communication via product quality IRs. The contractor will also use the interview (and survey, if deployed) data to consider trends across IRs, compare IRs before and after implementation of Four-Part Harmony, and add context to the contractor's review of the sample IRs, as well as any other data collected. The contractor will synthesize and interpret the results to develop a set of findings and recommendations for the Program to be included in a final assessment report. In turn, FDA will use the independent assessment findings and recommendations to:

- determine the success of Four-Part Harmony in improving communications via product quality IRs;
- determine whether and how to refine implementation of Four-Part Harmony during the remainder of PDUFA VII;
- demonstrate compliance with the commitment to conduct the independent assessments
- and publish them for public comment; and
- share information about the Program with the regulated community, the public health community, Congress, and the general public.

In the **Federal Register** of March 21, 2022 (87 FR 16006), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received; however, we have slightly increased the estimate from our 60-day notice to fully align with planned program goals.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Surveys	120 (one to three per application).	1	120	0.25 (15 minutes)	30
Interviews	120 (one to three per application).	1	120	1.5	180
Total					210

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

We plan interviews with up to three sponsor representatives per each application in each interview under the Program. Sponsors will participate in interviews via teleconference. In addition, if the contractor decides to conduct a survey, sponsors will respond to surveys (one survey response per individual) by completing a fillable form online. We estimate that 120 applicant representatives will expend approximately 15 minutes to complete a survey, for a total of 30 annual burden hours. We further estimate that up to 120 applicant representatives (up to three sponsor representatives for each of up to 40 applications) will participate in the interviews each year and that each interview will last approximately 90 minutes, for a total of 180 burden hours. There will be no recordkeeping or third-party disclosure burdens for this information collection.

Dated: August 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18546 Filed 8–26–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1503]

Q2(R2) Validation of Analytical Procedures and Q14 Analytical Procedure Development; International Council for Harmonisation; Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of two draft guidances for industry entitled ''Q2(R2) Validation of Analytical Procedures'' and ''Q14 Analytical Procedure Development.'' These draft guidances were prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation. These draft guidances harmonize scientific approaches for analytical procedure development and include validation of a wider range of analytical techniques. The draft guidances are intended to facilitate regulatory evaluations and facilitate potential flexibility in postapproval change management of analytical procedures. The draft Q2(R2) guidance revises the ICH guidance for industry ''Q2(R1) Validation of Analytical Procedures: Text and Methodology'' published in November 2005.

DATES: Submit either electronic or written comments on the draft guidance by September 28, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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–2022–D–1503 for ''Q2(R2) Validation of Analytical Procedures'' and ''Q14 Analytical Procedure Development.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or 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. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: David Keire, Center for Drug Evaluation and Research, Food and Drug Administration, 645 S Newstead Ave., Rm. 2008, St. Louis, MO 63110–1116, *David.Keire@fda.hhs.gov.*

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of two draft guidances for industry entitled ''Q2(R2) Validation of Analytical Procedures'' and ''Q14 Analytical Procedure Development.'' The draft guidances were prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are the FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In March 2022, the ICH Assembly endorsed the draft guidelines entitled ''Q2(R2) Validation of Analytical Procedures'' and ''Q14 Analytical Procedure Development'' and agreed that the guidelines should be made available for public comment. The draft guidelines are the product of the Quality Expert Working Group of the ICH. Comments about these draft guidances will be considered by FDA and the Quality Expert Working Group.

The draft Q2(R2) guideline revises the Q2(R1) guideline published in 2005 to cover a broader range of analytical

procedures, including those used for process control and that apply to multivariate methods. The draft Q14 guideline harmonizes scientific approaches for analytical procedure development and describes principles to facilitate more efficient and science-based and risk-based postapproval change management. The two guidelines are intended to facilitate regulatory evaluations and facilitate potential flexibility in postapproval change management of analytical procedures where scientifically justified.

These draft guidances have been left in the original ICH format. The final guidances will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidances, when finalized, will represent the current thinking of FDA on the topics they address. They do not establish any rights for any person and are 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for investigational new drug applications have been approved under OMB control number 0910–0014; the collections of information for review of new drug applications have been approved under OMB control number 0910–0001; and the collections of information for review of biologics license applications have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidances at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: August 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18516 Filed 8–26–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1791]

E14 and S7B Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential—Questions and Answers; International Council for Harmonisation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''E14 and S7B Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential—Questions and Answers.'' The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation. The guidance contains revised questions and answers (Q&As) for the ICH guidance for industry ''E14 Clinical Evaluation of the QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs'' and new Q&As for the ICH guidance for industry ''S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals'' that provide recommendations on considerations for an integrated risk assessment combining nonclinical and clinical data—in particular, at later stages of drug development when clinical data are available. The guidance is intended to provide a harmonized approach to integrate nonclinical and clinical information for proarrhythmia risk assessment to streamline drug development and provide clarity on regulatory decision making. This guidance finalizes the draft guidance of the same title issued in September 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on August 29, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–2020–D–1791 for ''E14 and S7B Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential—Questions and Answers.'' Received comments 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