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TRANSMISSION OK

TX/RX NO	4668
CONNECTION TEL	00396466050
SUBADDRESS	
CONNECTION ID	
ST. TIME	27/03 11:40
USAGE T	00 '19
PGS. SENT	1
RESULT	OK



Australian Government

Department of Health and Ageing  
 Therapeutic Goods Administration

[REDACTED]  
 Legal Director Asia/Pacific  
 Specsavers Pty Ltd  
 520 Graham Street  
 PORT MELBOURNE VIC 3207

Dear [REDACTED]

**Application for Approval for the use of 'restricted representations' under  
 s. 42DE of the *Therapeutic Goods Act 1989***

Further to our previous correspondence of 22 December 2011, I am writing to you in relation to your submission of 12 December 2012, in which you seek approval under s.42DF(1) of the *Therapeutic Goods Act 1989* (the Act) for the product, 'Ophthalmic Camera (ARTG Number 177741) sponsored by Ellex Australia Pty Ltd to be marketed to consumers with "restricted representations".

I am the delegate of the Secretary to the Department of Health and Ageing for the purposes of this request.

Prior to making my decision, the Delegate must take into consideration any recommendation received by the Therapeutic Goods Advertising Code Council (TGACC) about your application (s.42DF(4)(a) of the Act refers). Your application has been considered by the TGACC at its most recent meeting, which was held on 1 February 2012.

I am writing under s.42DG(2) of the Act to advise you that it is necessary to extend the 60 day time period to allow me to take into consideration the recommendation from the TGACC when making the decision about your application.

Consequently, I am extending the time period to **6 April 2012**.



Australian Government  
Department of Health and Ageing  
Therapeutic Goods Administration

36

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Yours sincerely

Mick O'Connor  
Delegate of the Secretary to the Department of Health and Ageing;  
Director  
Recalls and Advertising Section  
Office of Product Review

27 March 2012

R12/353995