

**Information for Healthcare Professionals:
Sedative-hypnotic drug products:
Labeling strengthened to include warnings about risk of severe allergic reactions and sleep-driving**

According to MedWatch, FDA notified healthcare professionals and consumers of its request 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. FDA also requested that each product manufacturer send letters to health care providers to notify them about the new warnings, and that manufacturers develop patient Medication Guides for the products to inform consumers about risks and advise them of potential precautions that can be taken.

The complete MedWatch 2007 Safety summary, including a link to the FDA press release, is available at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Sedative>

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