US FDA issues labeling changes for testosterone products

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Bengaluru: The U.S. Food and Drug Administration said on Friday it issued new labeling changes for testosterone products based on results from clinical and post-market studies testing the products for blood pressure and cardiovascular effects.

The FDA said it is recommending label changes based on results from a clinical trial testing cardiovascular effects of testosterone-replacement therapy in middle-aged and older men with hypogonadism - a condition in which the body does not produce enough of the testosterone hormone.

Results from the trial concluded there was no increase in the risk of adverse cardiovascular outcomes in men using testosterone for hypogonadism.

The agency said it is recommending adding results from the trial to the labeling in all testosterone products, retaining the "limitation of use" terminology for age-related hypogonadism while removing language related to an increased risk of adverse cardiovascular outcomes.

It also made it a requirement to add a new warning about increased blood pressure for such formulations which do not already include it in their labeling, based on results from post-market studies measuring blood pressure.

Current FDA-approved testosterone formulations include oral, topical gel, transdermal patch and injection. Testosterone is approved only for use in men who lack or have low levels of the hormone associated with a medical condition, according to the FDA.

News Source:

https://pharma.economictimes.indiatimes.com/news/regulatory-update/us-fda-issues-labeling-changes-for-testosterone-products/118662947?utm_source=whatsapp_web&utm_medium=social&utm_campaign=socialsharebuttons