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.

FOR FURTHER INFORMATION CONTACT: Lakshmi Kannan, Bldg. 32, Rm. 2333, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–9440, *OWHmeetings@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Menopause represents a significant biological transition for women, marked by cessation of ovarian function and decreased levels of all ovarian steroids, including estrogen and testosterone. Testosterone in women naturally declines with age. Levels in the late 40s are approximately half of those in the early 20s, reaching a nadir in the late 50s, followed by stabilization or modest increases starting in the 60s. The role of declining ovarian testosterone levels in menopausal women and its relationship to medical conditions, such as frailty, depressive symptoms, sleep, sexual function, cognition, and musculoskeletal health, are not well understood. Unlike estrogen-containing products, there are no FDA approved indications for testosterone therapy for menopausal women. Nevertheless, the off-label use of testosterone in women nearing or after menopause has increased over the past decade. Testosterone is currently approved for hypoactive sexual desire disorder (HSDD) in women in Australia, New Zealand, the UK, and South Africa. Beyond HSDD, there are limited data on the treatment effect of testosterone for other clinical uses. While short-term safety data exist for physiologic doses, long-term safety data beyond 24 months are limited, particularly regarding cardiovascular and breast cancer risks. Additionally, challenges exist in testosterone measurement and understanding the relationship between testosterone levels and various clinical outcomes. This public workshop will examine the current scientific evidence and knowledge gaps related to testosterone use in menopausal women to inform future research and potential drug development of testosterone products for menopausal women.

II. Topics for Discussion at the Public Workshop

This public workshop will include presentations and session discussions by experts in the fields of women's health, endocrinology, clinical pharmacology, clinical care, and regulators. The patient perspective will also be explored. Sessions will address testosterone physiology throughout a woman's life, navigating measurement challenges, clinical guidelines and practice perspectives, and regulatory considerations for drug approval, including the identification of clinically meaningful endpoints for various indications. Each session will include panel discussions to explore critical research gaps and chart a path forward for testosterone therapy in menopausal women.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://fda.zoomgov.com/webinar/register/WN_vqCrP60TSOGU7fc9uAWUbQ#/registration.* Please provide complete contact information for each attendee, including name, title, affiliation, email, and select whether attendance will be virtual or in-person.

Registration is free and based on space availability, with priority given to early registrants. People interested in attending this public workshop in-person must register by September 10, 2026, 11:59 p.m. Eastern Time. Those planning to attend virtually may register up until the date of the meeting. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact the FDA Office of Women's Health at *OWHmeetings@fda.hhs.gov* no later than September 1, 2026.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast, accessible at: *https://fda.zoomgov.com/webinar/register/WN_vqCrP60TSOGU7fc9uAWUbQ#/registration.*

Notice of this meeting is given pursuant to 21 CFR 10.65.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16829 Filed 8–17–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5974]

Determining Whether To Submit an ANDA or a 505(b)(2) Application; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry titled ''Determining Whether to Submit an ANDA or a 505(b)(2) Application.'' This draft guidance is intended to serve as a foundational guidance to assist applicants in determining which one of the abbreviated approval pathways under the Federal Food, Drug, and Cosmetic Act (FD&C Act) is appropriate for the submission of a marketing application to FDA. This draft guidance revises the guidance for industry titled ''Determining Whether to Submit an ANDA or a 505(b)(2) Application'' issued in May 2019 and, when finalized, will replace the 2019 guidance for industry.

DATES: Submit either electronic or written comments on the draft guidance by October 19, 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–2017–D–5974 for ''Determining Whether to Submit an ANDA or a 505(b)(2) Application.'' 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: David Coppersmith, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1666, Silver Spring, MD 20993–0002, 301–796–9193.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry titled ''Determining Whether to Submit an ANDA or a 505(b)(2) Application.'' This draft guidance is intended to serve as a foundational guidance to assist applicants in determining which one of the abbreviated approval pathways under the FD&C Act is appropriate for the submission of a marketing application to FDA. This draft guidance highlights criteria for submitting applications under the abbreviated approval pathways described in sections 505(j) and 505(b)(2) of the FD&C Act (21 U.S.C. 355(j) and 21 U.S.C. 355(b)(2), respectively), identifies considerations to help potential applicants determine whether an application would be more appropriately submitted under section 505(j) or pursuant to section 505(b)(2) of the FD&C Act, and provides direction to potential applicants on requesting assistance from FDA in making this determination.

