

p.m. Eastern Time”, the **DATES** portion of the document is changed to read as follows:

The meeting will be held virtually on December 10, 2025, from 9 a.m. to 3:30 p.m. Eastern Time.

On page 42588, in the third column to page 42589, in the first column “FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2025–N–0008. The docket will close on November 10, 2025. 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 November 10, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before September 24, 2025, will be provided to the Committee. Comments received after this date will be taken into consideration by FDA. The **ADDRESSES** portion of the document is changed to read as follows:

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2025–N–0008. The docket will close on January 9, 2026. 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 January 9, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before December 1, 2025, will be provided to the Committee. Comments received after this date will be taken into consideration by FDA.

On page 42589, in the third column, Agenda: On October 8, 2025, the **SUPPLEMENTARY INFORMATION** portion of the document is changed to read as follows:

*Agenda:* On December 10, 2025.

On page 42589, in the third column to page 42590, in the first column, “Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions made to the Docket (see **ADDRESSES**) on or before September 24, 2025, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact

person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 18, 2025. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 22, 2025. The **SUPPLEMENTARY INFORMATION** portion of the document is changed to read as follows:

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions made to the Docket (see **ADDRESSES**) on or before December 1, 2025, will be provided to the Committee. Oral presentations from the public will be scheduled on December 10, 2025, between approximately 11:30 a.m. and 12:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 3, 2025. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 3, 2025.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to the advisory committees.

**Lowell M. Zeta,**

*Deputy Commissioner of Strategic Initiatives, Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–20608 Filed 11–20–25; 8:45 am]

**BILLING CODE 4164–01–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 January 20, 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>.

[www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf](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](mailto: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 October 2, 2025 (90 FR 47778). 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)
Aprocitentan.
Berdazimer sodium.
Budesonide.
Carbidopa; Levodopa (multiple reference listed drugs).
Danicopan.
Dasatinib.
Deuruxoutinib phosphate.
Dexamethasone.
Eltrombopag choline.
Flunisolide.
Givinostat hydrochloride.
Glucagon.
Inavolisib.
Lazertinib mesylate.
Mavoxifaor.
Metronidazole.
Minocycline hydrochloride.
Nilotinib tartrate.
Oxaprozin.
Probenecid; Sulopenem etzadroxil.
Resmetirom.
Sacubitril; Valsartan.
Seladelpar lysine.
Tirzepatide.
Tovorafenib (multiple reference listed drugs).
Travoprost.
Trospium chloride; Xanomeline tartrate.
Vadadustat.
Valbenazine tosylate.
Vorasidenib.

## 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)
Acidinium bromide.
Acidinium bromide; Formoterol fumarate.
Ambrisentan.
Amino acids; Calcium chloride; Dextrose; Magnesium sulfate; Potassium chloride; Sodium acetate; Sodium glycerophosphate; Soybean oil.

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

Active ingredient(s)
Amphetamine.
Asciminib hydrochloride.
Beclomethasone dipropionate (multiple reference listed drugs).
Bosentan (multiple reference listed drugs).
Budesonide.
Buprenorphine hydrochloride.
Ciclesonide.
Copper Cu-64 dotatate.
Crofelemer.
Diazepam.
Epinephrine (multiple reference listed drugs).
Fish oil triglycerides.
Fish oil; medium chain triglycerides; Olive oil; Soybean oil.
Fludrocortisone acetate.
Gabapentin.
Gallium Ga 68 edotreotide.
Glycopyrrolate.
Glycopyrrolate; Indacaterol maleate.
Hydroxychloroquine sulfate.
Indacaterol maleate.
Ipratropium bromide.
Iron dextran <sup>1</sup> .
Isotretinoin.
Macitentan.
Macitentan; Tadalafil.
Metronidazole (multiple reference listed drugs).
Minocycline hydrochloride.
Mometasone furoate.
Neratinib maleate.
Olive oil; soybean oil.
Palbociclib.
Pexidartinib hydrochloride.
Rifampin.
Sodium ferric gluconate complex <sup>2</sup> .
Soybean oil.
Valbenazine tosylate.

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

<sup>1</sup> The previous version of this product-specific guidance identified the active ingredient as ferric oxyhydroxide. FDA has concluded that the active ingredient is iron dextran and is revising the product-specific guidance to, among other things, reflect that conclusion. See Letter to Sean Griffin and Emily Marden, Sidley Austin LLP, from George Tidmarsh, M.D., Ph.D., Director, Center for Drug Evaluation and Research, Docket No. FDA–2021–P–0893 (August 8, 2025).

<sup>2</sup> The previous version of this product-specific guidance identified the active ingredient as ferric oxyhydroxide. FDA has concluded that the active ingredient is sodium ferric gluconate complex and is revising the product-specific guidance to, among other things, reflect that conclusion. See Letter to Sean Griffin and Emily Marden, Sidley Austin LLP, from George Tidmarsh, M.D., Ph.D., Director, Center for Drug Evaluation and Research, Docket No. FDA–2021–P–0893 (August 8, 2025).

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>, or <https://www.regulations.gov>.

#### Grace R. Graham,

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

[FR Doc. 2025–20548 Filed 11–20–25; 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; Nucleic Acid Therapeutic Delivery (NATD).

*Date:* December 15–16, 2025.

*Time:* 09:00 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:* Jingwu Xie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–8625, [jingwu.xie@nih.gov](mailto:jingwu.xie@nih.gov).

Registration is not required to attend this meeting.

(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: November 19, 2025.

#### Rosalind M. Niamke,

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2025–20624 Filed 11–20–25; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Advisory Board.

The meeting will be held virtually and is open to the public, as indicated below. Individuals who plan to view the virtual meeting and require special assistance or other reasonable accommodation should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: <http://videocast.nih.gov/>. A portion of the meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended. The intramural programs and projects and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning