



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of a restricted representation by Blue Frog Optics Pty Ltd

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 Blue Frog Optic Pty Ltd, 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) provide the conditions in paragraph (c) and (d) are met::

- (a) "glaucoma", "macular degeneration", "diabetic retinopathy" and "vision threatening conditions";
- (b) "Spectral Domain Optical Coherence Tomography" device (ARTG Number 197023);
- (c) The use of the restricted representations "glaucoma", "macular degeneration", "diabetic retinopathy" and "vision threatening conditions" must be limited to representing the product identified in paragraph (b) as an aid (or words to that effect) in the detection and monitoring of glaucoma, macular degeneration, diabetic retinopathy and vision threatening conditions; and
- (d) The product identified in paragraph (b) is not to be represented in any way to be for the diagnosis and/or treatment of glaucoma, macular degeneration, diabetic retinopathy and vision threatening conditions.

Dated this 31 day of August 2012

Dr Jane Cook
Delegate of the Secretary to the Department of Health and Ageing; and
Office Head
Office of Product Review