MedicalXpress

New sleeping pill poised to hit US markets

May 21 2013

An experimental sleeping pill from US drug company Merck is effective at helping people fall and stay asleep, according to reviewers at the US Food and Drug Administration, which could soon approve the new drug.

But the experts warned of dangerous side effects at high doses—including residual sleepiness during the day and, in a small number of subjects, suicidal thoughts—according to their report posted Tuesday.

The FDA has convened a group of independent experts for Wednesday to make recommendations to the agency on whether to authorize the medication for the US market.

The FDA is not required to follow the recommendations of the panel, but generally does so.

The drug, Suvorexant, also known as MK-4305, is a new class of sleeping pill, which works by blocking "wakefulness-promoting orexin neurons" from working, thus helping the body transition to sleep.

Merck has proposed a dose of 15 milligrams for people over 65 and 20 milligrams for those under 65, with doses up to twice as high recommended for those whose symptoms persist.

But the FDA noted clinical trials indicated a dose of just 10 milligrams was safe and effective, and it planned to ask the independent panel to consider recommending all patients start with this smaller dose and

whether it should ask Merck to study if doses under 10 milligrams might also be effective.

In January, the FDA asked the pharmaceutical companies behind Ambien and other similar sleep aids to reduce their recommended dosages after studies showed an increased risk of daytime sleepiness and related car accidents.

The FDA notably required the companies to cut by half the recommended doses for some sleeping pills for women—whose bodies apparently metabolize the drugs more slowly.

Insomnia affects up to 30 percent of US adults, the FDA said.

According to analysts, Suvorexant could generate for Merck some $650 million in sales by 2018.