FOR FURTHER INFORMATION CONTACT: Ranjani Prabhakara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6648, Silver Spring, MD 20993–0002, 240–402–4652.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Quality Considerations for Topical Ophthalmic Drug Products.'' This revised draft guidance provides information regarding quality considerations for ophthalmic drug products consistent with the requirements outlined in section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(B)) and 21 CFR parts 210 and 211 for all drug products, 21 CFR part 601 for biological products, 21 CFR part 4 for combination products, and, for ophthalmic drug products with a U.S. Pharmacopeia (USP) monograph, the applicable criteria from the USP. The revised draft guidance also provides recommendations to industry on the documentation that should be submitted in the chemistry, manufacturing, and controls (CMC) section of NDAs, ANDAs, and BLAs for certain CMC attributes for ophthalmic drug products.

This revised draft guidance revises the guidance of the same name published on October 13, 2023 (88 FR 70997). FDA is revising this draft guidance to address microbiological considerations related to product sterility for all ophthalmic drug products subject to current good manufacturing practice (CGMP) requirements and the prevention of contamination of ophthalmic drug products packaged in multidose containers, given several recent recalls of ophthalmic drug products and instances of consumer injury and death from microbiologically contaminated ophthalmic drug products.

FDA is also revising the draft guidance to clarify its stated scope. As originally published, the scope explicitly included NDA, ANDA, and BLA products regulated by the Center for Drug Evaluation and Research; OTC monograph drugs marketed under section 505G of the FD&C Act (21 U.S.C. 355h); and combination products. It was not FDA's intention to specifically exclude products that are not marketed under an approved application or under section 505G of the FD&C Act; however, the draft guidance may have been interpreted that way. Therefore, FDA is clarifying that the guidance also applies to other drugs that, while also subject to CGMP requirements, are not marketed under a drug application, including drugs compounded by outsourcing facilities pursuant to section 503B of the FD&C Act (21 U.S.C. 353b).

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on ''Quality Considerations for Topical Ophthalmic Drug 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. Previous Submission of Comments

In commenting on this revised draft guidance, you do not need to reiterate comments that you previously submitted regarding the draft guidance issued on October 13, 2023. Your previously submitted comments will still be considered. You may instead submit updates to previously submitted comments, as needed, and comments related to the new section on microbiological considerations and the clarified scope of this revised draft guidance.

III. 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 314 for NDAs and ANDAs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 for BLAs have been approved under OMB control number 0910–0338. The collections of information in 21 CFR parts 210 and 211 pertaining to CGMP have been approved under OMB control number 0910–0139. The collections of information in 21 CFR 201.56 and 201.57 relating to certain prescription product labeling requirements have been approved under OMB control number 0910–0572. The collections of information for section 351(k) submission 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 pertaining to human drug compounding under section 503B of the FD&C Act have been approved under OMB control number 0910–0858.

IV. Electronic Access

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

Dated: December 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28595 Filed 12–27–23; 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; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance entitled ''Potency Assurance for Cellular and Gene Therapy Products.'' FDA is issuing this draft guidance to provide 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.

DATES: Submit either electronic or written comments on the draft guidance by March 27, 2024 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–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 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 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, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Potency Assurance for Cellular and Gene Therapy Products.'' FDA is issuing this draft guidance to provide 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).

In this draft guidance, we provide 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.

In this draft guidance, we emphasize 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 draft guidance regarding the selection and design of potency assays are necessarily general.

This draft guidance, when finalized, is intended to supersede the document entitled ''Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products,'' dated January 2011.

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 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 part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR 312.23 have been

approved under OMB control number 0910–0014; the collections of information in 21 CFR 600.14 have been approved under OMB control number 0910–0458; and the collections of information in 21 CFR part 601 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, http://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28596 Filed 12–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Advanced Nursing Education Program Specific Form OMB No. 0915–0375—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than February 26, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Advanced Nursing Education (ANE) Program Specific Form OMB No. 0915–0375—Revision

Abstract: HRSA provides advanced nursing education grants to educational institutions to increase the supply, distribution, quality of, and access to advanced education nurses through the ANE Programs. The ANE Programs are authorized by section 811 of the Public Health Service Act (42 U.S.C. 296j), as amended. This clearance request is for continued approval of the information collection OMB No. 0915–0375 with revisions. This revision request seeks to add the Advanced Nursing Education-Nurse Practitioner Residency and Fellowship (ANE–NPRF) Program and the Maternity Care Nursing Workforce Expansion Program to the ANE Program Specific Form, and to remove programs that have closed, which include the Advanced Nursing Education-Nurse Practitioner Residency (ANE–NPR) Program and the Advanced Nursing Education-Nurse Practitioner Residency Integration Program. The activities previously supported under the ANE–NPR and the Advanced Nursing Education-Nurse Practitioner Residency Integration Program are now supported under the ANE–NPRF Program.

Need and Proposed Use of the Information: Section 811 of the Public Health Service Act provides the Secretary of Health and Human Services with the authority to award grants to and enter into contracts with eligible entities to meet the costs of: (1) projects that support the enhancement of advanced nursing education and practice; and (2) traineeships for individuals in advanced nursing education programs. Under this section, HRSA makes awards to entities who train and support nurses characterized as ''advanced education nurses.'' In awarding such grants, funding preference is given to applicants with projects that will substantially benefit rural or underserved populations or help meet public health nursing needs in state or local health departments; special consideration is given to an eligible entity that agrees to extend the award to train advanced education nurses who will practice in designated Health Professional Shortage Areas.

The ANE Program Specific Form allows HRSA to effectively target funding and measure the impact of the ANE Programs in meeting the legislative intent and program goals of supporting the enhancement of advanced nursing education and creating opportunities for individuals in advanced nursing education programs to increase the number of advanced practice nurses, especially in rural and underserved areas. Additionally, collecting this data assists HRSA in carrying out the most impactful program and ensuring resources are used responsibly. The proposed updates to this information collection are to accurately list the current ANE Programs.

Likely Respondents: Likely respondents will be current ANE Programs awardees and new applicants to ANE Programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name (includes the ANE program specific tables and attachments)	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Advanced Nursing Education Workforce	156	1	156	7	1,092
Nurse Anesthetist Traineeship	64	1	64	7	448