Merck: FDA wants more studies of insomnia drug

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Drugmaker Merck & Co. says federal regulators have ruled that they won't approve high doses of its experimental insomnia medication because of concerns about their safety.

But Merck says the Food and Drug Administration has indicated it would approve lower doses of the drug, called suvorexant, after Merck provides additional data.

Merck spokesman Steve Cragle says the company is talking with the FDA to determine exactly what studies are needed.

However, the company says that at minimum it will have to do manufacturing studies on a low, 10-milligram dose, which the FDA wants to be the starting dose for most patients. That means Merck will have to repeatedly produce batches at that dose, which it hasn't done before, to show it can produce pills meeting strict specifications.

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