directed to the Agency and span multiple disciplines, including regulatory review; CMC; pharmacology/toxicology; clinical; and clinical pharmacology.

The guidance was created as part of FDA's response to the Prescription Drug User Fee Act (PDUFA) VII commitment to increase efficiency and to support development of CGT products by providing a repository of common questions posed to the Office of Therapeutic Products by sponsors and other key stakeholders. The Agency compiled FAQs received from a variety of sources, including FDA interactions with sponsors in development programs.

The guidance covers relevant, current, and timely topics related to the development of CGT products, which may be updated to include additional FAQs as appropriate. Sponsors are encouraged to visit the Cellular and Gene Therapy Guidances web page on the FDA website for a full list of finalized as well as draft guidances relevant to the development of CGT products.

In the **Federal Register** of November 19, 2024 (89 FR 91404), FDA announced the availability of the draft guidance of the same title dated November 19, 2024. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes adding additional FDA resources and addressing typos. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated November 19, 2024.

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 ''Frequently asked Questions—Developing Potential 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 part 312 pertaining to investigational new drug applications, clinical trials, clinical trial design, meetings with FDA, and Form FDA 1571, have been approved under OMB control number 0910–0014. The collections of information in section 402(j)(5)(B) of the Public Health Service Act (42 U.S.C. 282(j)(5)(B)), which requires certification that all applicable requirements of section 402(j) have been met on Form FDA 3674, and the collections of information in 21 CFR part 601 pertaining to the submission of biologics license applications and Form FDA 356h 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. 2026–16959 Filed 8–19–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–D–8561]

Potency Assessment of Active Immunotherapy Products; Draft 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 draft document titled ''Potency Assessment of Active Immunotherapy Products.'' The draft guidance document provides recommendations for developing assays to assess potency as a part of a potency assurance strategy for active immunotherapy products (ACTIMPs). When finalized, this guidance will describe the FDA's current thinking regarding design, validation, and evaluation of potency tests for ACTIMPs. This guidance is intended to supplement the December 2023 draft guidance for industry, when finalized, on ''Potency Assurance for Cellular and Gene Therapy Products'' with additional advice and considerations specifically for ACTIMPs, including peptide- and-protein based ACTIMPs that are not cellular or gene therapy products.

DATES: Submit either electronic or written comments on the draft guidance by November 18, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2026–D–8561 for ''Potency Assessment of Active Immunotherapy 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 draft 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 label to assist the office in processing your requests. The draft 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: Janet Goldberg, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document titled ''Potency Assessment of Active Immunotherapy Products.'' The draft guidance document provides recommendations for developing assays [1] to assess potency [2] as a part of a potency assurance strategy for ACTIMPs.[3] When finalized, this guidance will describe the FDA's current thinking regarding design, validation, and evaluation of potency tests for ACTIMPs. This guidance is intended to supplement the December 2023 draft guidance for industry, when finalized, on ''Potency Assurance for Cellular and Gene Therapy Products'' (Ref. 1) with additional advice and considerations specifically for ACTIMPs, including peptide- and protein-based ACTIMPs that are not cellular or gene therapy products (Ref. 2).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Potency Assessment of Active Immunotherapy 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

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 (CGMP regulations) have been approved under OMB control number 0910–0139. The collections of information in 21 CFR 312.23(a)(7)(i) pertaining to submission of proper identification, quality, purity, and strength of an investigational drug in an IND application 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 biological license applications have been approved under OMB control number 0910–0338.

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.*

IV. References

The following references are on display at 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.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA, ''Potency Assurance for Cellular and Gene Therapy Products; Draft Guidance for Industry'' December 28, 2023. Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/potency-assurance-cellular-and-gene-therapy-products.*
2. FDA, ''Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products'' October 14, 1993. Available at *http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/UCM148113.pdf.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16960 Filed 8–19–26; 8:45 am]

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[1] For the purposes of this guidance document, the term ''assay'' is synonymous with the terms ''test'' and ''analytical procedures''.

[2] As defined in 21 CFR 600.3(s), ''potency'' is interpreted to mean ''the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.''

[3] Active immunotherapy refers to the process of inducing an immune-mediated antigen-specific therapeutic effect in the human body. Active immunotherapy products activate or modulate the immune system to treat preexisting conditions. The effects of active immunotherapies on the immune system may persist even after the product is no longer detectable in the body.