## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–D–2484]**

### Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products and Combination Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry and FDA staff entitled ''Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products, and Combination Products.'' This document provides guidance to industry and FDA staff on the purpose and content of a use-related risk analysis (URRA) and how a URRA, along with other information, can be used to determine human factors (HF) data needs during product development and to support a marketing application.

**DATES:** Submit either electronic or written comments on the draft guidance by September 9, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2024–D–2484 for ''Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products and Combination Products.'' 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 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; 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; or the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jason Flint, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 22, Rm. 4488, Silver Spring, MD 20993–0002, 240–402–6293, *OSE.PMKTREGS@fda.hhs.gov;* Tania Reina, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2502, Silver Spring, MD 20993–0002, 301–221–7499; John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002, 301–796–8930, *combination@fda.gov;* or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7226, Silver Spring, MD 20993–0002, 240–402–5923.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products, and Combination

Products.'' This guidance provides recommendations to industry and FDA staff on the purpose and content of a URRA and how a URRA, along with other information, can be used to determine HF data needs during product development and to support a marketing application. This guidance applies to drug- and biologic-led combination products that are the subject of an investigational new drug application (IND), a new drug application (NDA), or a biologics license application (BLA) and supplements to these applications. This guidance also applies to human prescription drug products, including biological products, that are the subject of an IND, NDA, or BLA and supplements to these applications, and to human nonprescription drug products that are the subject of an IND or NDA and supplements to these applications. This guidance does not describe the methods used to design, conduct, or analyze human factors studies (for example, human factors validation studies or comparative use human factors studies).

The URRA is a risk management tool that supports the entire human factors engineering process and should be considered as part of an overall risk management framework. The URRA can be used in all phases of the medical product lifecycle. As part of evaluating the products as described above, FDA will evaluate human factors data submitted by sponsors to support the product user interface when submission of such data is warranted. The URRA can be used as one data element to help determine whether submission of human factors data is warranted.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products and Combination Products.'' 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. 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 in 21 CFR part 312 pertaining to the submission of INDs have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to the submission of NDAs and supplements to NDAs have been approved under 0910–0001. The collections of information in 21 CFR part 601 pertaining to the submissions of BLAs and supplements to BLAs have been approved under OMB control number 0910–0338.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *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, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 2, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–15003 Filed 7–8–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–N–6395]**

### Request for Applications for New Members of the Clinical Trials Transformation Initiative/Food and Drug Administration Patient Engagement Collaborative

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for applications.

**SUMMARY:** The Food and Drug Administration (FDA or Agency), in collaboration with the Clinical Trials Transformation Initiative (CTTI), is requesting applications from patient advocates interested in participating on the Patient Engagement Collaborative (PEC). The PEC is an ongoing, collaborative forum coordinated through the FDA's Patient Affairs Staff, Office of Clinical Policy and Programs (OCPP), Office of the Commissioner at FDA, and is hosted by CTTI. Through the PEC, the patient community and FDA staff are able to discuss an array of topics related to increasing meaningful patient engagement with diverse populations in medical product development and regulatory discussions at FDA. The activities of the PEC may include, but are not limited to, providing diverse perspectives on topics such as systematic patient engagement, transparency, and communication; providing considerations for implementing new strategies to enhance patient engagement at FDA; and proposing new models of collaboration in which patient, caregiver, and patient advocate perspectives can inform medical product development and regulatory discussions.

**DATES:** Applications can be submitted starting at 11:59 p.m. Eastern Time on July 9, 2024. This announcement is open to receive a maximum of 75 applications. Applications will be accepted until 11:59 p.m. Eastern Time on August 8, 2024 or until 75 applications are received, whichever happens first.

**ADDRESSES:** All applications should be submitted to FDA's Patient Affairs Staff in OCPP. The preferred application method is via the online submission system provided by CTTI, available at *https://duke.qualtrics.com/jfe/form/SV_3DllHjcaGryUIlg.* For those applicants unable to submit an application electronically, please call FDA's Patient Affairs Staff at 301–796–8460 to arrange for mail or delivery service submission. Only complete applications, as described under section IV of this document, will be considered.

**FOR FURTHER INFORMATION CONTACT:** Wendy Slavit, Office of the Commissioner, Office of Clinical Policy and Programs, Patient Affairs Staff, Food and Drug Administration, 301–796–8460, *PatientEngagementCollaborative@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background and Purpose

The CTTI is a public-private partnership cofounded by FDA and Duke University whose mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. FDA and CTTI have long involved patients and considered patient perspectives in their work. Furthering the engagement of diverse patients as valued partners across the medical product research and development continuum requires an open forum for patients and regulators to discuss and exchange ideas.

The PEC is an ongoing, collaborative forum in which the patient community and FDA Staff discuss an array of topics related to increasing patient engagement