food and drug administration Requests Label Change for All Sleep Disorder Drug Products

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March 14, 2007， The U.S. Food and Drug Administration (FDA) has requested that all manufacturers of sedative-hypnotic drug products, a class of drugs used to induce and/or maintain sleep, strengthen their product labeling to include stronger language concerning potential risks. These risks include severe allergic reactions and complex sleep-related behaviors, which may include sleep-driving. Sleep driving is defined as driving while not fully awake after ingestion of a sedative-hypnotic product, with no memory of the event.

"There are a number of prescription sleep aids available that are well-tolerated and effective for many people," said Steven Galson, M. D., MPH, director of FDA's Center for Drug Evaluation and Research. "However, after reviewing the available post-marketing adverse event information for these products, FDA concluded that labeling changes are necessary to inform health care providers and consumers about risks."

FDA has been working with the product manufacturers over the past three months to update labeling, notify health care providers and inform consumers of these risks.

Along with the labeling revisions, FDA has requested that each product manufacturer send letters to health care providers to notify them about the new warnings. Manufacturers will begin sending these letters to providers starting this week.

In addition, FDA has requested that manufacturers of sedative-hypnotic products develop Patient Medication Guides for the products to inform consumers about risks and advise them of potential precautions that can be taken. Patient Medication Guides are handouts given to patients, families and caregivers when a medicine is dispensed. The guides will contain FDA-approved information such as proper use and the recommendation to avoid ingesting alcohol and/or other central nervous system depressants. When these Medication Guides are available, patients being treated with sleep medications should read the information before taking the product and talk to their doctors if they have questions or concerns. Patients should not discontinue the use of these medications without first consulting their health care provider.

Although all sedative-hypnotic products have these risks, there may be differences among products in how often they occur. For this reason, FDA has recommended that the drug manufacturers conduct clinical studies to investigate the frequency with which sleep-driving and other complex behaviors occur in association with individual drug products.

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