Viracept OK Again for Children, Pregnant Women

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Pfizer has met new manufacturing standards set by the Food and Drug Administration (FDA) for Viracept (nelfinavir), and the drug is now considered safe again for use in children and pregnant women in the United States, according to a letter sent to health care providers by Pfizer earlier this month. Pfizer is still in negotiations with Canadian regulators for distribution there, and Roche, the distributor of Viracept in Europe, hasn't yet brought the product back onto the market there despite having its license reinstated.

In September 2007, Pfizer alerted patients and providers that higher-than-acceptable levels of ethyl methanesulfonate (EMS), an impurity that occurs during the manufacturing of Viracept, had been found in U.S. batches of the drug. Because EMS may be cancer-causing, Pfizer and the FDA warned children and pregnant women against using the drug until safe limits for the impurity could be determined. In Europe, Viracept was recalled from all markets and Roche's license to sell the drug was suspended.

Pfizer states that as of March 31, 2008, all supplies of the drug currently available for sale in the U.S. meet the new FDA manufacturing standards, and that recommendations warning against the use of the drug in children and pregnant women are no longer necessary.

The license to market Viracept in Europe has been reinstated, but Roche has not yet returned to selling the drug. Pfizer is waiting on the Canadian government to set an EMS safety level so that use among children and pregnant women can once again be permitted.

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