Gazette

Published by the Commonwealth of Australia

**GOVERNMENT NOTICES** 

## **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

PO Box 100 Woden ACT 2606 ABN 40 939 406 804

Phone: 02 6232 8444 Fax: 02 6203 1605 Email: info@tga.gov.au Website: http://www.tga.gov.au