TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section; activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 1.914; Waiver petitions | 2 | 1 | 2 | 24 | 48 |

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

We estimate one waiver petition from each of two firms will be submitted and respondents will spend 24 hours to prepare and submit the petition to FDA.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

| 21 CFR section; activity | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|---|---|---|---|---|
| 1.908; Disclosure of sanitary specifications; operating temperature conditions. | 226 | 1 | 226 | 0.5833 (~35 minutes). | 132 |

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

Finally, we estimate an annual third-party disclosure burden of 132 hours, assuming each of 226 firms will spend an average of 35 minutes, annually, disclosing written records as required under § 1.908.

Based on an evaluation of the information collection, we have made no adjustments to our burden estimate.

Dated: June 9, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–12914 Filed 6–14–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–D–0705]**

### Q9(R1) Quality Risk Management; International Council for Harmonisation; Draft Guidance for Industry; Availability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**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Q9(R1) Quality Risk Management.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The current Q9 guideline published in 2006 provides a common, harmonized framework for Quality Risk Management (QRM) that can enable more effective and consistent risk-based decisions, both by regulators and industry, regarding the quality of drug substances and drug products across the product lifecycle. This draft guidance is a targeted revision that addresses four areas for improvement, including high levels of subjectivity in risk assessments and in QRM outputs; product availability risks; lack of understanding as to what constitutes formality in QRM work; and lack of clarity on risk-based decision-making. The revisions are intended to update the original Q9 guideline based on implementation experience to promote improved lifecycle management of hazards and prevent defects, recalls, and shortages.

**DATES:** Submit either electronic or written comments on the draft guidance by July 15, 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–0705 for ''Q9(R1) Quality Risk Management.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' are 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 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, or 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. 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:* Rick Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4348, Silver Spring, MD 20993–0002, 301–796–3268, *Rick.Friedman@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, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a guidance for industry entitled ''Q9(R1) Quality Risk Management.'' The guidance was 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 November 2021, the ICH Assembly endorsed the draft guideline entitled ''Q9(R1) Quality Risk Management'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Quality Expert Working Group of the ICH. Comments about this draft guidance will be considered by FDA and the Quality Expert Working Group.

FDA is thus announcing the availability of a guidance for industry entitled ''Q9(R1) Quality Risk Management.'' The current Q9 guideline published in 2006 provides a common, harmonized framework for Quality Risk Management that can enable more effective and consistent risk-based decisions, both by regulators and industry, regarding the quality of drug substances and drug products across the product lifecycle. This draft guidance is a targeted revision that addresses four areas for improvement: (1) high levels of subjectivity in risk assessments and in QRM outputs; (2) product availability risks; (3) lack of understanding as to what constitutes formality in QRM work; and (4) lack of clarity on risk-based decision-making. The revisions are intended to update the original Q9 guideline based on implementation experience to promote improved lifecycle management of hazards and prevent defects, recalls, and shortages.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''Q9(R1) Quality Risk Management.'' 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

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. 3501–3520) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collection of information in 21 CFR part 211 has been approved under OMB control number 0910–0139.

### III. Electronic Access

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

Dated: June 8, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–12919 Filed 6–14–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Announcement of Intent To Establish the 2025 Dietary Guidelines Advisory Committee and Solicitation of Nominations for Membership

**AGENCY:** U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Health; U.S. Department of Agriculture (USDA), Food, Nutrition, and Consumer Services.

**ACTION:** Notice.

**SUMMARY:** The Departments of Health and Human Services and Agriculture announce the intent to establish a Dietary Guidelines Advisory Committee and invite nominations for the Committee.

