



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF TELOTRISTAT ETIPRATE 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 Telotristat etiprate as an orphan drug on 29 July 2016 for the treatment of Carcinoid Syndrome.

The dose form of Telotristat etiprate for this indication is film coated tablet.

The sponsor of Telotristat etiprate is Ipsen Pty Ltd.

(Signed by)

Dr Anthony Gill
Delegate of the Secretary

29 July 2016