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Sanofi drug fails to win USFDA backing

Sanofi failed to win US regulatory approval for its multiple sclerosis drug Lemtrada, denting the company's ambitions of capturing a larger share of the $20 billion market for the disease. The US Food and Drug Administration said Sanofi's Genzyme unit didn't submit evidence from "adequate and well-controlled studies" showing that the benefits of Lemtrada outweigh its side effects, the Paris-based company said in a statement on Monday. Sanofi disagrees with the conclusion and plans to appeal, the company said. Lemtrada, which was approved in the European Union in September, and in Australia and Canada this month, was a key part of Sanofi's $20.1-billion acquisition of Genzyme in 2011.

Regulatory / Company.