(a)(7)(i) and (ii) pertaining to submission of chemistry, manufacturing, and control information sufficient to assure the proper identification, quality, purity, and strength of an investigational drug in an IND application, and 21 CFR 312.47(a) pertaining to meetings between FDA and sponsors, including pre-IND meetings, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR 600.14(b) pertaining to biological product deviation reporting is included in OMB control number 0910–0458. The collections of information in 21 CFR part 601 pertaining to biologics license applications have been approved under OMB control number 0910–0338.

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.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22427 Filed 11–2–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request: Faculty Loan Repayment Program, OMB No. 0906–0082—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than December 3, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to: *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.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Faculty Loan Repayment Program OMB No. 0906–0082—Revision.

Abstract: HRSA administers the Faculty Loan Repayment Program (FLRP). FLRP provides health professionals from disadvantaged backgrounds, defined as a geographic and/or economic vulnerability, the opportunity to enter into a contract with HHS to receive repayment of qualifying educational loans in exchange for a minimum of 2 years of service as a full-time or part-time faculty member at an eligible health professions school. The applicant completes and submits an electronic application that identifies for the Secretary of HHS that the applicant comes from an economically or geographically vulnerable background, has a contract with an eligible health professions school to serve as a full-time or part-time faculty member for a minimum of 2 years, and has qualifying outstanding educational loans. In addition, for each undergraduate and/or graduate loan for which repayment is sought, the applicant is required to submit loan documentation verifying the establishment of the educational loan(s) and lender account statements, promissory notes including the original date, and current balance of the outstanding educational loan(s).

This revised ICR contains two new forms. The first is the Employer's Agreement to Loan Repayment Match/Request for a Waiver of the Loan Repayment Match form, which is needed to ensure applicant eligibility and school compliance with the statute. The second is the Semi-annual In-Service Verification form, which is sent to current participants and the institution twice each year to confirm their employment status. The addition of these forms and an increased number of respondents/applicants to the FLRP will increase the estimated burden hours.

This proposed ICR also contains updated terminology with respect to Disadvantaged Background and accompanying definitions by updating the following:

- Changing form title to ''Certification Regarding Vulnerable Background,''
- Replacing ''disadvantaged'' with ''vulnerable'' throughout the form, and
- Replacing ''environmentally disadvantaged'' with ''geographically vulnerable.''

These changes are needed to align the form with the Administration's priority of reinforcing programs that direct resources to areas of greatest need to improve health outcomes. The FLRP statute defines eligible individuals as coming from ''disadvantaged backgrounds'' (42 U.S.C. 293b(a)) but does not define the term. HRSA's use of ''vulnerable background'' operationalizes the statutory term by identifying individuals whose geographic or economic circumstances inhibited their ability to obtain the knowledge, skills, and abilities required to enroll in and graduate from an eligible health professions school. This approach remains consistent with the statute's intent while incorporating more current terminology. These updates were made throughout the form to improve consistency and help ensure that applicants and reviewers understand the criteria using current terminology.

FLRP will define ''vulnerable background'' as ''coming from a geographically vulnerable background or an economically vulnerable background that has inhibited the individual from obtaining the knowledge, skills, and abilities required to enroll in and graduate from an eligible health professions school.''

Examples of indicators that an individual comes from a geographically vulnerable background include, but are not limited to: