

**THERAPEUTIC GOODS ACT 1989**

I, CRAIG DAVIES, Director - Advertising Section, 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 representations described in paragraph (a) below, have been approved for use in advertisements directed to consumers, for the products listed in paragraph (b) provided the conditions identified in paragraph (c) are met :

(a) Representations to the effect that advertisements to consumers for the above medicines may include the following questions as part of a nine point questionnaire:

- "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 Tablets	(AUST L 167291)
Caltrate 600mg with 400IU Vitamin D Tablets	(AUST L 167282)
Caltrate Plus with 400IU Vitamin D and Minerals Tablets	(AUST L 167283)

sponsored by Wyeth Consumer Healthcare Pty Ltd

(c) Subject to the conditions that:

1. the questionnaire (presented as Attachment 1 to Wyeth's application) must be used in its entirety, that is, all nine questions should be used together; and
2. the following advisory paragraph must also be included in the questionnaire –

"If you answered 'yes' to any one 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 8th day of July 2010



CRAIG DAVIES  
Delegate of the Secretary to the Department of  
Health and Ageing