4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0481]

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

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 [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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 Uses--21 CFR Part 511

OMB Control Number 0910-0117--Extension

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to approve new animal drugs. Section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) authorizes FDA to issue regulations relating to the investigational use of new animal drugs. The regulations setting forth the conditions for investigational use of new animal drugs have been codified at part 511. 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. Before shipping a new animal drug for clinical investigations in animals, a sponsor must submit to FDA a Notice of Claimed Investigational Exemption (NCIE). 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. Part 511 also requires that records be established and maintained to document the distribution and use of the

investigational new animal drug to assure that its use is safe, and that the distribution is controlled to prevent potential abuse. The Agency uses these required records under its Bioresearch Monitoring Program to monitor the validity of the studies submitted to FDA to support new animal drug approval and to assure that proper use of the drug is maintained by the investigator.

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. Respondents to this collection of information are the persons who use new animal drugs for investigational purposes.

In the Federal Register of April 2, 2015 (80 FR 17758), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received but neither responded to any of the four information collection topics solicited and are therefore not addressed by the Agency.

FDA estimates the burden of this information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
511.1(b)(4)	263	5.30	1,395	1	1,395
511.1(b)(5)	263	.26	69	8	552
511.1(b)(6)	263	.01	2	1	2
511.1(b)(8)(ii)	263	.06	15	2	30
511.1(b)(9)	263	.06	15	8	120
Total					2,099

[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	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
511.1(a)(3)	263	2.07	545	1	545
511.1(b)(3)	263	5.30	1,395	1	1,395
511.1(b)(7)(ii)	263	5.30	1,395	3.5	4,882.5
511.1(b)(8)(i)	263	5.30	1,395	3.5	4,882.5
Total					11,705

[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 informal Agency communication with industry. Based on the number of sponsors subject to animal drug user fees, FDA estimates that there are 263 respondents. We use this estimate consistently throughout the table and calculate the "annual frequency 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 Agency records.

Dated: June 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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