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FDA approves first generic version of Sabril to treat seizures

21 January 2019 | News

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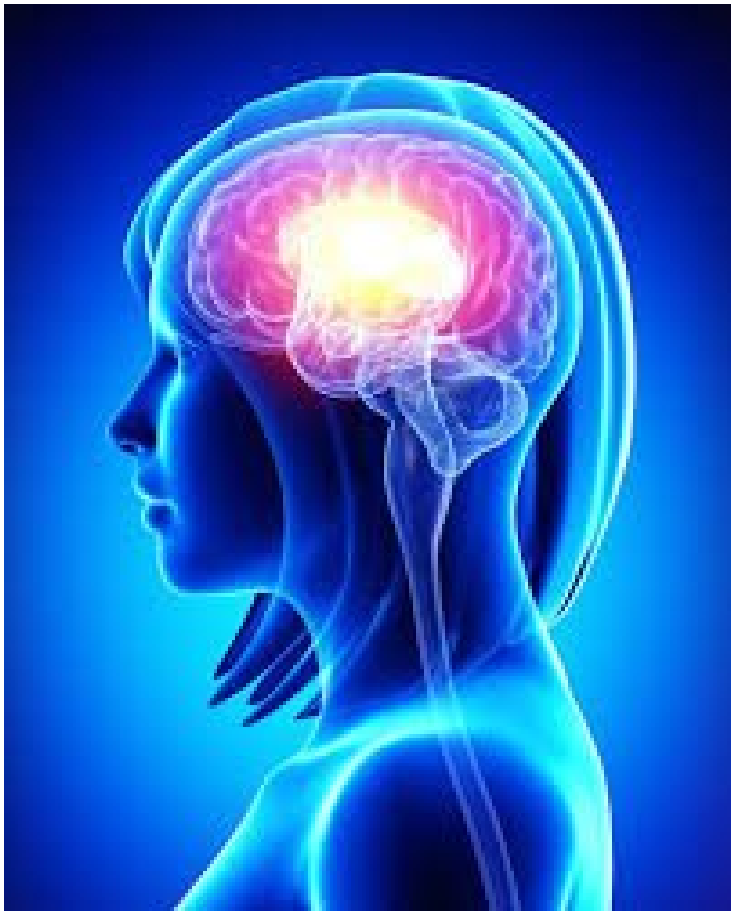

The U.S. Food and Drug Administration approved the first generic version of Sabril (vigabatrin) 500 mg tablets for treating complex partial seizures, also called focal seizures, as an adjunctive therapy (given with another primary treatment) in patients 10 years and older who have responded inadequately to several alternative (refractory) treatments.

"Prioritizing the approval of generic drugs to compete with medicines that face little or no competition is a key part of our efforts to support access and reduce drug costs to patients. The availability of high-quality generic alternatives of critically important medicines, once the period of patent protection or exclusivity has ended on the brand drug, helps advance access and saves consumers billions of dollars each year," said FDA Commissioner Scott Gottlieb, M.D. "We know there has been past interest in developing a generic alternative to this product. Earlier this year, we also highlighted this drug, along with many others, on a list of off-patent, off-exclusivity branded drugs without approved generics, to clarify that there were no patents or exclusivities that should impede its approval.

Today's action demonstrates that there is an open pathway to approving products like this one. We're especially focused on new policies aimed at making the generic review process more predictable, efficient and lower cost so we can entice more generic firms to enter this space, and help facilitate more generic drug launches after generic approvals. We know it's not enough just to approve a record number of generic medicines. We also want to see firms launch these products so that patients can benefit from their availability, and we intend to take steps to advance these goals."

Complex partial seizures, a common type of seizures, start in a specific area of the brain and can affect consciousness. Typically, complex partial seizures last between 30 and 90 seconds, and are often followed by a period of disorientation, confusion and/or fatigue.

The FDA requires appropriate data and information to demonstrate that generic drugs meet the agency's rigorous approval standards to ensure quality drug products that are as safe and effective as their brand name counterparts. As with brand-name drugs, the FDA also inspects manufacturing and packaging facilities for generic drugs to ensure that they are capable of consistently producing quality products.

Labeling for vigabatrin tablets includes a boxed warning for permanent vision loss. Teva's generic vigabatrin tablets is part of a single shared-system Risk Evaluation and Mitigation Strategy (REMS) program with other drug products containing vigabatrin to ensure the safe use of the product. Brand and generic drug makers are required to develop a single shared-system REMS program (unless FDA waives the single shared system requirement) when a generic drug seeks approval and the brand drug has a REMS associated with it.