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FDA won't allow Cephalon to expand use of painkiller

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Cephalon Inc. said yesterday the Food and Drug Administration won't allow the Frazer biotechnology company to expand uses of its painkiller Fentora unless the company finds better ways to inform patients and doctors about the drug's risks.

- > The company said the FDA did not ask for additional safety or efficacy studies.
- > Fentora already is approved for treatment of what is known as breakthrough pain: brief but intense flare-ups in cancer patients already being treated with prescription opioid painkillers.
- > Fentora, which contains the narcotic fentanyl, currently is sold under an FDA safety alert for potential life-threatening risks. Cephalon has reported five patient deaths due to negative reaction or overdose on the drug.
- > Cephalon has been seeking FDA approval to prescribe Fentora to treat breakthrough pain in patients with chronic lower back and nerve pain who are already taking prescription opioids.
- > Cephalon said it had been expecting this answer from the FDA since May, when the company discussed ways to reduce the risks that arise from improper prescriptions of Fentora.
- > Also in May, an FDA panel of outside experts voted 17-3 against wider use of the drug, citing potential harm from misuse in a broader population and the availability of other treatments.
- > In February, Cephalon sent doctors a letter warning them to follow dosage instructions carefully and to prescribe Fentora only for patients already taking opioid painkillers around the clock.
- > The company said it will continue to educate doctors, patients and pharmacists to assure that Fentora is prescribed appropriately.
- > Fentora is part of the opioid class of prescription painkillers, which also includes morphine and codeine. The drugs can be highly addictive and are sometimes abused. The FDA approved Fentora in 2006 under strict guidelines. But as sales have grown, more than 80 percent of patients take the drug off-label, meaning for an unapproved use.
- > In the first six months of this year, Cephalon reported \$75.3 million in Fentora sales, up from \$68 million in the same period of 2007.

> Cephalon shares fell \$1.65, or 2.1 percent, to \$75.38 yesterday. The company has gained 5 percent this year, compared with a 14 percent drop in the 14-member Standard & Poor's 500 Pharmaceutical Index.

