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US health watchdog rejects Sanofi's MS drug

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French drug giant Sanofi announced Monday US health authorities had rejected its Lemtrada drug for some forms of multiple sclerosis, which is already approved in the European Union, Canada and Australia.

The Food and Drug Administration (FDA) said Sanofi's subsidiary Genzyme, which makes the drug aimed at treating relapsing forms of the disease, had "not submitted evidence from adequate and well-controlled studies that demonstrate the benefits of Lemtrada outweigh its serious adverse effects."

The FDA has also decided "one or more" clinical trials are necessary before approval of the drug—a move Sanofi said would likely prevent the drug from being approved on the US market by March 31 next year, as originally planned.

"We are extremely disappointed with the outcome of the review and the implications for patients in the US suffering with multiple sclerosis who remain in need of alternative therapies to manage a devastating disease," Genzyme President David Meeker said in a statement.

"Genzyme strongly disagrees with the FDA's conclusions and plans to appeal the agency's decision," the statement added.

Lemtrada is one of the most promising drugs in Sanofi's pipeline, and was a key motivation behind the French firm's 2011 takeover of Genzyme for more than $20 billion.

The drug is already approved in the European Union, Canada and Australia.

Multiple sclerosis, a degenerative disease of the nervous system which disrupts the brain's ability to communicate with the body, affects some 2.1 million people in the world, including 410,000 in the United States.

According to Sanofi, the most common side effects of Lemtrada include infections of the upper respiratory tract and urinary tract and lymphopenia—a reduction in the number of lymphocytes, a subset of white blood cells. Serious autoimmune conditions can also occur.