



Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Luxottica Retail Australia Pty Ltd

I, Jane Cook, Office Head, Office of Product Review, Therapeutic Goods Administration and delegate of the Secretary to the Department of Health, on receipt of an application by Luxottica Retail Australia Pty Ltd, have approved under section 42DF (1) of the *Therapeutic Goods Act 1989* (the Act) the restricted representations 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) "serious eye diseases", "vision threatening conditions", "glaucoma", "macular degeneration", "retinal changes that may be associated with hypertensive and cardiovascular disease", "retinal changes that may be associated with diabetes", "diabetic macular edema" and "diabetic retinopathy";
- (b) "Digital Retinal Scanner – Scanning-laser ophthalmic imaging system" device (ARTG Number 194550);
- (c) The use of the restricted representations "serious eye diseases", "vision threatening conditions", "glaucoma", "macular degeneration", "retinal changes that may be associated with hypertensive and cardiovascular disease", "retinal changes that may be associated with diabetes", "diabetic macular edema" and "diabetic retinopathy" 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 "serious eye diseases", "vision threatening conditions", "glaucoma", "macular degeneration", "retinal changes that may be associated with hypertensive and cardiovascular disease", "retinal changes that may be associated with diabetes", "diabetic macular edema" and/or "diabetic retinopathy"; and
- (d) The product identified in paragraph (b) is not to be represented in any way to be for the diagnosis, treatment or follow up control of "serious eye diseases", "vision threatening conditions", "glaucoma", "macular degeneration", "retinal changes that may be associated with hypertensive and cardiovascular disease", "retinal changes that may be associated with diabetes", "diabetic macular edema" or "diabetic retinopathy".

Dated this 14 day of October 2013

Jane Cook
Delegate of the Secretary to the Department of Health;
Office Head, Office of Product Review