4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0628]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Associated with New Animal Drug Applications

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 0910-0032. 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.

Reporting Associated with New Animal Drug Applications (NADA)--21 CFR 514.1, 514.4, 514.5, 514.6, 514.8, 514.11, 558.5--

OMB Control Number 0910-0032--Extension

Under Section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(b)(1)), any person may file a new animal drug application (NADA) seeking our approval to legally market a new animal drug. Section 512(b)(1) sets forth the information required to be submitted in a NADA. Sections 514.1, 514.4, 514.6, 514.8, and 514.11 of our regulations (21 CFR 514.1, 514.4, 514.6, 514.8, and 514.11) further specify the information that the NADA must contain. The application must include safety and effectiveness data, proposed labeling, product manufacturing information and, where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food producing animals. FDA Guidance #152 outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs. We request that applicants utilize Form FDA 356V, as appropriate, to ensure efficient and accurate processing of information to support new animal drug approval.

Under section 512(b)(3) of the FD&C Act, any person intending to file a NADA or supplemental NADA or a request for an investigational exemption under section 512(j) of the FD&C Act is entitled to one or more conferences with us prior to making a submission. Section 514.5 of our regulations (21 CFR 514.5) describes the procedures for requesting, conducting, and documenting pre-submission conferences. We have found that these meetings have increased the efficiency of the drug development and drug review processes. We encourage sponsors to

submit data for review at the most appropriate and productive times in the drug development process. Rather than submitting all data for review as part of a complete application, we have found that the submission of data supporting discrete technical sections during the investigational phase of the new animal drug is the most appropriate and productive. This "phased review" of data submissions has created efficiencies for both us and the animal pharmaceutical industry.

Finally, § 558.5(i) of our regulations (21 CFR 558.5(i)) describes the procedure for requesting a waiver of the labeling requirements of § 558.5(h) in the event that there is evidence to indicate that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed.

The reporting associated with NADAs and related submissions is necessary to ensure that new animal drugs are in compliance with section 512(b)(1) of the FD&C Act. We use the information collected to review the data, labeling, and manufacturing controls and procedures to evaluate the safety and effectiveness of the proposed new animal drug.

In the Federal Register of March 2, 2016 (81 FR 10871), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

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

21 CFR Section; Activity	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Avg. Burden Per Response	Total hours
514.1 & 514.6; applications and amended applications	182	.05	9	212	1,908
514.1(b)(8) and 514.8(c)(1)[2]; evidence to establish safety and effectiveness	182	.10	19	90	1,710
514.5(b), (d), (f); requesting presubmission conferences	182	.49	89	50	4,450
514.8(b); manufacturing changes to an approved application	182	1.40	255	35	8,925
514.8(c)(1); labeling and other changes to an approved application	182	.05	10	71	710

514.8(c)(2) & (3); labeling and other changes to an approved application	182	.43	79	20	1,580
514.11; submission of data, studies and other information	182	.09	16	1	16
558.5(i); requirements for liquid medicated feed	182	.01	1	5	5
Form FDA 356V	182	2.92	531	5	2,655
TOTAL			1009		21,959

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall pre-approval safety evaluation.

Based on the number of sponsors subject to animal drug user fees, we estimate an average of 182 annual respondents during the 5 fiscal years, from October 1, 2010, through September 30, 2014, on which these estimates were made. We use this estimate consistently throughout the table and calculate the "annual frequency per respondent" by dividing the total annual responses by the total number of respondents. We base our estimates of the average burden per response on our experience with NADAs and related submissions.

Dated: May 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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