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Sincerely,

–/S/–

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dated: June 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12100 Filed 6–6–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1955]

E6(R3) Guideline for Good Clinical Practice; International Council for Harmonisation; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''E6(R3) Guideline for Good Clinical Practice.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance outlines modernized Good Clinical Practice considerations to guide thoughtful design and responsible conduct of clinical trials in a manner that ensures participant safety and the reliability of trial results. This draft guidance encourages innovation, focuses on quality, and establishes proportionate and risk-based approaches for conducting clinical trials, while minimizing unnecessary complexities. The draft guidance is intended to provide flexible, modern, and clear Good Clinical Practice for conducting clinical trials.

DATES: Submit either electronic or written comments on the draft guidance by September 5, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2023–D–1955 for ''E6(R3) Guideline for Good Clinical Practice.'' 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 the draft 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, 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 Center for Biologics Evaluation and Research at 800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Amy Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6334, Silver Spring, MD 20993–0002, 240–402–0992, *amy.chi@fda.hhs.gov;* or Diane Maloney, 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, *diane.maloney@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 draft guidance for industry entitled ''E6(R3) Guideline for Good Clinical Practice.'' The draft guidance was 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 May 2023, the ICH Assembly endorsed the draft guideline entitled ''E6(R3) Guideline for Good Clinical Practice'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Efficacy Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Efficacy Expert Working Group.

The draft guidance on Good Clinical Practice is intended to support the responsible conduct of clinical trials in a manner that safeguards participant safety and the reliability of trial results. This guidance facilitates the use of innovations and encourages a focus on the important aspects in trial, while minimizing unnecessary complexities.

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 ''E6(R3) Guideline for Good Clinical Practice.'' 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. 3501–3521) 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 found in 21 CFR part 312 for investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information under 21 CFR part 312.145 pertaining to good clinical practice have been approved under OMB control number 0910–0843. The collections of information found in 21 CFR parts 50 and 56 pertaining to protection of human subjects, institutional review boards and informed consent have been approved under OMB control number 0910–0130. The collections of information found in 21 CFR part 314 relating to the review of new drug applications have been approved under OMB control number 0910–0001. The collections of information found in 21 CFR part 601 relating to the review of biologic licensing applications have been approved under OMB control number 0910–0338. The collections of information found in 21 CFR part 11 pertaining to electronic records and electronic signatures have been approved under OMB control number 0910–0303. The collections of information found in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice have 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, 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 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12099 Filed 6–6–23; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2023–0015; OMB No. 1660–0040]

Agency Information Collection Activities: Proposed Collection; Comment Request; Standard Flood Hazard Determination Form (SFHDF)

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 60-Day notice of renewal and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on an extension, without change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning this instrument, which is used by Federally-regulated lending institutions when making, increasing, extending, renewing or purchasing each loan for the purpose of determining whether flood insurance is required and available.

DATES: Comments must be submitted on or before August 7, 2023.

ADDRESSES: To avoid duplicate submissions to the docket, please submit comments at *www.regulations.gov* under Docket ID FEMA–2023–0015. Follow the instructions for submitting comments.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Susan Bernstein, Insurance Specialist, Federal Insurance and Mitigation Administration, Marketing and Outreach Branch at (303) 701–3595 or *Susan.Bernstein@fema.dhs.gov.* You may contact the Information Management Division for copies of the proposed collection of information at email address: *FEMAInformation-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: Section 1365 of the National Flood Insurance Act of 1968 (NFIA) (42 U.S.C. 4104b), as added by section 528 of the National Flood Insurance Reform Act of 1994 (Pub. L. 103–325, title V), requires that FEMA develop a standard hazard determination form for recording the determination of whether a structure is located within an identified Special Flood Hazard Area and whether flood insurance is available. Regulated lending institutions, Federal Agency lenders, the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation, and the Government National Mortgage Association must complete this form for any loan made, increased, extended, renewed or purchased by these entities. The requirement for Federally-regulated lending institutions to determine whether a building or mobile home securing a loan is located in an area having special flood hazards and whether flood insurance is available has been in effect since the enactment of the Flood Disaster Protection Act of 1973, although the use of a standard form was not required until the enactment of the section 1365 of the NFIA. The establishment of the SFHDF has enabled lenders to provide consistent information.

Collection of Information

Title: Standard Flood Hazard Determination Form (SFHDF).

Type of Information Collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660–0040.

FEMA Forms: FEMA Form FF–119–FY–22–128 (formerly 086–0–32), Standard Flood Hazard Determination Form (SFHDF).

Abstract: This form is used by Federally-regulated lending institutions, Federal Agency lenders, the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation, and the Government National Mortgage Association. Federally-regulated lending institutions complete this form when making, increasing, extending, renewing or purchasing each loan for the purpose is of determining whether flood insurance is required and available. FEMA is responsible for maintaining the form and making it available.

Affected Public: Business and other for-profit; and Individuals or Households.

Estimated Number of Respondents: 26,616,265.

Estimated Number of Responses: 26,616,265.

Estimated Total Annual Burden Hours: 8,871,200.

Estimated Total Annual Respondent Cost: $254,426,016.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $1,764.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the Agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Millicent Brown Wilson,

Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2023–12154 Filed 6–6–23; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2023–0016]

Agency Information Collection Activities: Technical Assistance Request and Evaluation

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: 60-Day notice and request for comments; extension/renewal.