respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–15149 Filed 7–13–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0341]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drugs for Investigational Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 15, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0117. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

New Animal Drugs for Investigational Use

OMB Control Number 0910–0117—Extension

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 an 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 21 CFR part 511 set forth the conditions for investigational use of new animal drugs and require reporting and recordkeeping. 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.

Reporting: 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. 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 nonclinical 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) (21 CFR 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)). 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 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 Bio-Research Monitoring Program. This program permits us to monitor the validity of the studies and to ensure the proper use of the drugs is maintained by the investigators.

Recordkeeping: 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)).

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. Investigators may include individuals from these entities, as well as research firms and members of the medical professions.

In the **Federal Register** of February 22, 2018 (83 FR 7735), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

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); submission of NCIE	104	15.38	1,600	1	1,600
511.1(b)(5); submission of data to obtain authorization for the use of edible food products	104	0.30	31	8	248
511.1(b)(6); submission of any additional information upon request of FDA	104	0.02	2	1	2
511.1(b)(8)(ii); reporting of findings that may suggest significant hazards pertinent to the safety of the new animal drug	104	0.14	15	2	30
511.1(b)(9); reporting by importers of investigational new animal drugs for clinical investigational use in animals	104	0.14	15	8	120
Total			1,663		2,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

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); maintain records showing the name and post office address of the expert or expert organization to whom the new animal drug 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	104	2.5	260	1	260
511.1(b)(3); maintain records showing the name and post office address of the expert or expert organization to whom the new animal drug or feed containing same 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	104	15.38	1,600	1	1,600
511.1(b)(7); maintain records of the investigation, including records of the receipt and disposition of each shipment or delivery of the investigational new animal drug	104	15.38	1,600	3.5	5,600
511.1(b)(8)(i); maintain records of all reports received by a sponsor from investigators	104	15.38	1,600	3.5	5,600
Total			5,060		13,060

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

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 104 respondents. We use this estimate consistently throughout the table and calculate the ''number of responses per respondent'' by dividing the total annual responses by number of respondents. 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. The burden for this information collection has changed since the last OMB approval. We estimate an overall increase in burden that we attribute to an increase in the number of annual responses and records.

Dated: July 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–15087 Filed 7–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2515]

Hypertension: Conducting Studies of Drugs To Treat Patients on a Background of Multiple Antihypertensive Drugs; Draft 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 draft guidance for industry entitled ''Hypertension: Conducting Studies of Drugs to Treat Patients on a Background of Multiple Antihypertensive Drugs.'' This draft guidance is intended to clarify the recommended approach for sponsors developing drugs to treat hypertension for patients who are on a background of multiple antihypertensive drugs.

DATES: Submit either electronic or written comments on the draft guidance by September 14, 2018 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: