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 [1].
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 [2].
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 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

[1] 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).

[2] 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).

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.*

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