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Merck's insomnia drug gets USFDA approval

14 August 2014 | News | By BioSpectrum Bureau

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Merck got the US Food and Drug Administration (USFDA) nod for its insomnia drug Belsomra. It is an orexin receptor antagonist is the first approved drug in that class. It regulates the sleep-wake cycle by altering the action of the neurotransmitter in the brain.

Belsomra has been approved in four different strengths - 5, 10, 15, and 20 mg. The FDA has recommended that Belsomra be categorised as a controlled substance (schedule IV) because it can be abused or lead to dependence.

It will be dispensed with an FDA-approved medication guide once a final decision on scheduling is made by the US Drug Enforcement Administration. Merck has said that Belsomra should be available by late 2014 or early 2015. The recommended dosage for the drug is 10mg, taken no more than once per night and within 30 minutes of going to bed, and at least seven hoursÂ before the planned wake up time.

Mr David Michelson, head of neurosciences at Merck Research Laboratories, said, "Belsomra is the result of more than a decade of study and provides tangible evidence of our long-standing commitment to innovation". He added that the approval allows for the introduction of a new treatment option for patients suffering from insomnia.

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