Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2648]

Heritable Intentional Genomic Alterations in Animals: The Approval Process; 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 #187B entitled ''Heritable Intentional Genomic Alterations in Animals: The Approval Process.'' This guidance clarifies FDA's requirements and recommendations for developers of intentional genomic alterations (IGAs) in animals. The guidance is one of two companion documents. ''Heritable Intentional Genomic Alterations in Animals: The Approval Process'' describes how the FDA approval process applies to heritable IGAs in animals. The companion final guidance, GFI #187A entitled ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach,'' describes FDA's risk-based regulatory approach to the oversight of heritable IGAs in animals.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

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–2019–D–2648 for ''Heritable Intentional Genomic Alterations in Animals: The Approval Process.'' 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 Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Adam Moyer, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–796–2319, *Adam.Moyer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On May 2, 2024, FDA announced in the **Federal Register** the availability of two companion guidances to describe FDA's approach to regulating IGAs in animals. The notice of availability of the first of these two guidances, final GFI #187A, entitled ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach'' (89 FR 35832), describes FDA's risk-based approach to the oversight of IGAs in animals.

The second companion IGA guidance, draft GFI #187B entitled ''Heritable Intentional Genomic Alterations in Animals: The Approval Process'' (89 FR 35834), describes how the FDA approval process applies to heritable IGAs in animals. Interested parties had until July 31, 2024, to comment on the draft guidance.

FDA received approximately 5,000 comments on draft GFI #187B, with 4,982 of them resulting from two write-in campaigns. Those campaigns

criticized FDA regulation of IGAs in animals for neglecting animal welfare. The remaining comments came from industry (companies that produce IGAs and trade associations), individual developers of IGAs in animals, academics, non-governmental organizations (consumer, environmental), and individual consumers.

FDA has made changes in the final GFI #187B that include additional explanation or clarification about: (1) how FDA's animal safety review includes animal health and well-being; (2) how compositional analysis relates to the food safety evaluation; (3) what FDA means by a ''significant change'' with respect to durability; (4) what can be included in a single IGA-related application; (5) what methods, including methods other than whole genome sequencing, may be most appropriate for molecular characterization of the lineage of animals with the IGA; (6) further clarification regarding data expectations, including what data constitutes a ''full characterization'' of the site of alteration and potential unintended alterations; and (7) more detailed information on review timelines. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated May 2024.

This level 1 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 ''Heritable Intentional Genomic Alterations in Animals: The Approval Process.'' 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 25 have been approved under OMB control number 0910–0322; the collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; the collections of information in 21 CFR part 207 have been approved under OMB control number 0910–0045; 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 part 511 have been approved under OMB control number 0910–0117; the collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0284; and the collections of information in 21 CFR 558.6(a)(4) have been approved under OMB control number 0910–0363.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4689]

Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products; Draft Guidance for Industry; Availability; Comment Request

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 guidance for industry entitled ''Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products.'' In accordance with its mission of protecting, promoting, and advancing public health, FDA's Center for Drug Evaluation and Research (CDER), in collaboration with the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), the Center for Veterinary Medicine (CVM), the Oncology Center of Excellence (OCE), the Office of Combination Products (OCP), and the Office of Inspections and Investigations (OII), is issuing this draft guidance to provide recommendations to industry on the use of artificial intelligence (AI) to produce information or data intended to support regulatory decision-making regarding the safety, effectiveness, or quality for drug and biological products.

DATES: Submit either electronic or written comments on the draft guidance by April 7, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by April 7, 2025.

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'').

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- *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.