Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of a restricted representation by Bayer Australia Pty Ltd

I, Jane Cook, Head, Office of Product Review, Therapeutic Goods Administration and delegate of the Secretary to the Department of Health and Ageing, on receipt of an application from Bayer Australia Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989* (the Act) the restricted representations described in paragraph (a) below for use in advertisements directed to consumers, for the product identified in paragraph (b), provided the condition identified in paragraph (c) is met:

(a) "Neural tube defects" and "spina bifida"

(b) 'Elevit film-coated tablet' (AUSTR 213113)

(c) The advisory statement: "If you have had a baby with a neural tube defect/spina bifida, seek medical advice" must appear in all consumer advertising in which the restricted representations described in paragraph (a) are used.

Dated this 9 day of September 2013

Jane Cook
Delegate of the Secretary to the Department of Health and Ageing; and
Head
Office of Product Review

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6203 1605 Email: info@tga.gov.au
www.tga.gov.au