



FDA Statement

FOR IMMEDIATE RELEASE

Statement
April 8, 2009

Media Inquiries:
Rita Chappelle, 301-796-4672
Consumer Inquiries:
888-INFO-FDA

FDA Statement on the Voluntary Withdrawal of Raptiva From the U.S. Market

Today, Genentech, the manufacturer of the psoriasis drug Raptiva (efalizumab), announced that it has begun a voluntary, phased withdrawal of the product from the U.S. market. The company is taking this action because of a potential risk to patients of developing progressive multifocal leukoencephalopathy (PML), a rare, serious, progressive neurologic disease caused by a virus that affects the central nervous system. By June 8, 2009, Raptiva will no longer be available in the United States.

Prescribers are being asked not to initiate Raptiva treatment for any new patients. Prescribers should immediately begin discussing with patients currently using Raptiva on how to transition to alternative therapies. The FDA strongly recommends that patients work with their health care professional to transition to other alternative therapies for psoriasis.

The risk that an individual patient taking Raptiva will develop PML is rare and is generally associated with long-term use. Generally, PML occurs in people whose immune systems have been severely weakened and often leads to an irreversible decline in neurologic function and death. There is no known effective treatment for PML. On Oct. 16, 2008, FDA updated the FDA-approved labeling for Raptiva to warn of the risk of life-threatening infections, including PML. On Feb. 19, 2009, the FDA issued a Public Health Advisory informing patients and prescribers of the risk of PML in patients taking Raptiva, after receiving reports of four patients with PML, three of whom died. On March 13, 2009, the FDA approved a Medication Guide for Raptiva and included additional information in Raptiva's labeling regarding PML.

Raptiva was approved by the FDA in 2003. It is a once-weekly injection for adults with moderate to severe plaque psoriasis.

Prescribers should continue to monitor patients on Raptiva for neurologic symptoms that might represent PML. Prescribers and patients may report adverse events to the FDA's MedWatch program at 800-FDA-1088, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or online at www.fda.gov/medwatch/report.htm.

More information about the withdrawal of Raptiva is available on the Genentech Web site: www.gene.com/gene/products. Prescribers with questions about Raptiva may contact Genentech Medical Communications at (800) 821-8590.

#

Additional Information

[Efalizumab \(marketed as Raptiva\) Information](#)

[RSS Feed for FDA News Releases](#) [\[what's this?\]](#)

[Get email updates](#) about FDA press releases.

[FDA Newsroom](#)

[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#)

FDA Website Management Staff