

FDA NEWS RELEASE

For Immediate Release: July 16, 2009

FDA Approves Opioid Pain Reliever with Required Risk Reduction Plan

The U.S. Food and Drug Administration today approved Onsolis, medication intended for certain patients with cancer to help manage breakthrough pain - severe flares of pain that break through regular pain medication.

Onsolis is in a class of drugs that deliver the potent opioid fentanyl through the mouth's mucous membranes. Onsolis delivers fentanyl via an absorbable film that sticks to the inside of the cheek. The drug is indicated for the management of breakthrough pain in patients with cancer, ages 18 and older, who already use opioid pain medication around the clock and who need and are able to safely use high doses of an additional opioid medicine. Such patients are considered opioid tolerant because of their current opioid medication use.

Because fentanyl is subject to abuse and misuse, Onsolis was approved with a Risk Evaluation and Mitigation Strategy, or REMS, which is a required plan for managing risks associated with a drug or biological product.

"Onsolis can provide strong pain relief to patients who are opioid tolerant. But for patients who are not opioid tolerant, it can lead to overdose, sudden serious breathing difficulties and death," said Bob Rappaport, M.D., director, Division of Anesthesia, Analgesia and Rheumatology Products in the FDA's Center for Drug Evaluation and Research (CDER). "For this reason, Onsolis should be prescribed only under the safeguards provided by the FDA-required REMS and by health care professionals knowledgeable about Onsolis and the use of potent opioid medications."

The Food and Drug Administration Amendments Act of 2007 gave the FDA the authority to require that drugs and biological products have a REMS to ensure that the benefits of a drug or biological product outweigh its risks.

As part of the REMS, Onsolis will only be available through a restricted distribution program called the FOCUS program. Under this program, only those prescribers, patients and pharmacies registered with the program will be able to prescribe, dispense, and receive Onsolis. The FOCUS program will provide training and educational materials to prescribers and pharmacy personnel, and a counseling call will be placed to patients prior to dispensing to ensure they have been adequately educated about the appropriate use of the drug. Prescription orders will be filled only by participating pharmacies that send the product directly to the patients' homes.

Onsolis was approved with a boxed warning, which states that the medication should not be used for the management of migraines, dental pain, or postoperative pain or by patients who use opioids intermittently, or on an as-needed basis. It also warns that the drug should be kept out of the reach of children and should not be substituted for other fentanyl products.

In February, the FDA announced that it would require a REMS for a different class of opioids that offer long-acting and extended-release medication. The FDA has held a series of meetings with stakeholders, including a large public meeting, and also solicited written public comments to hear more about how to develop this REMS.

"The REMS for Onsolis was specifically tailored to that drug and should not be viewed as a

model REMS for long-acting and extended-release opioid products," said Douglas Throckmorton, M.D., deputy director of CDER. "Developing the comprehensive REMS for these other products is a complex undertaking. We will take the time necessary to review all of the public comments and will proceed in a deliberate manner toward the mutual goals of patient access and patient protection."

Onsolis is manufactured by Aveva Drug Delivery Systems, Miramar, Fla., and marketed under license from BioDelivery Sciences International Inc. of Raleigh, N.C., by Meda Pharmaceuticals Inc., based in Somerset, N.J.

For more information see:

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm172039.htm>