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ASIA EDITION

FDA approves pill with sensor

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The product is approved for the treatment of schizophrenia

Singapore – The U.S. Food and Drug Administration approved the first drug in the U.S. with a digital ingestion tracking system. Abilify MyCite (aripiprazole tablets with sensor) has an ingestible sensor embedded in the pill that records that the medication was taken. The product is approved for the treatment of schizophrenia, acute treatment of manic and mixed episodes associated with bipolar disorder and for use as an add-on treatment for depression in adults.

The system works by sending a message from the pill's sensor to a wearable patch. The patch transmits the information to a mobile application so that patients can track the ingestion of the medication on their smart phone. Patients can also permit their caregivers and physician to access the information through a web-based portal.

"Being able to track ingestion of medications prescribed for mental illness may be useful for some patients," said Mitchell Mathis, M.D., director of the Division of Psychiatry Products in the FDA's Center for Drug Evaluation and Research. "The FDA supports the development and use of new technology in prescription drugs and is committed to working with companies to understand how technology might benefit patients and prescribers."

It is important to note that Abilify MyCite's prescribing information (labeling) notes that the ability of the product to improve

patient compliance with their treatment regimen has not been shown. Abilify MyCite should not be used to track drug ingestion in "real-time" or during an emergency because detection may be delayed or may not occur.

Prior to initial patient use of the product, the patient's health care professional should facilitate use of the drug, patch and app to ensure the patient is capable and willing to use the system.

Abilify was first approved by the FDA in 2002 to treat schizophrenia. The ingestible sensor used in Abilify MyCite was first permitted for marketing by the FDA in 2012.

The FDA granted the approval of Abilify MyCite to Otsuka Pharmaceutical Co., Ltd. The sensor technology and patch are made by Proteus Digital Health.