raised in the previous OHS Tribal Consultations.

The consultation session includes elected or appointed Leaders of Tribal governments and their designated representatives. Designees must have a letter from the Tribal government authorizing them to represent the Tribe. Tribal governments must submit the designee letter at least 3 days before the consultation session to the Office of Head Start at *AIANHeadStart@acf.hhs.gov.* Other representatives of Tribal organizations and Native nonprofit organizations are welcome to attend as observers.

Within 45 days of the consultation process, a detailed report of the consultation session will be available for all Tribal governments receiving funds for Head Start and Early Head Start programs. Tribes can submit written testimony for the report to the Office of Head Start at *AIANHeadStart@acf.hhs.gov* prior to the consultation session or by October 6, 2026. OHS will summarize oral testimony and comments from the consultation session in the report, along with topics of concern and recommendations.

**Roshelle M. Brooks,**

*Management Analyst and OFR Liaison.*

[FR Doc. 2026–16826 Filed 8–17–26; 8:45 am]

**BILLING CODE 4184–40–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2026–N–5479]**

### Testosterone Use in Menopausal Women; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration's (FDA) Office of Women's Health and the Center for Drug Evaluation and Research are announcing a public workshop titled ''Testosterone Use in Menopausal Women.'' The purpose of the public workshop is to examine the current scientific evidence and critical knowledge gaps related to testosterone use in menopausal women to help inform future research and potential drug development of testosterone products for menopausal women. Researchers, educators, industry, clinicians, patients, and consumers may benefit from attending this scientific workshop. Presentations will examine the physiological roles of testosterone throughout a woman's life, including age-related decline, the menopausal transition, challenges associated with measuring and interpreting testosterone blood levels, and how these levels correlate with clinical symptoms and conditions. Speakers will review current and potential clinical uses of testosterone in menopausal women and examine the strengths and limitations of available data supporting those uses. Speakers will discuss regulatory considerations, including the development of robust efficacy and safety data, to support a marketing application for testosterone in menopausal women for the treatment of various clinical conditions, and study design considerations for evaluating long-term safety outcomes in women.

**DATES:** The public workshop will be held on September 17, 2026, from 9:00 a.m. to 4:30 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held as a hybrid event via webcast and an in-person option at the FDA White Oak Campus, Great Room, Bldg. 31, 10903 New Hampshire Ave., Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information/public-meeting-information* and *https://www.fda.gov/about-fda/visitor-information/visitor-parking-and-campus-map.*

You may submit comments, data, and information as follows. 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 October 19, 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.

*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 Docket No. FDA–2026–N–5479 for ''Testosterone Use in Menopausal Women; Public Workshop; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

**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