Food and Drug Administration Approves First Generic Versions of Ambien (Zolpidem Tartrate) for the Treatment of Insomnia

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April 23, 2007， The U.S. Food and Drug Administration (FDA) today approved the first generic versions of Ambien (zolpidem tartrate) immediate-release tablets. Zolpidem (ZOLE-pi-dem) tartrate is a sedative-hypnotic drug indicated for the short-term treatment of insomnia.

"The FDA’s Office of Generic Drugs ensures that generic drugs are safe and effective for the American public through a rigorous scientific and regulatory process," said Gary J. Buehler, director, Office of Generic Drugs. "This approval offers Americans more alternatives when choosing their prescription drugs."

Zolpidem tartrate tablets in formulations of five milligrams and 10 milligrams are manufactured by multiple generic drug companies in the United States. The following 13 manufacturers have received FDA approval for zolpidem tartrate tablets: Mylan Pharmaceuticals Inc., TEVA Pharmaceuticals USA, Roxane Laboratories Inc., Watson Laboratories Inc., Ranbaxy Laboratories Ltd., Dr. Reddy’s Laboratories Ltd., Apotex Inc., Synthon Pharmaceuticals Inc., Genpharm Inc., Mutual Pharmaceutical Company Inc., Caraco Pharmaceutical Laboratories Ltd., Carlsbad Technology Inc., and Lek Pharmaceuticals.

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