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

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.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

New Animal Drugs for Investigational Use—21 CFR 511

OMB Control Number 0910–0117—Extension

This information collection helps support implementation of Agency statutory and regulatory requirements regarding the approval of new animal drugs. FDA has the authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to approve new animal drugs. A new animal drug application (NADA) cannot be approved until, among other things, the new animal drug has been demonstrated to be safe and effective for its intended use(s). In order to properly test a new animal drug for an intended use, appropriate scientific investigations must be conducted. Under specific circumstances, section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) permits the use of an investigational new animal drug to generate data to support a NADA approval. Section 512(j) of the FD&C Act authorizes us to issue regulations relating to the investigational use of new animal drugs.

Our regulations in part 511 (21 CFR part 511) set forth the conditions for investigational use of new animal drugs and require reporting and recordkeeping to qualify for the exemption from section 512(a) of the FD&C Act. The information collected is necessary to protect the public health. We use the information to determine that investigational animal drugs are distributed only to qualified investigators, adequate drug accountability records are maintained, and edible food products from treated food-producing animals are safe for human consumption. We also use the information collected to monitor the validity of the studies submitted to us to support new animal drug approval.

Our regulations require that certain information be submitted to us in a ''Notice of Claimed Investigational Exemption for a New Animal Drug'' (NCIE) to qualify for the exemption and to control shipment of the new animal drug and prevent potential abuse. We also require reporting by importers of investigational new animal drugs for clinical investigational use in animals (§ 511.1(b)(9)). The information provided by the sponsor in the NCIE is needed to help ensure that the proposed investigational use of the new animal drug is safe and that any edible food will not be distributed without proper authorization from FDA. Information contained in an NCIE submission is monitored under our Bioresearch Monitoring Program. This program permits us to monitor the validity of the studies and to help ensure the proper use of the drugs is maintained by the investigators.

Sponsors use eSubmitter, a secure online, question-based submission tool, to submit the NCIE electronically (*https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-programs*).

Description of Respondents: Respondents to this collection of information are persons who use new animal drugs for investigational purposes. Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government (*i.e.,* sponsors of investigational new animal drugs). Investigators may include individuals from these entities, as well as research firms and members of the medical professions. With respect to this information collection, the term respondent includes sponsors who are subject to user fees and sponsors who are not subject to user fees.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

21 CFR section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
511.1(b)(4), 511.1(b)(5) 511.1(b)(6) 511.1(b)(8)(ii), and 511.1(b)(9); submissions of NCIE, data to obtain authorization, any additional information upon request of FDA, reporting of findings that may suggest significant hazards, and reporting by importers of investigational new animal drugs for clinical investigational use in animals ...	257	5.70	1,466	1.12	1,634

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals may not sum due to rounding.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 CFR section/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
511.1(a)(3), 511.1(b)(3), 511.1(b)(7), and 511.1(b)(8)(ii); Maintain records showing the name and post office address of the expert or expert organization to whom the new animal drug, or feed containing the same is shipped and the date, quantity, and batch or code mark of each shipment and delivery; maintain records of the investigation and all reports received by a sponsor from investigators	257	17.44	4,482	2.57	11,519

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals may not sum due to rounding.

The NCIE must contain, among other things, the following specific information: (1) identity of the new animal drug, (2) labeling, (3) statement of compliance of any non-clinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals (§ 511.1(b)(4)). If the new animal drug is to be used in food-producing animals (*e.g.,* cattle, swine, chickens, fish, etc.), certain data must be submitted to us to obtain authorization for the use of edible food products from treated food-producing animals (§ 511.1(b)(5)). We require sponsors upon request to submit information with respect to the investigation to determine whether there are grounds for terminating the exemption (§ 511.1(b)(6)). We require sponsors to report findings that may suggest significant hazards pertinent to the safety of the new animal drug (§ 511.1(b)(8)(ii)).

If the new animal drug is only for tests in vitro or in laboratory research animals, the person distributing the new animal drug must maintain records showing the name and post office address of the expert or expert organization to whom it is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery (§ 511.1(a)(3) and (b)(3)).

We require complete records of the investigation, including records of the receipt and disposition of each shipment or delivery of the investigational new animal drug (§ 511.1(b)(7)). We also require records of all reports received by a sponsor from investigators to be retained for 2 years after the termination of an investigational exemption or approval of a new animal drug application (§ 511.1(b)(8)(i)).

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on our informal communication with industry. Based on the number of sponsors subject to animal drug user fees, we estimate that there are 257 respondents. We use this estimate throughout both tables to calculate the ''number of responses per respondent'' by dividing the total annual responses by number of respondents. The burden we attribute to reporting and recordkeeping activities is assumed to be distributed among the individual elements of the respective information collection activities.

Additional information needed to make a final calculation of the total burden hours (*i.e.,* the number of respondents, the number of recordkeepers, the number of NCIEs received, etc.) is derived from our records. There is a decrease in the total burden hours of 2,401, which we attribute to a decrease in the number of respondents as well as the number of annual responses and records.

Dated: April 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09526 Filed 5–1–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1940]

Request for Nominations of a Nonvoting Representative of the Interest of Tobacco Growers on the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for a nonvoting representative of the interests of the tobacco growers to serve on the Tobacco Products Scientific Advisory Committee (TPSAC), in the Center for Tobacco Products. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and