

ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act (PRA) of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The ORR–6 is designed to satisfy the statutory requirements of

the Immigration and Nationality Act (INA). Specifically, section 412(a)(7) of INA (8 U.S.C. 1522(a)(7)) requires that the Director monitor refugee resettlement assistance, including collecting data on the services provided and the results achieved. Data elements include output data that measure services provided by programs for school-aged youth, elderly populations, and for overall health promotion. The data collected will inform evidence-based policymaking and program design. The ORR–6 is an OMB-approved

form under PRA. ORR proposes to extend OMB approval for the ORR–6 with minor changes to the instructions. ORR staff and ORR funding recipients will benefit from accurate and clear instructions that support current reporting requirements. ACF estimates the proposed changes will not increase response burden.

Respondents: States, Replacement Designees, and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
ORR–6 Performance Report	70	2	15	2,100

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.

Authority: 8 U.S.C.1522(a)(7).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–22021 Filed 12–4–25; 8:45 am]

BILLING CODE 4184–89–P

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, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of additional draft and revised draft

product-specific guidances. The draft 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 draft 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 February 3, 2026 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: Joseph Kotsybar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 3623A, Silver Spring, MD 20993-0002, 240-402-1062, 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 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 November 21, 2025 (90 FR 223). 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)
Acoramidis hydrochloride
Apomorphine hydrochloride
Arimoclomol citrate
Birch triterpenes
Bupropion hydrochloride; Dextromethorphan hydrobromide
Cabergoline
Cefepime hydrochloride; Enmetazobactam
Crinacerfont (multiple reference listed drugs)
Desmopressin acetate
Deutivacaftor; Tezacaftor; Vanzacaftor calcium
Docetaxel
Elafibranor
Elexacaftor, Ivacaftor, Tezacaftor; Ivacaftor
Ensartinib hydrochloride
Escitalopram oxalate
Estradiol; Norethindrone Acetate; Relugolix
Estradiol; Progesterone
Fenfluramine hydrochloride
Flurpiridaz F-18
Gepotidacin mesylate

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

Active ingredient(s)
Hydrochlorothiazide
Hydroxychloroquine sulfate
lomeprol (multiple reference listed drugs)
Isotretinoin
Ketorolac tromethamine; Phenylephrine hydrochloride
Levacetylleucine
Omeprazole; Sodium bicarbonate
Pegulicanine acetate
Pivmecillinam hydrochloride
Potassium chloride
Prednisolone acetate
Primidone
Pyridostigmine bromide (multiple reference listed drugs)
Revumenib citrate
Roflumilast
Selpercatinib
Suzetrigine
Talazoparib tosylate
Tenapanor hydrochloride
Testosterone undecanoate
Treosulfan

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)
Baclofen
Baricitinib
Brigatinib
Budesonide (multiple reference listed drugs)
Calcitonin salmon
Carbinoxamine maleate
Carvedilol phosphate
Cenobamate
Dabrafenib mesylate
Dasiglucagon hydrochloride
Diltiazem hydrochloride
Epinephrine (multiple reference listed drugs)
Etodolac
Fluticasone propionate
Glucagon (multiple reference listed drugs)
Hydrochlorothiazide; Metoprolol tartrate
Ixazomib
Liraglutide (multiple reference listed drugs)
Mesalamine
Omeprazole; Sodium bicarbonate
Pegcetacoplan (multiple reference listed drugs)
Posaconazole
Pyridostigmine bromide
Semaglutide
Sunitinib malate
Tapinarof
Teriparatide

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

Active ingredient(s)
Tirzepatide
Treprostinil
Tretinoin
Trospium chloride
Vosoritide

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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

IV. Paperwork Reduction Act of 1995

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drugs have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for applications for FDA approval to market a new drug and in 21 CFR part 320 for bioavailability and bioequivalence requirements have been approved under OMB control number 0910–0001.

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](https://www.regulations.gov), or <https://www.regulations.gov>.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22131 Filed 12–4–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 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; Auditory and Hearing Sciences.

Date: January 16, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1009–J, Bethesda, MD 20892, 301–594–8015, rayk@nidcd.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 3, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–22097 Filed 12–4–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 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: Social and Community Influences on Health Integrated Review Group; Psychosocial Development, Risk and Prevention Study Section.

Date: January 22, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Anna L Riley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7759, Bethesda, MD 20892, 301–435–2889, rileyann@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 3, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–22082 Filed 12–4–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 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