

## FDA links some prostate drugs to cancer risk

June 9 2011

(AP) -- The Food and Drug Administration expanded the warning label on a group of prostate drugs Thursday, saying they may increase the risk of a more serious form of prostate cancer.

The FDA is updating the warning information on a group of drugs including <u>GlaxoSmithKline</u> PLC's Avodart and <u>Merck</u> & Co.'s Proscar, which are used to shrink the prostate. The warning indicates the drugs are linked to a greater risk of high-grade prostate cancers. While the drugs have been shown to reduce the risk of <u>prostate cancer</u> overall, the FDA said the drugs were linked to an increased risk of more serious cancers.

Earlier this year, Merck, based in Whitehouse Station, N.J., and British drugmaker GlaxoSmithKline asked the FDA to approve the drugs as preventive treatments for prostate cancer, but the agency refused, citing the risk of high-grade cancer. In March, GlaxoSmithKline said it was abandoning global efforts to get Avodart approved as a preventive cancer drug.

The agency is basing its conclusions on a review of two studies in which about 27,000 men 50 and older used the drugs for several years. The FDA said the risk of high-grade prostate cancers is small, but doctors should be aware of it.

The drugs are also known as dutasteride and finasteride, respectively. Finasteride is also available as a low-cost generic.



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