



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF SODIUM PHENYLBUTYRATE (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 Sodium Phenylbutyrate (TBA) as an orphan drug on 22 March 2017 for the treatment of urea cycle disorders.

The dose form of Sodium Phenylbutyrate (TBA) for this indication is tablet.

The sponsor of Sodium Phenylbutyrate (TBA) is Orpharma Pty Ltd.

(Signed by)

Dr Anthony Gill
Delegate of the Secretary
22 March 2017