



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF BEVACIZUMAB (AVASTIN) 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 Bevacizumab (AVASTIN) as an orphan drug on 4 January 2017 for the treatment of malignant mesothelioma.

The dose form of Bevacizumab (AVASTIN) for this indication is concentrated injection.

The sponsor of Bevacizumab (AVASTIN) is Roche Products Pty Limited.

(Signed by)

Dr Anthony Gill
Delegate of the Secretary
4 January 2017