4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0450]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Abbreviated 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 0910-0669. 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, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 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.

Abbreviated New Animal Drug Applications—Sections (b)(2) and (n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)(2) and (n)(1)) --

OMB Control Number 0910-0669—Extension

Under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), any person may file an abbreviated new animal drug application (ANADA) seeking approval of a generic copy of an approved new animal drug. The information required to be submitted as part of an ANADA is described in section 512(n)(1) of the FD&C Act. Among other things, an ANADA is required to contain information to show that the proposed generic drug is bioequivalent to, and has the same labeling as, the approved new animal drug. We use the information submitted, among other things, to assess bioequivalence to the originally approved drug and thus, the safety and effectiveness of the generic new animal drug. We allow applicants to submit a complete ANADA or to submit information in support of an ANADA for phased review. Applicants may submit Form FDA 356v with a complete ANADA or a phased review submission to ensure efficient and accurate processing of information.

In the **Federal Register** of May 11, 2016 (81 FR 29273), 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]

FD&C Act Sections 512 (b)(2) and (n)(1)	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours

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

FD&C Act Sections 512 (b)(2) and (n)(1)	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
ANADA	356v	18	1	18	159	2,862
Phased Review with Administrative ANADA	356v	3	5	15	31.8	477
Total						3,339

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

We base our estimates on our experience with ANADA submissions and requests for phased review. We estimate that we will receive 21 ANADA submissions per year over the next three years and that three of those submissions will request phased review. We estimate that each applicant that uses the phased review process will have approximately five phased reviews per application. We estimate that an applicant will take approximately 159 hours to prepare either an ANADA or the estimated 5 ANADA phased review submissions and the administrative ANADA.

Dated: August 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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