All eVAERS submitters are expected to transition from version 2.2 to the current version 2.3 as soon as possible.

Additional information about electronically submitting postmarket individual case safety reports (ICSRs) for vaccines to VAERS is available at *https://www.fda.gov/industry/about-esg/cber-vaccine-icsr-implementation.*

Dated: December 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28594 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–4177]

Quality Considerations for Topical Ophthalmic Drug Products; Revised Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Quality Considerations for Topical Ophthalmic Drug Products.'' This revised draft guidance discusses certain quality considerations for ophthalmic drug products (*i.e.,* gels, ointments, creams, and liquid formulations such as solutions, suspensions, and emulsions) intended for topical delivery in and around the eye. Specifically, this revised draft guidance discusses microbiological considerations; approaches to evaluating visible particulate matter, extractables and leachables, and impurities and degradation products; use of in vitro drug release/dissolution testing as an optional quality control strategy for certain ophthalmic dosage forms; recommendations for design and delivery and dispensing features of container closure systems; and recommendations for stability studies. The revised draft guidance applies to marketed products including ophthalmic drug products approved under new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs), as well as to over-the-counter (OTC) monograph drugs, drugs compounded by outsourcing facilities, and the drug or biological product constituent part of a combination product. This guidance revises the draft guidance for industry of the same name issued in October 2023.

DATES: Submit either electronic or written comments on the revised draft guidance by February 26, 2024 to ensure that the Agency considers your comment on this revised draft guidance before it begins work on the final version of the guidance.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–4177 for ''Quality Considerations for Topical Ophthalmic Drug 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 revised draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised draft guidance document.

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]

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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: