4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1517]

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: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, 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--Section 512(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 (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 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. 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 believe the demonstration of bioequivalence required by the statute does not need to be established on the basis of in vivo studies (blood level bioequivalence or clinical endpoint bioequivalence) for soluble powder oral dosage form products and certain Type A medicated articles. We are adding to this information collection applicant requests to waive the requirement to establish bioequivalence through in vivo studies (biowaiver requests) for soluble powder oral dosage form products or certain Type A medicated articles based upon either of two methods. We will consider granting a biowaiver request if it can be shown that the generic

soluble powder oral dosage form product or Type A medicated article contains the same active and inactive ingredient(s) and is produced using the same manufacturing processes as the approved comparator product or article. Alternatively, we will consider granting a biowaiver request without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s) (API) is the same as the pioneer product, is soluble, and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. We use the information submitted by applicants in the biowaiver request as the basis for our decision whether to grant the request.

Additionally, we have found that various uses of veterinary master files have increased the efficiency of the drug development and drug review processes for both us and the animal pharmaceutical industry. A veterinary master file is a repository for submission to FDA's Center for Veterinary Medicine of confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more veterinary drugs. Veterinary master files are used by the animal pharmaceutical industry in support of information being submitted for new animal drug applications (NADAs), ANADAs, investigational new animal drug (INAD) files, and generic investigational new animal drug (JINAD) files. In previous information collection requests, we included the time necessary to compile and submit such information to veterinary master files within the burden estimates provided for applications and amended applications (for NADAs and INAD files) and abbreviated applications and amended abbreviated applications (for ANADAs and JINAD files), respectively. We recently combined the time necessary to compile and submit such information to veterinary master files within the burden estimates provided in the collection of information supporting new animal drug applications (OMB control number 0910-0032).

The reporting associated with ANADAs and related submissions is necessary to ensure that new animal drugs are in compliance with section 512(b)(2) of the FD&C Act. As noted, 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.

Description of Respondents: The respondents for this collection of information are veterinary pharmaceutical manufacturers.

In the *Federal Register* of April 18, 2019 (84 FR 16270), 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]

Activity	FDA Form No.	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
Biowaiver request for soluble powder oral dosage form product, using same formulation/manufacturing process approach	N/A	1	1	1	5	5
Biowaiver request for soluble powder oral dosage form product, using same API/solubility approach	N/A	5	1	5	10	50
Biowaiver request for Type A medicated article, using same formulation/manufacturing process approach	N/A	2	1	2	5	10
Biowaiver request for Type A medicated article, using same API/solubility approach	N/A	10	1	10	20	200
Total				51		3,604

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

We base our estimates on our records of generic drug applications. We estimate that we will receive 21 ANADA submissions per year over the next 3 years and that 3 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 five ANADA phased review submissions and the administrative ANADA. Our estimates of the burden of biowaiver requests for generic soluble powder oral dosage form products and Type A medicated articles differ based on the type of product and the basis for the request, as shown in table 1. We estimate that an applicant will take between 5 and 20 hours to prepare a biowaiver request.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our previous estimate of the number of respondents submitting generic drug applications. However, as discussed, the burden for this information collection was increased by 265 hours and 18 responses since the last OMB approval. This is due to adding to this collection burden hours and responses for biowaiver requests.

Dated: August 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-19078 Filed: 9/3/2019 8:45 am; Publication Date: 9/4/2019]