

Australian Government

Department of Health and Ageing Therapeutic Goods Administration

Therapeutic Goods Act 1989

I, Dr Jane Cook, Acting Head, Office of Product Review, Therapeutic Goods Administration and delegate of the Secretary to the Department of Health and Ageing for the purposes of section 42DF(1) of the Therapeutic Goods Act 1989, give notice that the restricted representation described in paragraph (a) below has been approved for use in advertisements directed to consumers, for the products identified in paragraph (b) provided the conditions identified in paragraph (c) are met:

- a. Representations to the effect that advertisements to consumers for the goods described in paragraph (b) may refer to: "Sleep Apnea/Apnoea", "Obstructive Sleep Apnea/Apnoea (OSA)" and "Central Sleep Apnea/Apnoea (CSA)".
- b. Continuous Positive Airway Pressure (CPAP or PAP) units and equipment.
- c. The claims made in the advertisements must not extend beyond their intended purpose on the Australian Register of Therapeutic Goods. The advertisements in which the representations are made must comply with the Therapeutic Goods Advertising Code 2007, as amended from time to time, and must advise consumers to seek advice from their medical practitioner or health care professional.

Dated this day of February 2011

Dr Jane Cook

Acting Office Head

Office of Product Review

Delegate of the Secretary to the Department of Health and Ageing