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This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Heritable Intentional Genomic Alterations in Animals: The Approval Process.''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

''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. 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. 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, 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 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

**FOR FURTHER INFORMATION CONTACT:** Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, at 240–402–8743, or *debarments@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 306(a)(2)(A) of the FD&C Act requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product. On September 11, 2023, Dr. Giron was convicted as defined in section 306(l)(1) of the FD&C Act in the United States District Court for the Southern District of Florida-Miami Division when the court accepted her plea of guilty and entered judgment against her for one count of Conspiracy to defraud the United States in violation of 18 U.S.C. 371. The underlying facts supporting the conviction are as follows: As contained in the Information and the Factual Proffer in Support of Guilty Plea, from Dr. Giron's case, she was a licensed physician and served as a clinical investigator at AMB Research Center, Inc. (AMB), a medical clinic located in Miami, Florida. AMB conducted clinical trials of new drugs for pharmaceutical companies and other sponsors. AMB entered into a Clinical Trial Agreement with a Clinical Research Organization (CRO) that managed and oversaw a clinical trial designed to evaluate the safety and efficacy of an investigational drug intended to treat persons with Clostridium difficile-associated diarrhea (CDAD clinical trial) on behalf of a sponsor (a pharmaceutical company). Dr. Giron agreed to serve as the clinical investigator, also known as the principal investigator, for the CDAD clinical trial at AMB and signed the Form FDA 1572, Statement of Investigator, for the CDAD clinical trial. By signing the Form FDA 1572, she knew that as the clinical investigator she was required to, among other things, (1) conduct the CDAD clinical trial according to the study protocol and in compliance with all applicable Federal regulations; (2) personally conduct and supervise the CDAD clinical trial; (3) obtain informed consent from the subjects; and (4) comply with the clinical trial protocol and applicable Federal regulations relating to obtaining informed consent and the informed consent process.

As the CDAD principal investigator, Dr. Giron was also responsible for complying with all requirements regarding the eligibility of subjects in accordance with the protocol; dispensing study medication; collecting and reporting data; reporting adverse events; and ensuring that all employees working on the study met those same obligations. Dr. Giron was also required to prepare and maintain case histories which were records relating to the CDAD clinical trial. These case histories for each subject participating in the CDAD clinical trial included informed consent forms and medical records, drug dispensation records, and records of all observations and other data pertinent to the CDAD clinical trial.

For purposes of obtaining money from the Sponsor and/or CRO, Dr. Giron, along with her co-conspirators, created false and fraudulent study records. For example, electronic case record files (eCRFs) falsely represented that the subjects completed the informed consent form (ICF) process, which required Dr. Giron to review the ICF with each subject and personally obtain the subject's written informed consent. In truth and fact, Dr. Giron did not obtain written informed consent for any of the 22 subjects enrolled in the CDAD clinical trial. Dr. Giron knew that the study subjects did not participate in the CDAD clinical trial in accordance with the study protocol and applicable Federal regulations.

In addition, along with her co-conspirators, Dr. Giron falsified data of enrolled subjects in the CDAD clinical trial. For example, Dr. Giron did not conduct the required clinical investigator assessments at the second, third and fifth visits. She also knew that falsified and fraudulent information was submitted in case report forms and eCRFs falsely representing she had completed those required assessments according to the protocol. Furthermore, Dr. Giron also knew that false information and data was submitted in the case report forms and eCRFs representing that the subjects had satisfied eligibility criteria to participate in the CDAD clinical trial, received and taken the study medication, and completed the required documents and journals.

After an on-site audit of AMB by the Sponsor in April 2017, the Sponsor notified the FDA in writing of potential scientific misconduct by AMB. The Institutional Review Board for the CDAD clinical trial sent AMB a copy of the Sponsor's notification to FDA. Dr. Giron, along with a co-conspirator, signed a letter entitled ''Site response to the Notification of Potential Scientific Misconduct.'' At the time of signing that response letter Dr. Giron knew that it contained materially false and fraudulent representations including that (1) she was present for all subjects' informed consent and gave each subject the time to understand, read, and resolve any questions prior to signing the informed consent form; (2) AMB took special care with ICF signatures and the ICF process to ensure that subjects understood the study and its risks and could make an informed decision whether to participate; (3) all participating subjects had completed the study treatment and follow up visits; and (4) she and AMB site staff acted in accordance with the study protocol to the best of their knowledge. Dr. Giron received $58,119.60 in proceeds for the CDAD clinical trial. AMB received more than $250,000 for the CDAD clinical trial.

As a result of this conviction, FDA sent Dr. Giron, by certified mail, on January 10, 2024, a notice proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A), that Dr. Giron was convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug

product. The proposal informed Dr. Giron of the proposed debarment and offered her an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Giron received the proposal and notice of opportunity for a hearing on January 17, 2024. Dr. Giron failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

## II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Angela Maria Giron, M.D. has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product.

As a result of the foregoing finding, Dr. Giron is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(A) and 306(c)(2)(A)(ii) of the FD&C, (335a(c)(2)(A)(ii))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Dr. Giron during her debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Giron provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Dr. Giron during her period of debarment, other than in connection with an audit under section 306 of the FD&C Act. Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262)'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: April 29, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–09528 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–2024–N–1464]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drugs for Investigational Use

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements of our regulations concerning new animal drugs for investigational use.

**DATES:** Either electronic or written comments on the collection of information must be submitted by July 1, 2024.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 1, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*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–N–1464 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drugs for Investigational Use.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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