

Australian Government

Department of Health Therapeutic Goods Administration

<u>Therapeutic Goods Act 1989</u> Approval under section 42DF for use of a restricted representation by Medical Developments International Limited

I, 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 Medical Developments International Limited, 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) "Asthma"
- (b) 'Breath-Alert®' (Peak Flow Meter, manual) ARTG Number: 145194
- (c) The advisory statement: "To be used as directed by your doctor" (or words to that effect).

Dated this 1 day of October 2013

Delegate of the Secretary to the Department of Health; Head Office of Product Review

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