Merck: FDA Needs More Time To Review Surgery Drug

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Drugmaker Merck & Co. said Friday that U.S. regulators have delayed a decision on whether to approve a drug, already rejected once, for helping anesthetized patients "wake up" after surgery.

The world's third-biggest drugmaker said the Food and Drug Administration notified the company that it will need an additional three months to review the research data on sugammadex and decide whether to allow U.S. sales.

The injected drug, if approved, would be the first in a new class of medicines in the U.S. for reversing effects of certain muscle-relaxing drugs given along with anesthesia during surgery.

Sugammadex was approved in 2009 in European Union countries. The year before, the FDA rejected it over concerns about allergic reactions and bleeding in some participants in clinical studies.

Merck, which is based in Whitehouse Station, N.J., submitted additional information requested by the FDA in its latest attempt to win U.S. approval.

Merck had said in January that it expected a ruling from the FDA in the first half of this year. The maker of Type 2 diabetes drug Januvia and cholesterol drugs Zetia and Vytorin now says it expects a decision in the second half of 2013. The company wouldn't be more specific on the timing.

Sugammadex is among more than a half-dozen experimental drugs under review or for which Merck plans to apply for regulatory approval this year.

In late-morning trading, Merck shares fell 27 cents to $44. Its shares have traded between $37.02 and $48 over the last 52 weeks.

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