FDA tells drugmakers to lower doses for Ambien, other sleeping pills

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WASHINGTONThe makers of Ambien and similar sleeping pills will be required to lower the dosage of their drugs due to studies suggesting patients face a higher risk of injury due to morning drowsiness, the Food and Drug Administration said Thursday.

The agency said Thursday that new research shows that the drugs remain in the bloodstream at levels high enough to interfere with morning driving, which increases the risk of car accidents.

Regulators are ordering drug manufacturers to cut the dose of the medications in half for women, who process the drug more slowly. Doses will be lowered from 10 milligrams to 5 milligrams for regular products, and 12.5 milligrams to 6.25 milligrams for extended-release formulations.

Reasons why women and men break down the drugs differently are unknown, the FDA said in a press conference with reporters Thursday.

The FDA is recommending that manufacturers apply these lower doses to men as well, though it is not making them a requirement.

The new doses apply to all insomnia treatments containing the drug zolpidem, which is sold under brands including Ambien, Edluar and Zolpimist.

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FDA officials say doctors should aim to prescribe the lowest dose possible that will successfully treat insomnia.

Unger told reporters Thursday that while the recommendations apply to zolpidem, any sleeping pill can cause morning drowsiness, so the lowest dose is always ideal.The FDA at this time is not requiring other drugmakers to lower their doses, but the agency is requesting driving studies for sleeping pills that contain different active ingredients.

"Patients who must drive in the morning or perform some other activity requiring full alertness should talk to their health care professional about whether their sleep medicine is appropriate," said Dr. Ellis Unger, a director in FDA's Office of Drug Evaluation

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Unger said in a statement that the FDA has received a number of reports of car accidents connected to zolpiderm over the years. However, the agency did not have enough information to tell how much of a role the drug played in the incidents.

The agency decided to take action after recent driving simulation studies showed that, in some patients, drug levels remained high enough to cause difficulty driving.

"The elephant in the room is: Why did this take so long?" said Unger. He said the FDA is a science-based organization and the information took time to collect and analyze.

For now, patients should continue taking their currently prescribed dose until they can talk to their doctor about the best way to proceed.

Ambien is sold by Sanofi, Edluar by Meda Pharmaceuticals Inc. and Zolpimist by NovaDel Pharma Inc.

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