

## **Australian Government**

## **Department of Health and Ageing Therapeutic Goods Administration**

## <u>Therapeutic Goods Act 1989</u> <u>Approval under section 42DF for use of a restricted representation by</u> <u>GlaxoSmithKline Consumer Healthcare</u>

I, Dr 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 by GlaxoSmithKline Consumer Healthcare, have approved under section 42DF (1) of the *Therapeutic Goods Act 1989* (the Act) the restricted representation described in paragraph (a) below for use in advertisements directed to consumers, for the products identified in paragraph (b) provided that the condition in paragraph (c) is met:

- (a) "CONTRAINDICATION: Breathe Right Nasal Strips are not for the treatment of sleep apnoea. If you think that your snoring may be a symptom of sleep apnoea you should consult your doctor."
- (b) "Breathe Right Nasal Strips" ARTG No. 145628
- (c) the representation "sleep apnoea" may only be used in the context of the warning statement specified in paragraph (a) of this document.

Dated this 28 day of September 2012

Dr Jane Cook

Delegate of the Secretary to the Department of Health and Ageing; and

Head

Office of Product Review