Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989

I, Dr Jane Cook, Office 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 Pfizer Australia Pty Limited, 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):

(a) Representations to the effect that advertisements to consumers for the medicines described in paragraph (b) may refer to "low testosterone levels", "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 600mg (ARTG 196980), Caltrate 600mg with 500IU Vitamin D (ARTG 196978) and Caltrate Plus with 500IU Vitamin D and Minerals (ARTG 196979) 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 18 September 2012) 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."

This decision is effective from 22 October 2012