

of Respondents: 7; Total Annual Responses: 2; Total Annual Hours: 140. (For policy questions regarding this collection contact Angela Cimino at 410-786-2638.)

Dated: November 15, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022-25162 Filed 11-17-22; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Generic Clearance for Reviewer Recruitment Forms

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) proposes

to extend approval of the existing overarching generic clearance for Reviewer Recruitment Forms (Office of Management and Budget (OMB) #0970-0477). No changes are proposed to the terms of the overarching generic.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act (PRA) of 1995, ACF is soliciting public comments on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing opreinfocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The overarching generic clearance for Reviewer Recruitment Forms provides ACF with the opportunity to collect from potential reviewers, such as those who review grant proposals, conference proposals, research/evaluation plans, study designs, report drafts, and/or other ACF materials.

ACF developed this generic because each program office and within ACF has

slightly different needs for information about reviewer applicants based on the specific activities for which reviewers are needed, yet the individual forms submitted under the generic will serve an identical function. The overarching purpose is to select qualified reviewers for ACF review processes and activities based on professional qualifications. Information will be collection through questions on forms and documents provided by candidates. Example documents include writing samples and curriculum vitae and/or resume. ACF uses the information collected to recruit well-qualified reviewers with relevant background experience and knowledge.

The abbreviated clearance process of the generic clearance allows program offices to gather a suitable pool of candidates within the varied time periods available for reviewer recruitment.

These forms submitted under this generic will be voluntary, low-burden and uncontroversial.

Respondents: Individuals who may apply to review materials for ACF.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents (total over request period) | Number of responses per respondent (total over request period) | Avg. burden per response (in hours) | Total burden (in hours) |
|---------------------------------|---|--|-------------------------------------|-------------------------|
| Reviewer Recruitment Form | 3,000 | 1 | .5 | 1,500 |

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022-25202 Filed 11-17-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA

announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by January 17, 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-2007-D-0369 for "Product-Specific Guidances; Draft and Revised Draft Guidances for Industry." 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. 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: Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 301-796-2398, PSG-Questions@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products" that explained the process that would be used to make product-specific guidances available to the public on FDA's website at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>.

As described in that guidance, FDA adopted this process as a means to

develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on August 3, 2022 (87 FR 47425). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

| Active ingredient(s) |
|--|
| Ammonium lactate (multiple reference listed drugs). |
| Budesonide. |
| Calcitonin salmon. |
| Clindamycin phosphate. |
| Deferiprone. |
| Drospirenone; Estetrol. |
| Eteplirsen. |
| Fidaxomicin. |
| Fosdenopterin hydrobromide. |
| Hydrocortisone. |
| Hydroxyurea. |
| Inotersen sodium. |
| Ketotifen fumarate. |
| Magnesium sulfate; Potassium chloride; Sodium sulfate. |
| Melphalan flufenamide hydrochloride. |
| Miconazole nitrate; White petrolatum; Zinc oxide. |
| Mometasone furoate. |
| Nicardipine hydrochloride. |
| Omeprazole magnesium. |
| Patisiran sodium. |
| Ponesimod. |
| Ranolazine. |
| Tepotinib hydrochloride. |
| Tivozanib hydrochloride. |
| Triamcinolone acetonide. |
| Trilaciclib dihydrochloride. |
| Varenicline tartrate. |
| Voclosporin. |

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances

for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

| Active ingredient(s) |
|---|
| Acyclovir. |
| Baricitinib. |
| Calcium carbonate; Famotidine; Magnesium hydroxide. |
| Daunorubicin citrate. |
| Deferiprone. |
| Ethinyl estradiol; Norethindrone acetate. |
| Ferric oxyhydroxide (multiple reference listed drugs). |
| Goserelin acetate (multiple reference listed drugs). |
| Icosapent ethyl. |
| Lapatinib ditosylate. |
| Lidocaine. |
| Oxycodone. |
| Progesterone. |
| Ranolazine. |
| Rifaximin. |
| Sodium phosphate, dibasic, anhydrous; Sodium phosphate, monobasic, monohydrate. |
| Sumatriptan succinate (multiple product-specific guidances). |

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to <https://www.regulations.gov> and enter Docket No. FDA-2007-D-0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. 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/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: November 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-25210 Filed 11-17-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Member Conflict.

Date: December 2, 2022.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892-7510 (Virtual Meeting).

Contact Person: Jolanta Maria Topczewska, Ph.D., Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute Health, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892, (301) 451-0000, jolanta.topczewska@nih.gov.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Capstone Centers for Multidisciplinary Research in Child Abuse and Neglect.

Date: December 8-9, 2022.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2137C, Bethesda, MD 20892-7510 (Virtual Meeting).

Contact Person: Kimberly L. Houston, MD, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health & Human Development, National Institute Health, 6710B Rockledge Drive, Room 2137C,

Bethesda, MD 20892, (301) 827-4902, kimberly.houston@nih.gov.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Program Project Grants for HIV Research.

Date: December 13-14, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2121B, Bethesda, MD 20892-7510 (Virtual Meeting).

Contact Person: Christiane M. Robbins, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute Health, 6710B Rockledge Drive, Room 2121B, Bethesda, MD 20817, (301) 451-4989, crobbs@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: November 14, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-25165 Filed 11-17-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cardiovascular Sciences.

Date: December 7, 2022.

Time: 8:00 a.m. to 12:00 p.m.