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GOVERNMENT NOTICES

COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

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 19 August 2015 for the treatment of adult patients with non-infectious intermediate, posterior or pan-uveitis who have an inadequate response to corticosteroid therapy or who relapse when corticosteroid therapy is tapered down.

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

19 August 2015

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