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Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Bryan Spells, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993-0002, Bryan.Spells@fda.hhs.gov, 240-402-6511; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911; Norman Gregory, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl. (HFV-143), Rockville, MD 20855, Norman.Gregory@fda.hhs.gov, 240-402-0684; or Michael Kerrigan, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl. (HFV-143), Rockville, MD 20855, 240-402-0644, Michael.Kerrigan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

PQ/CMC is a term used to describe manufacturing and testing data of pharmaceutical products. PQ/CMC encompasses topics such as drug stability, quality specification, batch formula, and batch analysis, which are important aspects of drug development. PQ/CMC plays an integral part in the regulatory review process and life cycle management of pharmaceutical products. The development of a structured format for PQ/CMC data will enable consistency in the content and

format of PQ/CMC data submitted, thus providing a harmonized language for submission content, allowing reviewers to query the data, and, in general, contributing to a more efficient and effective regulatory decision-making process by creating a standardized data dictionary.

The impetus for this standardization effort was the provisions from the 2012 Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), which authorized the Agency to require certain submissions to be submitted in a specified electronic format. PQ/CMC standardization supports FDA’s regulatory needs in receiving structured and standardized data in pharmaceutical quality and includes two objectives: (1) To standardize the pharmaceutical quality data that is currently received by FDA in eCTD Module 3 from the sponsoring organizations, and (2) to use these structured elements and develop a FHIR data exchange solution.

Through this notice, the Agency is seeking comment on the mapping of the PQ/CMC data elements to the various FHIR Resources. After receiving comments, the Agency intends to issue guidance on the standardization of PQ/CMC data elements and terminologies for electronic submissions.

II. Electronic Access

Persons with access to the internet may obtain the draft data elements and terminologies at either <https://www.fda.gov/industry/fda-resources-data-standards> or <https://www.regulations.gov>.

Dated: March 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; Comment Request; Abbreviated New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency.

Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of abbreviated new animal drug applications.

DATES: Submit either electronic or written comments on the collection of information by May 17, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 17, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 17, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets

Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2019-N-1517 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Abbreviated New Animal Drug Applications.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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. Form FDA 356v is approved under OMB control number 0910-0032. 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.

The information collection also includes 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 use the information submitted by applicants in the biowaiver request as the basis for our decision whether to grant the request. Therefore, the information collection references the guidance document GFI #171—Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Containing Active Pharmaceutical Ingredients Considered to Be Soluble in Aqueous Media, which discusses statutory bioequivalence requirements as well as qualifications for requesting a waiver from the requirements. The guidance can be viewed on our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-171-demonstrating-bioequivalence-soluble-powder-oral-dosage-form-products-and-type-medicated>.

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. 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
ANADA	356v	20	1	20	159	3,180
Phased review with administrative ANADA	356v	6	5	30	31.8	954
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	5	1	5	20	100
Total				63		4,299

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 animal drug applications. We estimate that we will receive 26 ANADA submissions per year over the next 3 years and that 6 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.

Our estimated burden for the information collection reflects an overall increase of 695 hours and a corresponding increase of 12 responses. Based on a review of the information collection since our last request for OMB renewal, the increase in the burden hours estimate is attributable to an increase in the number of respondents submitting generic drug applications.

Dated: March 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-05782 Filed 3-17-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; SHIP COVID-19 Testing and Mitigation Program Data Collection, OMB No. 0906-0066—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than April 18, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the acting HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: SHIP COVID-19 Testing and Mitigation Program Data Collection OMB No. 0906-0066—Extension.

Abstract: The American Rescue Plan Act of 2021 (Pub. L. 117-2) provided one-time funding for awards that will be carried out under section 711 of the Social Security Act (42 U.S.C. 912(b)(5)). The Small Rural Hospital Improvement Program (SHIP) is requesting an extension of an information collection request. State grantees will improve health care in rural areas by using the funding to provide support to eligible rural hospitals to increase COVID-19 testing efforts, expand access to testing in rural communities, and expand the range of mitigation activities.

A 60-day Notice published in the **Federal Register**, 86 FR 74095 (December 29, 2021). There were no public comments.

Need and Proposed Use of the Information: The terms and conditions for this program specify that, "hospitals will be required to report on the number of tests provided and categories in which the funding is spent." The data will allow HRSA to ensure SHIP COVID-19 recipients are meeting the terms and conditions of their funding, while providing HRSA with information on the effectiveness of funds distributed through this program.

Likely Respondents: The respondents will be hospital staff and designated Representatives, and State Office of Rural Health Staff.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and