are categories of IGAs in animals that pose less risk and, if so, what data or information supports that contention. No commenters provided data to address the Agency's questions other than scientific literature references that were not directly applicable or conclusive.

In the notice announcing availability of the draft guidance, FDA also asked for comment on the appropriate terminology for animals with intentional genomic alterations. Commenters expressed different preferences, but there was no general consensus on an appropriate term. FDA has adopted ''intentional genomic alteration'' or ''IGA'' in animals as the term it will use to refer to intentional genomic alterations in animals regardless of whether they are developed with genetic engineering, including genome editing, or some other modern molecular technology. This term is simple and sufficiently broad to encompass intentional genomic alterations achieved through means that currently exist and those yet to be developed. Moreover, section 740(d)(4)(B) of the Federal Food, Drug, and Cosmetic Act uses this term (21 U.S.C. 379j-12(d)(4)(B)). However, the scope of the guidance does not include induction of polyploidy by heat, pressure, or chemical treatment, or selective breeding or other assisted reproductive technologies. Non-heritable intentional genomic alterations in animals are also outside the scope of this guidance document.

Changes FDA has made in response to comments include:

- Reorganization and use of plain language to make FDA's regulatory approach clearer to stakeholders;
- Expansion of IGAs for which FDA may decide it does not expect submission of an application for approval following a review of data and a determination that the IGA meets the Category 2 description in the guidance. The new types of IGAs include:
  - IGAs that are equivalent to genomic sequences that are found in animals of the same species with a history of safe use in animal agriculture food production and
  - IGAs that are equivalent to what could be theoretically achieved through conventional breeding under certain conditions,

including that the IGAs are not expected to result in changes to food composition and their intended use does not include any effect on disease or other health outcome;

- Clarification that if you are:
  - ;a farmer, grower, or other entity that just has animals with IGAs that FDA has approved or determined are Category 2 on your farm or other premises, including the offspring of those animals,
  - and you are not the developer of the IGA in the animal or marketing the animals with any new claims,

then, as a general matter, you do not have to register or list with FDA and you can engage in your ordinary activities (*e.g.,* breeding, growing, etc.) without contacting FDA; and

- Clarification that those who breed an animal containing an IGA that FDA has approved or has determined is Category 2:
  - with another animal containing an IGA that FDA has approved or also determined is Category 2 or
  - with an animal that does not contain an IGA

and make no new claims do not need to contact FDA and nothing further is required.

The guidance announced in this notice finalizes the draft guidance dated January 2017.

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: Risk-Based Approach.'' 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 regarding environmental analysis in 21 CFR part 25 have been approved under OMB control number 0910–0322; the collections of information regarding applications in 21 CFR part 514 have been approved under OMB control number 0910–0284; and the collections of information regarding investigational exemptions in 21 CFR part 511 have been approved under OMB control number 0910–0117.

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: April 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09278 Filed 5–1–24; 8:45 am]

BILLING CODE 4164–01–P

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; 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) #187B entitled ''Heritable Intentional Genomic Alterations in Animals: The Approval Process.'' This draft guidance is intended to clarify FDA's requirements and recommendations for developers of intentional genomic alterations (IGA) in animals. The draft guidance is being issued as 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. FDA is issuing GFI #187B as a draft guidance to solicit comments that will enable the Agency to update, and make as efficient as possible, the approval process for IGAs in animals. In addition, FDA requests comments on questions that it intends to address in the final version of this guidance document. 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. This means that, for people or companies developing certain types of IGAs in animals, FDA may not expect them to submit an application or get approval before marketing their product.

DATES: Submit either electronic or written comments on the draft guidance by July 31, 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–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 (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

In the **Federal Register** of January 19, 2017 (82 FR 6561), FDA published the notice of availability for a draft GFI #187 entitled ''Regulation of Intentionally Altered Genomic DNA in Animals'' giving interested persons until April 19, 2017, to comment on the draft guidance. On April 13, 2017, we published a notice announcing the extension of the comment period to June 19, 2017 (82 FR 17844). FDA received numerous comments on the draft guidance GFI #187 and those comments were considered as the guidance was revised. As noted, this draft guidance, GFI #187B, is intended to explain how FDA's approval process applies in the context of products related to heritable IGAs in animals.

The draft guidance is being issued as one of two companion documents. Draft GFI #187B, ''Heritable Intentional Genomic Alterations in Animals: The Approval Process,'' describes how the FDA approval process applies to heritable IGAs in animals. Final GFI #187A, ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach,'' whose notice of availability is published elsewhere in this edition of the **Federal Register**, describes FDA's risk-based approach to the oversight of IGAs in animals.

FDA received and reviewed comments on the draft guidance that came from industry (companies that produce IGAs and trade associations), individual consumers, academics, non-governmental organizations (consumer, environmental), other Federal and State government agencies, and individual developers of IGAs in animals. Among the changes made to the draft guidance, we have:

- Indicated our willingness to consider multiple heritable IGAs or a single IGA in multiple lines or breeds of animals of the same species under a single application;
- Clarified that FDA's review of applications is subject to specific timeframes;
- Acknowledged that it may not be feasible to gather data on multiple generations and encourage developers of heritable IGAs in animals to contact FDA to discuss alternative approaches of demonstrating durability;
- Indicated that alternative disposition methods for investigational animals may be acceptable if the sponsor contacts FDA's Center for Veterinary Medicine;
- Further described post-market records and reports requirements and clarified who they apply to; and
- Provided additional information on establishment registration requirements, including explaining that, as a general matter, pet stores, farms, or other animal production facilities do not have to register or list with FDA and can engage in ordinary activities (*e.g.,* breeding, growing, etc.) without contacting FDA.

FDA is issuing this draft guidance to solicit public comment that will further

improve it. To help inform our thinking as we begin the process of further updating the guidance, we invite comment on the following questions:

1. What are some alternative strategies for providing data that would support approval of heritable IGAs in animals?

a. How can a developer demonstrate the durability of a heritable IGA over time in situations where collection of data on multiple generations of animals is difficult or not possible?

b. What are possible strategies a developer could utilize to address the approval requirements for multiple heritable IGAs (*e.g.,* multiple iterations of the same alteration resulting in the same intended phenotype or multiple alterations resulting in more than one intended phenotype) under a single approval?

2. What areas of current good manufacturing practices and good laboratory practices specific to the production of heritable IGAs in animals do you believe need clarification through the publication of additional guidance?

3. Are there process improvements (*e.g.,* combining steps of the approval process) (see page 16, section IV.C. Recommended Process for Completing Pre-approval Assessments for IGAs in Animals, of the guidance) that you believe would make the approval process easier to navigate?

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: 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 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: April 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09279 Filed 5–1–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5018]

Angela Maria Giron: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Angela Maria Giron, M.D. from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Giron was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Dr. Giron was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of February 16, 2024 (30 days after receipt of the notice), Dr. Giron has not responded. Dr. Giron's failure to respond and request a hearing constitutes a waiver of Dr. Giron's right to a hearing concerning this matter.

DATES: This order is applicable May 2, 2024.

ADDRESSES: Any application by Dr. Giron for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–5018. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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