Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by Pfizer Australia Pty Ltd

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

(a) (i) Representations to the effect "may be of assistance in the prevention of osteoporosis."
(ii) Representations to the effect "Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life."
(ii) Representations to the effect of providing information to consumers about osteoporosis and its risk factors that is accurate and balanced and reflects the body of contemporary evidence, when such information accompanies claims made in accordance with paragraph (a)(i).

(b) Caltrate 600mg (Reformulation) (AUSTL 196980), Caltrate Bone Health (AUSTL 214784), Caltrate Bone & Muscle Health (AUSTL 214783), Caltrate 600mg with 500IU Vitamin D (AUSTL 196978) and Caltrate PLUS with 500IU Vitamin D & Minerals (AUSTL 196979).

(c) Representations to the effect "may assist in the prevention of osteoporosis" must only be used in conjunction with the phrase to the effect: "when dietary calcium intake is inadequate."

Dated this 8 day of September 2014

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

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