



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Potential New Indication for Testosterone Replacement Therapy

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing that we have reviewed information in published literature that seems promising regarding the potential use of testosterone replacement therapy (TRT) in the treatment of low libido in men with decreased libido associated with idiopathic hypogonadism. We encourage holders of approved TRT new drug applications (NDAs) that are interested in seeking approval for this new indication to contact FDA for further information regarding submission of a supplemental NDA, including data needed to support an approval.

DATES: Holders of currently approved TRT NDAs interested in seeking approval for the treatment of low libido in men with decreased libido associated with idiopathic hypogonadism are encouraged to contact FDA (see FOR FURTHER INFORMATION CONTACT) by April 30, 2026, for further information regarding submission of a supplemental NDA, including data needed to support the new indication.

FOR FURTHER INFORMATION CONTACT: Dorsa Jalali, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5333, 240-402-0543, dorsa.jalali@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Testosterone is the principal hormone secreted by the testes and is the main androgenic steroid in males. Endogenous androgens like testosterone are necessary and responsible for the

normal growth and development of the male sex organs and for the development and maintenance of secondary sex characteristics. Approved TRT drug products have been used for decades in the United States for certain conditions associated with a deficiency or absence of endogenous testosterone. In general, the goal of TRT is to reliably and safely restore concentrations of testosterone and its major metabolites (e.g., dihydrotestosterone, estradiol) to normal levels in men with low or absent testosterone levels from structural or genetic causes. FDA-approved TRTs include drug products that vary by dosage forms, strengths, and dosing regimens. These TRTs are currently indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone, specifically primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired). The approved TRTs also bear a limitation of use in the labeling to note that safety and efficacy of TRT in men with “age-related hypogonadism” have not been established.¹

II. Potential New Indication for TRT

On December 10, 2025, FDA convened an expert panel, “Expert Panel on Testosterone Replacement Therapy for Men” (recording available at <https://www.fda.gov/patients/fda-expert-panels/fda-expert-panel-testosterone-replacement-therapy-men-12102025>), to discuss TRT, including the use of testosterone in men for signs and symptoms associated with idiopathic hypogonadism (i.e., low testosterone levels from inadequate testicular stimulation or function without a known underlying cause).² The expert panel members discussed their individual views and available information on a range of topics related to the risks and benefits of testosterone therapy, including a potential broadening of the current approved indication for testosterone

¹ See, e.g., FDA-approved labeling for ANDROGEL (NDA 021015), ANDRODERM (NDA 020489), AVEED (NDA 022219), and JATENZO (NDA 206089) available at <https://www.accessdata.fda.gov/scripts/CDER/daf/>.

² In conjunction with the meeting of the expert panel, FDA announced a request for information regarding the scientific, regulatory, and practical considerations that shape TRT use (see 90 FR 57474, Dec. 11, 2025). FDA is in the process of reviewing the comments received.

products to include treatment of men with symptomatic hypogonadism without known structural or genetic etiologies.

FDA has conducted a preliminary review of the published literature on possible use of TRT to treat men with symptomatic idiopathic hypogonadism. In evaluating symptomatic idiopathic hypogonadism, FDA reviewed articles meeting the following criteria: (1) the studies involved prospective, controlled trials; and (2) the articles contained information about the study protocol, endpoints, statistical methods, sample size, and blinding procedures. Our preliminary review of the literature suggests that TRT may be safe and effective in treating low libido in men with decreased libido associated with idiopathic hypogonadism. The published literature we reviewed regarding this potential indication for TRT is listed in the REFERENCES section.

We encourage holders of currently approved TRT NDAs interested in seeking approval for the treatment of low libido in men with decreased libido associated with idiopathic hypogonadism to contact FDA (see FOR FURTHER INFORMATION CONTACT) by April 30, 2026, for further information regarding submission of a supplemental NDA, including data needed to support the new indication.³ Approval of any new indication will be based on rigorous scientific evidence and comprehensive risk-benefit analysis, consistent with applicable law.

III. References

The following references are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at <https://www.regulations.gov> as these references are copyright protected. Some may be available at the website addresses listed.

³ Drug products approved by FDA in supplemental NDAs (including new indications) may be protected by patents issued by the U.S. Patent and Trademark Office and/or by periods of exclusivity. Patent protections and exclusivities may have implications for the timing of approval of subsequent NDAs submitted pursuant to section 505(b)(2) of Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(b)(2)) and abbreviated new drug applications (ANDAs), including supplemental 505(b)(2) NDAs and ANDAs. See, e.g., sections 505(c)(3), 505(j)(5)(B), 505(j)(5)(F), 505A, and 527 of the FD&C Act (21 U.S.C. 355(c)(3), 355(j)(5)(B), 355(j)(5)(F), 355A, and 360cc); see also 21 CFR 314.107, 314.108, 316.31, and 316.34.

Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Pencina KM, Trivison TG, Cunningham GR, Lincoff AM, Nissen SE, Khera M, et al., 2024, “Effect of Testosterone Replacement Therapy on Sexual Function and Hypogonadal Symptoms in Men with Hypogonadism,” *J Clin Endocrinol Metab*, 109(2):569–580. Available at <https://doi.org/10.1210/clinem/dgad484>.

2. Snyder PJ, Bhasin S, Cunningham GR, Matsumoto AM, Stephens-Shields AJ, Cauley JA, et al., 2016, “Effects of Testosterone Treatment in Older Men,” *N Engl J Med*, 374(7):611–624. Available at <https://doi.org/10.1056/nejmoa1506119>.

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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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