



COMMONWEALTH OF AUSTRALIA

Department of Health  
Therapeutic Goods Administration

*THERAPEUTIC GOODS ACT 1989*

**DESIGNATION OF RUFINAMIDE (TBA) AS AN ORPHAN DRUG**

I, Dr Anthony Gill, Delegate of the Secretary for the purposes of 16J of the Therapeutic Goods Regulations 1990 ("the Regulations"), acting under subregulation 16J(2) of the Regulations, designate rufinamide (TBA) as an orphan drug on 23 September 2016 for the treatment of seizures associated with Lennox-Gastaut syndrome.

The dose form of rufinamide (TBA) for this indication is tablets and oral suspension.

The sponsor of rufinamide (TBA) is Eisai Australia Pty. Ltd.

(Signed by)

Dr Anthony Gill  
Delegate of the Secretary  
23 September 2016