



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989

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

- (a) Representations to the effect that advertisements to consumers for the medicine described in paragraph (b) may refer to "low testosterone levels", and "Coeliac disease and Crohn's disease" in the following questions as part of a nine point questionnaire entitled "One Minute Risk Test":

"5. For men: have you ever suffered from symptoms related to low testosterone levels?"
and

"9. Do you suffer from intestinal problems such as Coeliac disease or Crohn's disease?"

- (b) Caltrate Plus with 400IU Vitamin D and Mineral Tablets (ARTG 183240) sponsored by Pfizer Australia Pty Ltd.

- (c) Subject to the conditions that:

1. the questionnaire (presented as the "One Minute Risk Test" at Attachment 1 of Pfizer's application of 29 August 2011) must be used in its entirety; and

2. the final advisory paragraph of the "One Minute Risk Test" questionnaire must be included and read:

"If you answered 'yes' to any of these questions, you may be at risk of developing osteoporosis. Osteoporosis is a serious condition which needs close management by your doctor. Do not attempt to self-treat osteoporosis, consult your doctor and discuss the matter. The good news is that osteoporosis can be relatively easily diagnosed and treated under medical supervision."

Dated this 29 day of November 2011

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