

PUBLIC WORKSHOP: TESTOSTERONE USE IN MENOPAUSAL WOMEN

Hosted by the FDA Office of Women's Health (OWH) and Center for Drug Evaluation and Research (CDER)

Date: September 17, 2026 | Time: 9:00 AM – 4:30 PM ET

Location: FDA White Oak Campus, Silver Spring, MD and Virtual



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for more event information

AGENDA

Time	Session
9:00 – 9:05 AM	WELCOME <i>Lakshmi Kannan, PhD</i> — Senior Advisor, FDA OWH, Office of the Commissioner
9:05 – 9:15 AM	OPENING REMARKS <i>Kaveeta Vasisht, MD, PharmD</i> — FDA Associate Commissioner for Women's Health; Director, FDA OWH <i>Christina Chang, MD, MPH</i> — Division Director, Division of Urology, Obstetrics, and Gynecology, Office of New Drugs, CDER, FDA
9:15 – 9:30 AM	KEYNOTE ADDRESS <i>Admiral Brian Christine, MD</i> — Assistant Secretary for Health, HHS; Head of the United States Public Health Service Commissioned Corps <i>Dorothy Fink, MD</i> — Deputy Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health
9:30 – 10:10 AM	SESSION I: ROLE OF TESTOSTERONE IN FEMALE BIOLOGY
9:30 – 9:50 AM	Physiological Roles of Testosterone Throughout a Woman's Life – What We Know and What We Don't <i>Margaret E. Wierman, MD</i> — Professor of Medicine, Integrative Physiology and OBGYN, University of Colorado School of Medicine
9:50 – 10:10 AM	Measuring and Assessing Testosterone Levels in Women: Navigating Challenges <i>James A. Simon, MD, CCD, MSCP, IF, FACOG</i> — Clinical Professor, Department of Obstetrics and Gynecology, Division of Reproductive Endocrinology, The George Washington University School of Medicine; Medical Director, IntimMedicine Specialists, Washington DC

Time	Session
10:10 – 12:30 PM	SESSION II: CLINICAL GUIDELINES, PRACTICE, AND PERSPECTIVES FOR TESTOSTERONE USE IN MENOPAUSAL WOMEN
10:10 – 10:30 AM	Clinical Guidelines for Testosterone Therapy in Menopausal Women <i>Rajita Patil, MD, MSCP, FACOG</i> — Associate Clinical Professor, Department of Obstetrics and Gynecology; Director of the UCLA Comprehensive Menopause Program; Complex Family Planning Subspecialist
10:30 – 10:50 AM	Benefit-Risk and Dosing Considerations <i>Pelin Batur, MD, FACP, MSCP</i> — Center Director of Women’s Comprehensive Health and Research Center, Cleveland Clinic; Professor of Obstetrics and Gynecology & Reproductive Biology, Cleveland Clinic Lerner College of Medicine, Case Western Reserve University
10:50 – 11:10 AM	Clinician Perspective <i>Rachel Rubin, MD</i> — Urologist and Sexual Medicine Specialist, Assistant Clinical Professor, Department of Urology, Georgetown University School of Medicine
11:10 – 11:30 AM	Patient Perspective <i>Ms. Susan Amanda Swain Lake</i> , Menopause Hormone Therapy Patient
11:30 – 12:30 PM	PANEL I: DISCUSSION BASED ON SESSIONS I & II / Q&A Moderator: <i>Christine Pham Nguyen, MD</i> — Deputy Director Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine, Office of New Drugs, CDER, FDA
12:30 – 1:30 PM	Lunch Break

Time	Session
1:30 – 4:20 PM	SESSION III: REGULATORY CONSIDERATIONS AND CHARTING A PATH FORWARD
1:30 – 1:50 PM	General Considerations for Drug Approval <i>Marcea B. Whitaker, MD</i> — Senior Medical Officer, Division of Urology, Obstetrics, and Gynecology, Office of New Drugs, CDER, FDA
1:50 – 2:10 PM	Efficacy Considerations for the Use of Testosterone in Menopausal Women <i>Anandi D. Kotak, MD, MS, MPH, FACOG</i> — Lead Physician, Division of Urology, Obstetrics, and Gynecology, Office of New Drugs, CDER, FDA
2:10 – 2:30 PM	Clinical Outcome Assessments: Measuring What Matters <i>Selena R. Daniels, PharmD, PhD</i> — Deputy Director, Division of Clinical Outcome Assessment, CDER, FDA
2:30 – 2:50 PM	Safety Considerations for the Use of Testosterone in Menopausal Women <i>Linda S. Jaffe, MD</i> — Senior Physician, Division of Urology, Obstetrics, and Gynecology, Office of New Drugs, CDER, FDA; Part-time Assistant Professor of Medicine, Harvard Medical School, Boston, MA
2:50 – 3:10 PM	Break
3:10 – 3:30 PM	Role of Testosterone Concentration in Development of Testosterone Products for Female Indications <i>Doanh Tran, PhD</i> — Deputy Director, Division of Cardiometabolic and Endocrine Pharmacology, Office of Clinical Pharmacology, Office of Translational Science, CDER, FDA
3:30 – 4:20 PM	PANEL II: DISCUSSION BASED ON SESSION III / Q&A Moderator: <i>Christina Chang, MD, MPH</i> — Division Director, Division of Urology, Obstetrics, and Gynecology, Office of New Drugs, CDER, FDA
4:20 – 4:30 PM	CLOSING REMARKS FDA OWH

All times are Eastern Time (ET).