4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-2166]

# Draft Standardization of Pharmaceutical Quality/Chemistry Manufacturing and Control Data Elements and Terminologies; 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 standardized Pharmaceutical Quality/Chemistry Manufacturing and Control (PQ/CMC) data elements and terminologies for the electronic submission of PQ/CMC data. The establishment of standardized pharmaceutical quality data elements and terminologies will provide opportunities for FDA and industry to transform PQ/CMC submission data into a readily useable electronic format. As a result, these established data elements and terminologies will improve the efficiency and quality of the drug review process. The Agency is seeking comment on the accuracy, suitability, and appropriateness of these data elements and terminologies for submission of PQ/CMC data. FDA is considering implementing PQ/CMC requirements as a Health Level 7 (HL7) Structured Product Labeling (SPL) document. The proposed data elements and terminologies can be obtained on https://www.regulations.gov in Docket No. FDA-2017-N-2166.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE

60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. 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.

ADDRESSES: You may submit comments as follows:

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-2017-N-2166 for "Draft Standardization of Pharmaceutical Quality/Chemistry Manufacturing and Control Data Elements and Terminologies; Request for Comments." Received comments, those filed in a timely manner (see DATES), 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.

- 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Norman Schmuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 2526, Silver Spring, MD 20993-0002, 301-796-1454; 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, 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. Alternatively, send questions to the PQ-CMC mailbox: PQ-CMC@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, 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 standardization of PQ/CMC data elements and terminologies will facilitate the Agency's transition to an electronic review environment.

FDA intends to identify and standardize data elements and terminologies for information commonly used and submitted in support of drug product applications. The impetus for this standardization effort was the provisions from the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), which authorized the Agency to require certain submissions to be in a specified electronic format. 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.

After receiving comments, the Agency will consider future actions 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 proposed data elements and terminologies at https://www.regulations.gov.

Dated: July 5, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysys.

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