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FDA red signal for Genzyme, Bayer multiple sclerosis drug

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FDA gives red signal to Genzyme multiple sclerosis drug, LEMTRADA

Singapore: Genzyme, a Sanofi company, received a Refuse to File letter from the US FDA in response to the supplemental Biologics License Application (sBLA) for the approval of LEMTRADA (alemtuzumab) as a treatment for relapsing multiple sclerosis (MS).Genzyme is developing LEMTRADA in MS in collaboration with Bayer HealthCare.

Following collaborative consultations with the company, the FDA requested that the firm modify the presentation of the data sets to enable the agency to better navigate the application. The FDA has not requested additional data or further studies. Genzyme will work with the FDA over the coming weeks to resubmit the application as soon as possible.

"We have had constructive dialogue with the FDA, and we are very confident in our ability to address the agency's request and resubmit rapidly," said Mr David Meeker, president and CEO, Genzyme.

The company's marketing authorization application submitted to the European Medicines Agency has been accepted and the review process is underway.