This draft guidance focuses on those applications that can be submitted as abbreviated new drug applications (ANDAs) under section 505(j) of the FD&C Act, petitioned ANDAs under section 505(j)(2)(C) of the FD&C Act, or new drug applications (NDAs) pursuant to section 505(b)(2) of the FD&C Act. This draft guidance does not discuss stand-alone NDAs.

This draft guidance revises the guidance for industry titled ''Determining Whether to Submit an ANDA or a 505(b)(2) Application,'' which was announced in the **Federal Register** on May 10, 2019 (84 FR 20637). When finalized, this draft guidance will replace the 2019 guidance. Changes from the 2019 version include providing additional information on duplicates and eligibility for approval under section 505(j) of the FD&C Act, as well as other updates that are intended to clarify FDA's recommendations to industry.

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 FDA's current thinking on ''Determining Whether to Submit an ANDA or a 505(b)(2) Application.'' 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 draft 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 the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 for submission of 505(b)(2) or 505(j) applications have been approved under OMB Control number 0910–0001. The collections of information in 21 CFR part 201 for labeling of prescription drugs have been approved under OMB Control number 0910–0572. The collections of information for controlled correspondence and requests for communication with Office of Generic Drugs staff have been approved under OMB control number 0910–0727.

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, http://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. 2026–16837 Filed 8–17–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Allergy and Infectious Diseases Council, September 23, 2026, 8:00 a.m. to September 23, 2026, 5:00 p.m., National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20892 which was published in the **Federal Register** on August 3, 2026, 91 FR 48906.

Amendment to inform that the open sessions will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*). The meeting is partially open to the public.

Dated: August 13, 2026.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–16779 Filed 8–17–26; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Partially Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the NIH National Advisory Neurological Disorders and Stroke Council.

The meeting will be held as a virtual meeting and will be partially open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast and Podcasting website (*https://videocast.nih.gov/*).

The meeting 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 Advisory Neurological Disorders and Stroke Council.

Date: September 9–10, 2026.

Open: September 9, 2026, 4:00 p.m. to 5:30 p.m.

Agenda: Report by the Acting Director, NINDS; Report by the Director, Division of Extramural Activities; and Administrative and Program Developments; AD/ADRD Program Update; To discuss upcoming Concept Clearance Initiatives and other business of the Council.

Address: National Institutes of Health, Neuroscience Center, Room 1131, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Closed: September 10, 2026, 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, Room 1131, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Andrea Lynn Meredith, Ph.D., Director of Extramural Activities, National Institute of Neurological Disorders and Stroke, NIH, DHHS, Neuroscience Center, 6001 Executive Boulevard, Bethesda, MD 20892, (301) 496–9248, *andrea.meredith@nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice at least 10 days in advance of the meeting. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.ninds.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Extramural Research Programs in the Neurosciences and Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 13, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–16778 Filed 8–17–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM–2026–0793]

Notice of Availability of Outer Continental Shelf Official Protraction Diagrams

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Ocean Energy Management (BOEM), in accordance with its authority and responsibility under the Outer Continental Shelf Lands Act, is announcing the availability of new World Geodetic System 1984 (WGS84)-based Outer Continental Shelf (OCS) Official Protraction Diagrams (OPDs). These OPDs depict geographic areas located on the OCS offshore the Commonwealth of the Northern Mariana Islands (CNMI) covering the extent of the area identified for further consideration for potential OCS mineral leasing and environmental analysis in BOEM's CNMI Area Identification that was finalized on March 18, 2026. These diagrams may be used in the descriptions of potential OCS mineral lease sales off of CMNI. Additional OPDs for areas offshore CNMI that were not included in the March 2026 Area Identification are expected to be published in the future.

ADDRESSES: Copies of the OPDs are available for download in .pdf format from the Offshore Marine Cadastre (OMC) Navigator at *https://experience.arcgis.com/experience/eb21d5af8cf74c93b139c38c5b4163d1.*

FOR FURTHER INFORMATION CONTACT: Dr. Megan Carr, Associate Director for Strategic Resources, at (202) 294–3998 or via email at *megan.carr@boem.gov.*

SUPPLEMENTARY INFORMATION: The extent of the published diagram coverage is shown in Figure 1 below.

BILLING CODE 4340–98–P