likely to use the drug in clinical practice.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Cancer Clinical Trial Eligibility Criteria: Performance Status.'' 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 Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 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Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 23, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–09037 Filed 4–25–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–N–1592]**

### Promoting Effective Drug Development: Identifying Opportunities and Priorities for the Food and Drug Administration's Office of Clinical Pharmacology; Request for Comments

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

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is establishing a public docket entitled ''Promoting Effective Drug Development: Identifying Opportunities and Priorities for the Food and Drug Administration's Office of Clinical Pharmacology.'' The purpose of this docket is to solicit input from interested parties on specific and actionable policy topics that could be prioritized, developed, and implemented by the staff of the Center for Drug Evaluation and Research's (CDER's) Office of Clinical Pharmacology (OCP) to support effective drug development programs.

**DATES:** Although you can comment at any time, to ensure that the Agency considers your comment, submit either electronic or written comments by June 25, 2024.

**ADDRESSES:** You may submit comments 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–N–1592 for ''Promoting Effective Drug Development: Identifying Opportunities and Priorities for the Food and Drug Administration's Office of Clinical Pharmacology.'' 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.

- 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.

**FOR FURTHER INFORMATION CONTACT:** Anuradha Ramamoorthy, Office of

Clinical Pharmacology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1688, *anuradha.ramamoorthy@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

Clinical pharmacology impacts many important aspects of drug development including, but not limited to, dose selection and optimization, clinical trial inclusion and exclusion criteria, and evidence generation for safety and effectiveness determinations. Clinical pharmacology derived recommendations are also critical for optimizing pharmacotherapy in clinical practice (*e.g.,* by informing patient-specific treatment strategies).

Within CDER, OCP leverages clinical pharmacology information on drug disposition, disease biology, pharmacology, and determinants of response variability to support risk/benefit determinations and therapeutic individualization recommendations for patients and practitioners. OCP's mission is to advance the development of innovative new medicines by applying state-of-the-art scientific principles and promoting therapeutic optimization and individualization. OCP fulfills this mission through its core functions of regulatory review, regulatory research, and development and implementation of scientific guidances and policies.

To facilitate effective and efficient drug development, FDA is engaged in multiple, high-priority policy initiatives. Consistent with FDA's broader initiatives and modernization efforts, OCP works collaboratively with stakeholders to develop and implement contemporary guidance and policy in the multidisciplinary field of clinical pharmacology to share the current regulatory thinking on a topic and promote effective drug development programs. FDA is establishing a public docket to solicit input from interested parties on specific and actionable clinical pharmacology-relevant policy topics that could be prioritized, developed, and implemented by OCP staff.

## II. Request for Comments

FDA is soliciting specific, actionable policy suggestions that could be prioritized, developed, and implemented in the near-term by OCP staff to promote effective drug development programs. We emphasize that the focus of this request is to seek input in the multidisciplinary field of clinical pharmacology. The Agency welcomes any relevant information that interested parties wish to share in a submission to the docket. We are particularly interested in seeking input on:

1. Topics for development of new clinical pharmacology/translational medicine guidances to improve clarity and promote effective drug development. Please provide a rationale to support your suggestion and highlight relevant aspects that could be considered in guidance development.
2. Topics and concepts where further clarity on OCP's existing guidances may be warranted. Please provide a rationale to support your suggestions and actionable recommendations.
3. Topics that promote patient centricity in drug development and regulatory assessment. For FDA, patient-centric drug development and providing patient-centered clinical recommendations are important priorities.

## III. Electronic Access

Persons with access to the internet may obtain relevant clinical pharmacology guidances at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: April 22, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–08956 Filed 4–25–24; 8:45 am]

**BILLING CODE 4164–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–N–1382]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic User Fee Payment Request Forms

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on electronic user fee payment request forms.

**DATES:** Either electronic or written comments on the collection of information must be submitted by June 25, 2024.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 25, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*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–