**DATES:** Nominations must be submitted by 11:59 p.m. Eastern Time on July 15, 2022.

**ADDRESSES:** Nominations may be submitted by email to *DietaryGuidelines@hhs.gov.* Alternatively, nominations may be sent to: Dietary Guidelines Advisory Committee Nominations, Office of Disease Prevention and Health Promotion (ODPHP), Office of the Assistant Secretary for Health (OASH), HHS; 1101 Wootton Parkway, Suite 420; Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Janet de Jesus, MS, RD, Nutrition Advisor, telephone 240–453–8266, Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, *DietaryGuidelines@hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

*Authority and Purpose:* Section 301 of the National Nutrition Monitoring and Related Research Act of 1990 (7 U.S.C. 5341) requires the Secretaries of HHS and USDA to publish the *Dietary Guidelines for Americans* (*Dietary Guidelines*) jointly at least every five years. The law instructs that this publication shall contain nutritional and dietary information and guidelines for the general public, shall be based on the preponderance of scientific and medical knowledge current at the time of publication, and shall be promoted by each federal agency in carrying out any federal food, nutrition, or health program. The current edition of the *Dietary Guidelines* (2020–2025) provides guidance on the entire life span, from birth to older adulthood, including pregnancy and lactation. The *Dietary Guidelines for Americans, 2025–2030* will continue to provide food-based dietary guidance across the entire lifespan to help meet nutrient needs, promote health, and reduce the risk of chronic disease.

The 2025 Dietary Guidelines Advisory Committee (Committee) shall be formed and governed under the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C., App), which sets forth standards for the formation and use of advisory committees. The Committee is established to provide independent, evidence-based advice and recommendations to be considered by HHS and USDA in the Departments' development of the *Dietary Guidelines for Americans, 2025–2030.* The Committee's review and advice will focus on the scientific questions prioritized by HHS and USDA with the potential to inform nutrition guidance for Americans across the lifespan. Formation of the Committee is necessary to adequately review the science to inform the *Dietary Guidelines* and is in the public interest.

The Committee is expected to begin meeting in early 2023; the Committee will meet approximately five times during its operation. Pursuant to the FACA, all Committee meetings will be open to the public. The Committee will be established to accomplish a single, time-limited task. The Committee will develop a scientific report of its recommendations that will be submitted to the Secretaries of HHS and USDA. Upon delivery of its report to the Secretaries or when the Committee's charter expires two years after it is filed, the activities of the Committee will be terminated.

*Structure:* The Committee will consist of 15 to 20 members, including the Chair and Vice-Chairperson. Factors to be considered in selecting individuals to serve on the Committee include educational background, professional experience, and demonstrated scientific expertise in the issues to be examined by the Committee, as well as statutory obligations under FACA and desire for a balanced and diverse membership.

Expertise in human nutrition related to disease prevention and health promotion for the specific scientific topics identified by the Departments to be examined by the Committee will be sought. Expertise will also be sought related to health equity and the scientific approaches used to review the evidence (systematic reviews, food pattern modeling, and data analysis). Information on the scientific topics is available at *www.dietaryguidelines.gov.*

Equal opportunity practices regarding membership appointments to the Committee will be aligned with HHS and USDA policies. To the extent possible, HHS and USDA will ensure the Committee membership is balanced in expertise, experience, education, and institutional affiliation and is reflective of the racial, ethnic, gender, and geographic diversity within the United States.

Individuals will be appointed to serve as members of the Committee to evaluate the scientific evidence, not to represent the viewpoints of any specific group. Members of the Committee will be classified as Special Government Employees (SGE)s during their term of appointment and, as such, are subject to the ethical standards of conduct for federal employees. Upon entering the position and annually throughout the approximate 2-year term of appointment, members of the Committee will be required to complete and submit a report of their financial holdings.

*Nominations and Appointments for Memberships:* Nominees, including self-nominees, will be considered for appointment as members of the Committee. Only complete nomination packages submitted within the allotted time period will be considered. To be considered for an appointment, submission of the following information for each nominee is required: (1) a cover letter that clearly states the name and place of work of the nominee, the rationale for the nomination (*i.e.,* which specific topics they have expertise in, highlighting relevant experience in health equity and the scientific