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\*\*\* TX REPORT \*\*\*  
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TX/RX NO 4668  
CONNECTION TEL 00396466050  
SUBADDRESS  
CONNECTION ID  
ST. TIME 27/03 11:40  
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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

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 Specsavers Pty Ltd  
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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