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Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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

1. Pencina KM, Travison 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/>

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.

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.

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.)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–7121]

Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled "Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators." This draft guidance document provides a proposed compliance policy for and information about respirators approved by the Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) in accordance with 42 CFR part 84, specifically: surgical N95 respirators and N95 filtering facepiece respirators (FFRs) classified under 21 CFR 878.4040; other NIOSH approved, non-surgical respirators including powered air-purifying respirators (PAPRs), non-powered, air-purifying particulate FFRs, and reusable respirators (e.g., elastomeric half and full facepiece respirators); and FFRs for use by the general public in public health medical emergencies classified under 21 CFR 880.6260. These devices are collectively referred to in the guidance and this notice as "certain FFRs and reusable respirators." This guidance, once finalized, is intended to facilitate more efficient and effective use of resources, consistent with the least burdensome policies for devices. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by June 22, 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–2025–D–7121 for "Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or between 9 a.m. and 4 p.m., Monday through Friday, at the Dockets Management

Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Enforcement Policy for Premarket and Other Requirements for Certain NIOSH Approved Respirators" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive