are welcome to submit comments to the docket requesting topics to be included for future educational conferences (see **ADDRESSES**).

This third conference will focus on the following topics:

(1) Overview of Available Regulatory Pathways
(2) Conditional Approval and Indexing for Minor Use/Minor Species (MUMS)
(3) Expanded Conditional Approval and Reasonable Expectation of Effectiveness
(4) Real World Example of Regulatory Flexibility During a Public Health Emergency
(5) Animal Biotechnology Products and the Veterinary Innovation Program (VIP)
(6) Protocol Quality and Best Practices

The conference will also contain a Q&A session during which FDA will address specific questions from the in-person and virtual audience as time allows. Questions and comments received during each annual conference and comments submitted to the docket will inform the conversation and topics considered in subsequent conferences.

III. Participating in the Educational Conference

Registration: This educational conference is open to the public and will be available virtually and in-person. When registering, please provide complete contact information for each attendee, including name, title, affiliation (if any), address, and email. Also, please self-identify as a member of one of the stakeholder categories: regulated industry, scientific or academic experts, veterinary professionals, consumer advocacy groups, press/media relations, FDA, other government/congress, or other.

Early registration is recommended for persons who wish to attend in person. Registrants will receive confirmation when their registration has been received, and they will be provided the webcast link. Persons interested in attending this conference virtually may register until the start time of the conference. Persons interested in attending this conference in person are encouraged to register online at *https://events.gcc.teams.microsoft.com/event/8a5f6cc5-9964-48f3-8ae6-b8041bdef77e@7d2fdb41-339c-4257-87f2-a665730b31fc* no later than June 25, 2026.

If you need special accommodations due to a disability, please contact Krystyna Reign (see **FOR FURTHER INFORMATION CONTACT**) no later than June 25, 2026.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–11101 Filed 6–2–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–D–1257]

Leveraging Prior Knowledge in the Development of Human Gene Therapy Products Incorporating Genome Editing; 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 document entitled ''Leveraging Prior Knowledge in the Development of Human Gene Therapy Products Incorporating Genome Editing.'' The draft guidance document provides sponsors engaged in the development of human gene therapy (GT) products incorporating ex-vivo and in vivo genome editing (GE) of human somatic cells (GE products) with FDA's recommendations on the type of prior knowledge that may be scientifically appropriate to leverage to advance product development.

DATES: Submit either electronic or written comments on the draft guidance by September 1, 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–1257 for ''Leveraging Prior Knowledge in the Development of Human Gene Therapy Products Incorporating Genome Editing; Draft Guidance for Industry.'' 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, by emailing *industry.biologics@fda.hhs.gov.* 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: Rhea Chakraborty, 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 entitled ''Leveraging Prior Knowledge in the Development of Human Gene Therapy Products Incorporating Genome Editing; Draft Guidance for Industry.'' This draft guidance, when finalized, will reflect FDA's current thinking on the type of prior knowledge that may be scientifically appropriate to leverage to advance product development. This draft guidance also provides recommendations on how sponsors may consider leveraging prior knowledge to increase review efficiency and accelerate product development across multiple programs. These recommendations include how to leverage chemistry, manufacturing, and controls; nonclinical; and clinical prior knowledge. The ability to leverage prior knowledge to expedite product development may be particularly helpful in the context of GE products intended to treat rare diseases. While this draft guidance specifically focuses on GE products, some of the recommendations, when finalized, may also be applicable to other cell and GT products, such as adeno-associated viral vectors, nanoparticle-based GT products, and ex vivo-modified cell-based GTs that do not incorporate GE. However, additional considerations may also apply to these related product types, based on the specific product and manufacturing process, that are beyond those recommended in this draft guidance.

FDA is issuing this draft guidance in accordance with a commitment outlined in the reauthorization of the Prescription Drug User Fee Act (PDUFA VII) under the 2022 FDA User Fee Reauthorization Act.

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 ''Leveraging Prior Knowledge in the Development of Human Gene Therapy Products Incorporating Genome Editing.'' 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 relating to current good manufacturing practice have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 312 for the submissions of investigational new drug applications, including clinical trials, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 601 relating to the submissions of biologic license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 1271 relating to human gene therapy products have been approved under OMB control number 0910–0543.

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. 2026–11054 Filed 6–2–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–5580]

M15 General Principles for Model-Informed Drug Development; International Council for Harmonisation; 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 for industry entitled ''M15 General Principles for Model-Informed Drug Development.'' The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The guidance provides general recommendations for the planning, model evaluation, and documentation of evidence derived from model-informed drug development (MIDD). It establishes a harmonized assessment framework (including the associated terminology) for the MIDD evidence. It also provides recommendations for related regulatory interactions, reporting, and submission. This guideline is intended to facilitate a multidisciplinary understanding of MIDD and associated evidence generation. The guidance finalizes the draft guidance of the same title issued on December 30, 2024.

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

ADDRESSES: You may submit either electronic or written comments on