Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Therapeutic Goods Regulations 1990

DESIGNATION OF ADALIMUMAB (HUMIRA) 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 adalimumab (HUMIRA) as an orphan drug on the 2 November 2012 for the treatment of active Crohn's Disease defined as a Paediatric Crohn's Disease Activity Index (PCDAI) score >30 in paediatric patients (6 - 17 years of age) who have had an inadequate response to conventional therapy, or who are intolerant to or have contraindications for such therapies.

The dose form of adalimumab (HUMIRA) for this indication is solution for injection.

The sponsor of adalimumab (HUMIRA) is AbbVie Pty Ltd.

(Signed by)

Dr Anthony Gill
Delegate of the Secretary

2 November 2012

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