Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0611, *lynne.boxer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #260 entitled ''Type VII Veterinary Master File for Research and Development and Risk Reviews.'' A Type VII VMF is a file that can receive submissions to FDA's Center for Veterinary Medicine (CVM) that may contain confidential data and information related to unique regulatory considerations such as research and development of an ACTP, an IGA in an animal, gene therapy, or a risk review for an ACTP or IGA in an animal, where the information submitted is generally not intended to support product approval. The benefits of a Type VII VMF include: (1) confidential exchange of information with FDA that is not subject to user fees, (2) an opportunity for increased communication with FDA during early stages of product development, and (3) a process for reporting research studies outside of an investigational file.

The scope of this draft guidance is limited to the use of Type VII VMFs for research and development and risk review requests. There are other uses of Type VII VMFs, but they are not addressed in this draft guidance.

The use of a Type VII VMF is appropriate for research and development of ACTPs, gene therapies, and IGAs in animals, and for risk review of ACTPs and IGAs in animals because, for these types of novel products and rapidly evolving technologies, there may be unique regulatory considerations, concerning different types of issues, that may call for a developer's interactions with CVM at an earlier stage than would normally take place with traditional products that CVM regulates. As described in the draft guidance, developers should open a Type VII VMF to cover these interactions with CVM.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Type VII Veterinary Master File for Research and Development and Risk Reviews. 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 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, 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.

[FR Doc. 2024–31531 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4778]

Heritable Intentional Genomic Alterations in Animals of Food-Producing Species for Use as Models of Disease; 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 for industry (GFI) #251 entitled ''Heritable Intentional Genomic Alterations in Animals of Food-Producing Species for Use as Models of Disease.'' This draft guidance, when finalized, will set forth FDA's policy regarding heritable intentional genomic alterations (IGAs) in animals of food-producing species, such as swine and rabbits, that are intended to be marketed for use as models of human or animal disease in biomedical research under contained and controlled conditions. The draft guidance describes the conditions under which we generally may not expect developers of IGAs in animal models of disease to submit an application to FDA's Center for Veterinary Medicine (CVM) or to get our approval before marketing their animals following CVM's prior review of risk factor data.

DATES: Submit either electronic or written comments on the draft guidance by March 10, 2025 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–2024–D–4778 for ''Heritable Intentional Genomic Alterations in Animals of Food-Producing Species for Use as Models of Disease.'' 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 (HFV–6), 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 draft 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

FDA is announcing the availability of a draft guidance for industry #251 entitled ''Heritable Intentional Genomic Alterations in Animals of Food-Producing Species for Use as Models of Disease.'' This guidance, when finalized, will set forth FDA's policy regarding IGAs in animals of food-producing species, such as swine and rabbits, that are intended to be marketed for use as models of human or animal disease in biomedical research under contained and controlled conditions (IGAs in animal models of disease). This research may be basic research of general applicability (*e.g.,* understanding the underlying pathophysiology of a disease or disease processes) or it may be research or pre-clinical testing for a particular medical product that may support an application for product approval (*e.g.,* preclinical trials of safety or effectiveness in altered animal models closely resembling human disease).

In the **Federal Register** of May 2, 2024 (89 FR 35834), we announced the availability of final GFI #187A entitled ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach.'' GFI #187A clarifies that heritable IGAs in animals are subject to FDA oversight and are regulated according to our risk-based regulatory approach. GFI #187A indicates that while, in general, FDA approval of IGAs in animals is required, under certain conditions we do not expect developers of IGAs in animals to submit an application or get our approval before marketing their product following our prior review of risk factor data. Among these IGAs are those that GFI #187A describes as Category 2, for which we may not expect developers to submit an application for approval if, after analyzing data submitted about a product's risks, we find we understand the product's risks for the specified intended use; any identified risks, including their potential severity and likelihood of occurring, are appropriately mitigated; and we have no further questions for which we would need to see additional data.

In this draft GFI #251, we address those circumstances under which we may not expect developers to submit an application for approval of an IGA in an animal model of disease if, after looking at data submitted about that product's risk, we determine that it appropriately fits in Category 2. FDA believes that IGAs in animal models of disease are likely to fit in Category 2 in part because the animals are unlikely to enter the food supply or to escape and establish themselves in the environment. For these reasons, based on case-by-case evaluation of data and information as described in draft GFI #251, we may determine that IGAs in an animal model of disease fits in Category 2, and we do not expect developers of these IGAs to submit an application for approval to us prior to marketing.

This level 1 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 ''Heritable Intentional Genomic Alterations in Animals of Food-Producing Species for Use as Models of Disease.'' 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 514 have been approved under OMB control number 0910–0032; the collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; and the collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the draft 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.

[FR Doc. 2024–31530 Filed 1–6–25; 8:45 am]

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