

Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:**

Jessica Seo, Center for Drug Evaluation Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, [GIDAC@fda.hhs.gov](mailto:GIDAC@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Gastrointestinal Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal diseases and makes appropriate recommendations to the Commissioner.

Pursuant to its charter, the Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of gastroenterology, endocrinology, surgery, clinical pharmacology, physiology, pathology, liver function, motility, esophagitis, and statistics. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve either as Special Government Employees or non-voting representatives. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve

temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/human-drug-advisory-committees/gastrointestinal-drugs-advisory-committee> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: March 4, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**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; 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 final guidances for industry entitled “Q2(R2) Validation of Analytical Procedures” and “Q14 Analytical Procedure Development.” The guidances were prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The guidance entitled “Q2(R2) Validation of Analytical Procedures” provides a general framework for the principles of analytical procedure validation, including validation principles that cover the analytical use of spectroscopic data. The guidance entitled “Q14 Analytical Procedure Development” provides harmonized guidance on scientific approaches for analytical procedure development and describes principles to facilitate more efficient, science-based, and risk-based postapproval change management. The guidances are intended to facilitate regulatory evaluations and potential flexibility in postapproval change management of analytical procedures when scientifically justified. The guidances replace the draft guidances “Q2(R2) Validation of Analytical Procedures” and “Q14 Analytical Procedure Development” issued on August 29, 2022.

**DATES:** The announcement of the guidances is published in the **Federal Register** on March 7, 2024.

**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-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](mailto:David.Keire@fda.hhs.gov); or James Myers, 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.

*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, 301-796-5259, [Jill.Adleberg@fda.hhs.gov](mailto:Jill.Adleberg@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of the guidances for industry entitled "Q2(R2) Validation of Analytical Procedures" and "Q14 Analytical Procedure Development." The guidances were prepared under the auspices of ICH. ICH seeks to achieve 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 enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are 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. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to <https://www.ich.org/>).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and 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 the **Federal Register** of August 29, 2022 (87 FR 52784), FDA published a notice announcing the availability of the draft guidances entitled “Q2(R2) Validation of Analytical Procedures” and “Q14 Analytical Procedure Development.” The notice gave interested persons an opportunity to submit comments by September 28, 2022.

After consideration of the comments received and revisions to the guideline, final drafts of the guidelines were submitted to the ICH Assembly and endorsed by the regulatory agencies in November 2023.

These guidances finalize the draft guidances issued on August 29, 2022. The final “Q2(R2) Validation of Analytical Procedures” guidance resolves issues on range, response, reference material, biologics, replicates, and dissolution. In addition, guidance on data requirements for accuracy, precision, and the combined approach (*e.g.*, confidence intervals) were refined. The final “Q14 Analytical Procedure Development” guidance includes further clarification of concepts like minimum versus enhanced approach, the definition and description of the analytical targeting profile, and established conditions.

These guidances are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Q2(R2) Validation of Analytical Procedures” and “Q14 Analytical Procedure Development.” These guidances 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). 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 guidance at <https://www.regulations.gov>, <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

Dated: March 4, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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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; Information Collection Request Title: Advanced Nursing Education Program Specific Form OMB No. 0915-0375—Revision

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA 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 8, 2024.

**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](http://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 Joella Roland, the HRSA Information

Collection Clearance Officer, at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–3983.

## SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* Advanced Nursing Education (ANE) Program Specific Form OMB No. 0915–0375—Revision.

*Abstract:* HRSA provides advanced nursing education grants to educational institutions to increase the supply, distribution, quality of, and access to advanced education nurses through the ANE Programs. The ANE Programs are authorized by section 811 of the Public Health Service Act (42 U.S.C. 296j), as amended. This clearance request is for continued approval of the information collection OMB No. 0915–0375 with revisions. This revision request seeks to add the ANE-Nurse Practitioner Residency and Fellowship Program and the Maternity Care Nursing Workforce Expansion Program to the ANE Program Specific Form, and to remove programs that have closed, which include the ANE-Nurse Practitioner Residency Program and the ANE-Nurse Practitioner Residency Integration Program. The activities previously supported under the ANE Nurse Practitioner Residency Program and the ANE-Nurse Practitioner Residency Integration Program are now supported under the ANE-Nurse Practitioner Residency and Fellowship Program.

A 60-day notice published in the **Federal Register** on December 28, 2023, 88 FR 89709–10. There were no public comments.

*Need and Proposed Use of the Information:* Section 811 of the Public Health Service Act provides the Secretary of Health and Human Services with the authority to award grants to and enter into contracts with eligible entities to meet the costs of: (1) projects that support the enhancement of advanced nursing education and practice; and (2) traineeships for individuals in advanced nursing education programs. Under this section, HRSA makes awards to entities who train and support nurses characterized as “advanced education nurses.” In awarding such grants, funding preference is given to applicants with projects that will substantially benefit rural or underserved populations, or help meet public health nursing needs in state or local health departments; special consideration is given to an eligible entity that agrees to extend the award to train advanced education nurses who will practice in designated Health Professional Shortage Areas.

The ANE Program Specific Form allows HRSA to effectively target