



## FDA News

### FOR IMMEDIATE RELEASE

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### FDA Warns of Potential Serious Side Effects with Breakthrough Cancer Pain Drug

The Food and Drug Administration is alerting health care professionals and consumers to concerns over the use of Fentora (fentanyl buccal) tablets after recent reports of deaths and other adverse events.

Fentora, a potent opioid pain medication, is used only for treatment of breakthrough pain in cancer patients receiving opioid treatment and who have become tolerant to it. Breakthrough pain is intense increases in pain that occur with rapid onset, even when opioid pain-control medication is being used. Patients who take narcotic pain medications daily and around-the-clock develop tolerance and are more resistant to the dangerous side effects of these medications than patients who take narcotic pain medication on a less frequent basis.

The deaths reported were the result of improper selection of patients, dosing, or improper product substitution.

"FDA is monitoring this issue very closely," said Steven Galson, M.D., M.P.H., director of FDA's Center for Drug Evaluation and Research. "We are working with the manufacturer to ensure the safest use of this medicine. Health care professionals and patients need to be aware of the potential for fatal overdose with the improper use of Fentora."

In its Public Health Advisory and Health Care Professional Sheet published today, FDA warned physicians and other health care professionals that it is critical to follow product labeling when administering Fentora. FDA further stated that it is dangerous to use Fentora for any short-term pain such as headaches or migraines. It is critical that Fentora not be used in patients who are not opioid tolerant.

Patients also must be under a doctor's care and close supervision while taking Fentora and the dose should be carefully adjusted to control breakthrough pain adequately.

In addition, FDA is concerned about the improper substitution of Fentora, a quick acting pain drug, for other pain medicines. Fentora is not the same as other fentanyl products and cannot be substituted for Actiq, another fentanyl product used to treat breakthrough cancer pain. Because Fentora delivers more fentanyl to the blood than Actiq, substituting Fentora for Actiq using the same dose can result in a fatal overdose.

On Sept. 10, 2007, Cephalon Inc., the manufacturer of Fentora, sent letters to physicians and other health care providers advising them about the adverse events and deaths reported for Fentora. FDA is reviewing available information including adverse events. The agency has asked the company to strengthen warnings and improve the dosing instructions in the drug's product labeling. FDA also requested that the company improve their education plan for prescribers and pharmacists on the proper patient selection, dosing instructions and restrictions on substituting Fentora for other products.

Adverse events related to this product should be reported to MedWatch, the FDA's voluntary reporting program:

[www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

800-332-1088

Fax: 800-332-0178

Mail: MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787

For more information, please visit: [Fentanyl Buccal Tablets \(marketed as Fentora\)](#)

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