E 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-6743]

Food and Drug Administration Expert Panel on Testosterone Replacement Therapy for Men; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a request for information from interested parties and the public to share their perspectives with FDA on testosterone replacement therapy for men. The Agency intends to use the information submitted to help inform considerations related to testosterone therapy for men.

DATES: Either electronic or written comments on the notice must be submitted by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments 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 **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. 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 the Docket No. FDA-2025-N-6743 for "Food and Drug Administration Expert Panel on Testosterone Replacement Therapy for Men; Request for Information." 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: Renu Lal, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 240-753-3395, druginfo@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA plans to hold an Expert Panel on December 10, 2025, on Testosterone Replacement Therapy (TRT) for Men (the panel). The purpose of the panel is to allow individual panel members to share their perspectives on TRT.

During the meeting, FDA anticipates that the panel members may discuss a range of topics related to the risks and benefits of male hormone therapy. The panel may include discussion of myths surrounding testosterone, and its perception as a lifestyle medication. FDA anticipates that panel members may review data regarding trends in average testosterone levels in men over recent decades, the potential causes, preventive strategies, and a variety of other related issues.

Patient safety remains FDA's top priority, and any potential new indications will be based on rigorous scientific evidence and comprehensive risk-benefit analysis. The panel members may discuss safety concerns including, but not limited to, cardiovascular risks, prostate health, fertility impairment, and potential for abuse.

This multi-stakeholder panel will include healthcare professionals, researchers, industry representatives, and military health experts to ensure comprehensive perspectives. FDA recognizes the unique needs of different populations, including military personnel facing specific occupational health challenges. Evidence-based protocols that healthcare providers can confidently implement were discussed by the panel. Any potential updates to testosterone labeling, including revisions to approved indications, will undergo the FDA's standard rigorous review process. FDA will continue robust oversight of both prescription testosterone therapies and over-the-counter supplements.

II. Purpose of Request for Information

This request for information provides an opportunity for interested parties and the public—including commercial drug developers, health care providers, consumers, and other relevant groups—to share their perspectives with FDA on the indications, dosing, route of administration, duration of treatment, and goals of treatment. Specifically, FDA is interested in perspectives on the scientific, regulatory, and practical considerations that shape testosterone use.

III. Questions for Consideration

We seek input on the questions presented below. While the questions are aimed at gathering information most pertinent to the administration of TRT for men, we welcome any additional data and information regarding the real-world prescribing patterns and clinical uses for TRT that may improve our understanding and advance our public health mission. To help FDA review comments efficiently, please identify the question to which you are responding by its associated category and number. If you are responding to more than one question, please identify each question to which you are responding, and categorize each response by question.

A. General

1. What are the potential impacts of TRT on: cardiovascular and thromboembolic disease, genitourinary systems, musculoskeletal health, frailty, and depression?

2. How do the risks and benefits of TRT differ based on timing of hormone initiation, age of initiation of treatment, duration of use, formulation (type of testosterone replacement used), dose, and route of administration?

3. What are the biggest opportunities to improve education of providers and patients concerning the prescription of TRT?

4. How could interested parties--including, but not limited to, drug developers, health care providers, patients, consumers, and retailers--work together to further identify therapeutic uses of TRT and generate evidence supporting the safety and efficacy of these uses?

B. Scientific Considerations

1. FDA seeks input on definitions and diagnostic thresholds for age-related androgen deficiency.

2. FDA seeks input on research priorities that could enhance the scientific understanding of TRT for men, including areas where additional evidence or data generation may be most valuable.

3. What scientific barriers might limit progress in increasing the availability of TRT?

4. What additional scientific tools, technologies, or data sources could support the availability of TRT?

5. Are there specific diseases or conditions that have not, traditionally, been treated with TRT for which testosterone could be safely and effectively used and which are currently not indicated in FDA-approved product labeling? If so, please provide the data or evidence supporting these potential uses.

(Authority: 21 U.S.C. 355.)

Lowell M. Zeta,

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

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