4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1594]

Quality Metrics Technical Conformance Guide--Technical Specifications Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a Technical Specifications Document entitled "Quality Metrics Technical Conformance Guide, Version 1.0." This Guide provides technical recommendations for the submission of quality metric data. It serves as the technical reference for implementation of the draft FDA guidance for industry, when finalized, on "Request for Quality Metrics," dated July 28, 2015.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2016-D-1594 for "Quality Metrics Technical Conformance Guide--Technical Specifications Document." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guide to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Tara Gooen Bizjak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2109, Silver Spring, MD 20993-0002, Tara.Gooen@fda.hhs.gov, 301-796-3257; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a Technical Specifications Document for industry entitled "Quality Metrics Technical Conformance Guide, Version 1.0." This Guide supplements

the draft FDA guidance for industry on "Request for Quality Metrics," available at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm455957.pdf, and provides recommendations about submission of records and other information that will support FDA's calculation of quality metrics as part of the process validation lifecycle and pharmaceutical quality system (PQS) assessment. Since publication of "Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century--A Risk Based Approach" in 2004,[1] CDER has continued to promote its vision of a maximally efficient, agile, flexible manufacturing sector that reliably produces high-quality drug products without extensive regulatory oversight. The draft guidance for industry on "Request for Quality Metrics" and this technical reference document continues the outreach policy of FDA so as to ensure successful implementation of CDER's objectives outlined in the 21st Century publication. The objectives of CDER's metric program can best be achieved through collaboration and mutual recognition of standards for metric indicators and data exchange/reporting.

The purpose of this Guide is to provide technical recommendations for the submission of quality metric data. It is intended to ensure clear expectations for industry on the submission of quality metric data as described in the "Request for Quality Metrics" draft guidance. We note that the comment period for that draft guidance closed in November 2015 and that the comments that were received are undergoing evaluation. This Guide is intended to be a companion document to the July 28, 2015, draft guidance. There may be modifications to the draft guidance and this guide based on our evaluation of the submitted comments. Our goal is to institute efficient regulatory review, compliance oversight, and inspection policies established on risk-based methods, including quality metric reporting. This Guide is

[1]http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/QuestionsandAnswersonCurrentGoodManufacturingPracticescGMPforDrugs/ucm137175.htm (Fall 2004) (last visited: March 17, 2016).

intended to facilitate collaboration between industry and FDA regarding the best methodologies to address all issues of implementation. Due to the inherent variability among reporting establishments' implementation of the process validation lifecycle and PQS assessment, it is difficult to identify and compare quality issues between firms. As such, FDA recognizes the importance of industry input and agreement regarding standardized indicators of manufacturing and product quality.

This guide is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The current version of the guide will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guide refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Relevant to this collection of information, FDA published a document entitled "Request for Quality Metrics; Notice of Draft Guidance and Public Meeting; Request for Comments" in the Federal Register of July 28, 2015 (80 FR 44973). In Section IV, "Paperwork Reduction Act of 1995," FDA estimated the burden that would cover the use of technical standards discussed in this draft guide.

III. Electronic Access

Persons with access to the Internet may obtain the draft guide at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,

http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm or http://www.regulations.gov.

Dated: June 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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