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First generic versions of Cymbalta receive FDA nod

13 December 2013 | Regulatory | By BioSpectrum Bureau

Singapore: US Food and Drug Administration has approved the first generic versions of Cymbalta (duloxetine delayed-release capsules), a prescription medicine used to treat depression and other conditions.

Aurobindo Pharma, Dr. Reddy's Laboratories, Lupin, Sun Pharma Global FZE, Teva Pharmaceuticals USA, and Torrent Pharmaceuticals have received FDA approval to market duloxetine in various strengths.

"Health care professionals and consumers can be assured that these FDA-approved generic drugs have met our rigorous standards," said Ms Kathleen Uhl, acting director of the Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research. "Generic drugs offer greater access to health care for many people."

Depression is characterized by symptoms that interfere with a person's ability to work, sleep, study, eat, and enjoy once-pleasurable activities. Episodes of depression often recur throughout a person's lifetime. Signs and symptoms of depression include: depressed mood, loss of interest in usual activities, significant change in weight or appetite, insomnia or excessive sleeping (hypersomnia), restlessness/pacing (psychomotor agitation), increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, and suicide attempts or thoughts of suicide.

Duloxetine and other antidepressant drugs have a boxed warning describing the increased risk of suicidal thinking and behavior during initial treatment in children, adolescents, and young adults ages 18 to 24. The warning also says data do not show this increased risk in those older than 24 years and that patients ages 65 and older who take antidepressants have a decreased risk of suicidal thinking and behavior.