ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Stakeholders of local entities affected by TBDs.	Monthly surveys	10,000	12	15/60	30,000
	Final surveys	10,000	1	30/60	5,000
	Daily surveys	10,000	60	10/60	50,000
	Stakeholder Survey	1,000	1	30/60	500
Total					98,830

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–05753 Filed 3–17–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0297]

Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls Data Exchange; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting comment on the draft Pharmaceutical Quality/Chemistry Manufacturing and Controls (PQ/CMC) Data Exchange for the electronic submission of PQ/CMC data. This document provides draft design of Health Level 7 (HL7) Fast Health Interoperability Resources (FHIR) profiles that contain the data elements and terminologies associated with PQ/CMC subject areas and scoped to some of what is currently submitted in Module 3 of the electronic Common Technical Document (eCTD) submission. It is not intended to be comprehensive in covering all eCTD product quality information, only those concepts that were considered amenable to structuring and would bring value to the quality review process. The Agency is seeking comment on the mapping of the PQ/CMC data elements to the various FHIR Resources. This document should not be viewed as guidance, technical specification, or an implementation guide, as it is meant solely for comment. The FHIR mapping presented in this document is bound to the HL7 FHIR R5 draft release. As such, it is likely that some parts of the mapping presented in this document may change based on comments during the HL7 balloting and reconciliation process. However, since HL7 balloting has variable and extensive timelines, the Agency determined that it would be prudent to provide an early opportunity for comment that will inform final development of the exchange standard.

DATES: Submit either electronic or written comments 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–2022–N–0297 for ''Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls (PQ/CMC) Data Exchange for the electronic submission of PQ/CMC data; Request for Comments.'' 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.*

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.

[FR Doc. 2022–05790 Filed 3–17–22; 8:45 am]

BILLING CODE 4164–01–P

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:

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- 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

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