



Specsavers Pty Ltd
520 Graham Street
Port Melbourne VIC 3207
Australia
ABN: 82 097 147 932
Tel +61 (0)3 8645 0700
Fax +61 (0)3 9646 6050
www.specsavers.com.au

19 DEC 2011

12 December 2011

The Delegate of the Secretary to the Department of Health & Ageing
Attention: Director, Office of Devices, Blood & Tissues
C/ Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

Application for approval to use restricted representation in advertising

Please find enclosed for application for approval to use restricted representation in advertising for your consideration.

If you have any queries please do not hesitate to contact me on 0419 327 303.

Yours sincerely,

[Redacted]
Legal Director Asia / Pacific
Specsavers Pty Ltd



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

4

Application for approval to use a restricted representation in advertising

Sections 42DE and 42DF(1) of the Therapeutic Goods Act 1989

Application is made to the Secretary in a form approved by the Secretary. Use this form for your application. All fields are mandatory.

Name of the goods or substance

Digital Retinal Photography

AUSTL or AUSTR number or ARTG number 182315

Indications for use that are, or intended purpose that is, included on the ARTG

The intent of the advertisement is to promote the benefits of Digital Retinal Photography (DRP) as a device for helping optometrists identify serious eye diseases such as glaucoma, macular degeneration and diabetes. The proposed representation (set out below) is in line with the TGA public interest criteria, specifically, as it will promote the benefit of regular eye examinations using the latest technology. I attach an article from INSIGHT November 2011 edition which quotes [REDACTED] in his capacity as Chair of Vision 2020 Australia where he says that "the best defence against many of the main eye conditions is regular eye examinations". Specsavers optometrists using DRP have detected a number of eye diseases which may have gone undetected without the use of this advanced technology. Specsavers would like to promote the health benefit of DRP.

Attach additional page(s) if necessary (please number the pages)

Attachments – please include the following with this application, if applicable:

- For medicines, a copy of the product label or, for medical devices, instructions for use.
- A copy of any exemption for the restricted representation to appear on the label.
- Evidence to show that the use of the restricted representation meets the public interest criteria included in Appendix 6 of the Therapeutic Goods Advertising Code – refer to the guidance document.
- Evidence to show that the claim is accurate, balanced and not misleading, or likely to be misleading (refer section 42DF Therapeutic Goods Act 1989).

Proposed wording of the restricted representation

The proposed wording will be to the effect:

"Digital Retinal Photography is a powerful tool that helps optometrists detect serious eye diseases including glaucoma, macular degeneration and even diabetes".

Attach additional page(s) if necessary (please number the pages)

3.

Applicant contact details

Name:		Telephone:	0419 327 303
Postal address		Fax:	0396466237
C/ Specsavers 520 Graham Street PORT MELBOURNE, VIC, 3207		Email:	
Company	Specsavers		
Signature		Date:	12/12/11

Submit the completed form, together with the attachments, to:

The Delegate of the Secretary to Department of Health & Ageing

For medicines: Director, Non-Prescription Medicines Branch

For medical devices: Director, Office of Devices, Blood & Tissues

*c/- Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606*

*This form has been approved under s.42DE(a) of the Therapeutic Goods Act 1989 by:
Craig A Davies*

Delegate of the Secretary to the Department of Health and Ageing; and

Head - Advertising and Export Section

Non-Prescription Medicines Branch

Therapeutic Goods Administration

June 2007