

# FDA schedules meeting on twice-rejected female libido drug

7 May 2015, by Matthew Perrone

The Food and Drug Administration will ask a group of outside medical experts next month to evaluate a much-debated experimental drug designed to boost sexual desire in women.

The meeting is the latest twist in the ongoing saga of flibanserin, a proposed female libido pill which the FDA has already twice declined to approve. But the drug's backer, Sprout Pharmaceuticals, has enlisted women's groups and other advocates to lobby the agency to approve the pill, saying women's sexual problems have been too long overlooked by the federal government.

The FDA said Thursday in a posting it will convene a meeting of its reproductive drugs and drug safety panels on June 4. The agency is not required to follow the advice of such panels, though it often does.

For decades, drugmakers have tried unsuccessfully to develop a female equivalent to Viagra, the blockbuster drug that treats men's erectile dysfunction. But disorders of women's sexual desire have proven resistant to drugs that act on blood flow, hormones and other simple biological functions.

Sprout's drug flibanserin is the first attempt to increase libido by acting on brain chemicals linked to appetite and mood. But the FDA has already twice rejected the drug because of lackluster effectiveness and side effects including fatigue, dizziness and nausea.

In February Sprout refiled its application for the drug with FDA, adding information requested by agency scientists about how the pill affects driving ability. The FDA asked for that data after rejecting the drug in 2013, in part, due to results showing nearly 10 percent of women in company trials reported sleepiness as a side effect.

The FDA first rejected flibanserin in 2010 after a

panel of expert advisers unanimously voted against the drug, saying its benefits did not outweigh its risks.

If approved, flibanserin would be intended for premenopausal women with hypoactive sexual desire disorder, described as a lack of sexual appetite that causes emotional distress. Because so many factors affect female sexual appetite, there are a number of other possible causes doctors must rule out before diagnosing the condition, including relationship problems, hormone disorders, depression and mood issues caused by other drugs like sleeping aids and pain medications.

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