Makers of ‘Female Viagra’ Drug Try Once Again for FDA Approval

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Sprout Pharmaceuticals, the producers of a twice-rejected “female Viagra” pill designed to boost women’s sex drive, are resubmitting the drug to the U.S. Food and Drug Administration (FDA) for approval, CBS News reports.

The drug is called flibanserin and helps increase women’s sexual desire by acting on brain chemicals linked to appetite and food. It is the first drug of its kind designed for women, and politicians, women’s groups and consumer advocates are pushing to get the drug onto the market.

The FDA first rejected flibanserin in 2010, after a panel of experts unanimously voted against it, saying that the drug’s risks outweighed its benefits. Many were worried about what would happen if the pill was taken with other drugs or alcohol. In addition, the FDA also had concerns about how it would affect women’s ability to drive.

A May 2010 study on flibanserin showed 18 percent of women taking a 24-week treatment of the drug reported increased sexual desire. A 2013 study showed that 38 percent of test subjects who took flibanserin saw improvements in their sex lives.

While 30 percent of women in the later study reported side effects like headaches, nausea and sleepiness after taking the pill, only 8 percent said they were bad enough to make them want to stop treatment. Follow-up clinical studies showed about 10 percent of women overall experienced sleepiness with the drug.

“We see this not only as an important unmet women’s health issue, but an inflection point for the agency to ensure that similar standards are applied for drug approvals in conditions uniquely affecting women,” stated a letter signed by the National Organization for Women, the National Consumers League and four other groups that are advocating for the drug.

If approved, flibanserin would be labeled for premenopausal women diagnosed with hypoactive sexual desire disorder (a.k.a. HSDD). For more information about HSDD, click here.