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GOVERNMENT NOTICES

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

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