FDA clears safety test to screen Tysabri patients

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(AP) -- The Food and Drug Administration on Friday approved a new diagnostic test to help identify patients who have an increased risk of developing a rare brain infection while taking Biogen Idec's multiple sclerosis drug Tysabri.

Tysabri is one of a handful of drugs used to control multiple sclerosis, a debilitating disease in which the body attacks its own nervous system. Prescribing of the drug has been tightly controlled by the FDA because of a rare infection that causes inflammation of the brain, known as multifocal leukoencephalopathy, or PML. Currently there is no treatment or cure for PML, which is usually fatal.

The newly approved Stratify JCV test is designed to detect a common virus that increases the likelihood of developing the brain infection. The John Cunningham virus is harmless in most people, but can become dangerous in patients taking immune system-suppressing drugs like Tysabri.

Doctors can use the results of the blood-based test, combined with facts about the patient's medical history, to determine whether they are at risk of developing the brain infection. Other factors that influence a patient's risk include how long they've been taking Tysabri and whether they've previously taken other medications that weaken the immune system.

The test was developed by Quest Diagnostics.

The FDA also updated Tysabri's label to specify that patients who test positive for the virus have a higher risk of developing PML.

"This label change marks an important advance in assisting people with MS and their physicians to make better-informed decisions concerning the challenges of balancing effectiveness with safety," said Dr. Nicholas LaRocca, vice president of the National MS Society.

Tysabri was temporarily pulled from the market shortly after its launch in 2005 after three patients taking the drug developed PML. FDA allowed the drug back on the market the following year but under a restricted distribution program. Only doctors and pharmacies registered with the company's distribution program are permitted to prescribe and dispense the drug.

Biogen, based in Weston, Mass., sells Tysabri through a partnership with Elan Corp., an Irish drugmaker.