burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by May 6, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10440 Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Benefits Exchanges, Medicaid and CHIP Agencies

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Benefits Exchanges, Medicaid and CHIP Agencies; *Use:* Section 1413 of the Affordable Care Act directs the Secretary of Health and Human Services to develop and provide to each state a single, streamlined application form that may be used to apply for coverage through a Marketplace and for APTC/CSR, Medicaid, and CHIP (which we refer to collectively as insurance affordability programs). The application must be structured to maximize an applicant's ability to complete the form satisfactorily, taking into account the characteristics of individuals who may qualify for the programs by developing materials at appropriate literacy levels and ensuring accessibility.

45 CFR 155.405(a) provides more detail about the application that must be used by Marketplaces to determine eligibility and to collect information necessary for enrollment. Eligibility standards for the Marketplace are set forth in 45 CFR 155.305. The information will be required of each applicant upon initial application, with some subsequent information collections for the purposes of confirming accuracy of previous submissions and for changes in an applicant's circumstances. 42 CFR 435.907 and 457.330 establish the standards for state Medicaid and CHIP agencies related to the use of the application. CMS has designed a dynamic electronic application that will tailor the amount of data required from an applicant based on the applicant's circumstances and responses to particular questions in the FFM (please note SBM implementations may vary but the essence of the data collection must adhere to the same parameters). The paper version of the application will not be tailored in the same way but will require only the data necessary to determine eligibility.

Information collected by the Marketplace, Medicaid or CHIP agency will be used to determine eligibility for coverage through the Marketplace and insurance affordability programs (*i.e.,* Medicaid, CHIP, and APTC), and assist consumers in enrolling in a QHP if eligible. Applicants include anyone who may be eligible for coverage through any of these programs. Additionally, this application provides consumers interested in voting resources. *Form Number:* CMS–10440 (OMB control number: 0938–1191); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 5,550,000; *Total Annual Responses:* 5,550,000; *Total Annual Hours:* 2,446,440. (For policy questions regarding this collection contact Erin Richardson at 202–619–0630.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–04878 Filed 3–6–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0008]

Advisory Committee; Gastrointestinal Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Gastrointestinal Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Gastrointestinal Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the March 3, 2026, expiration date.

DATES: Authority for the Gastrointestinal Drugs Advisory Committee will expire on March 3, 2026, unless the

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.*

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.

[FR Doc. 2024–04845 Filed 3–6–24; 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; 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