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FDA to decide on Qnexa obesity drug in July

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US regulators will decide in July whether to approve Qnexa, the first obesity drug in more than a decade, extending the initial deadline by three months, the California-based drug-maker VIVUS said.

The extra time is a "standard extension period" offered by the US Food and Drug Administration in order to review additional risk management strategies that were submitted by the company, said a statement issued late Monday.

The new date for a decision is now set for July 17.

An advisory panel to FDA in February urged approval of Qnexa, after warning against its approval in 2010 due to safety concerns.

The panel voted 20-2 that the FDA should allow Qnexa on the market, saying the latest overall benefit-risk assessment supported its approval, but asking for more data on potential risks and how to avoid them.

For instance, some people who took high doses of the drug experienced increased heart rate. When taken by pregnant women it also boosted the risk of having a baby with cleft palate.

"The Qnexa REMS (risk evaluation and mitigation strategy) submission is comprehensive, with materials based on ongoing feedback from the FDA since our advisory committee meeting in February," said Leland Wilson, chief executive officer of VIVUS.

"We look forward to finalizing our REMS with the FDA while we move forward with our commercialization plans."

Qnexa combines two existing drugs, the appetite suppressant phentermine and topiramate, an anti-convulsant that can be used in conjunction with other drugs for weight loss.

Some doctors already prescribe the combination as an off-label use for helping patients manage their weight.

Studies have shown dieters could lose up to 10% of their weight when taking the drug, along with regular exercise and following a healthy diet.

The FDA does not have to follow the advice of the advisory panel, though it usually does.

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