SECTion 14 AND 14A NOTICE

I, MAYADA KAYALI, delegate of the Secretary to the Department of Health and Ageing for the purposes of sections 14, 14A and 15 of the *Therapeutic Goods Act 1989* (‘the Act’) hereby give my consent, pursuant to sections 14 and 14A of the Act, for Merck Sharp & Dohme (Australia) Pty Limited, Level 4, 66 Waterloo Road NORTH RYDE NSW 2113 to supply of Demazin Day & Night Cold & Flu tablets AUST R 133205 whose label does not comply with subclause 3(2)(l) of the *Therapeutic Goods Order No. 69 – General requirements for medicine labels* in that the label does not include the name and address of the current sponsor or supplier of the goods*.*

Pursuant to section 15(1) of the Act, my consent is subject to the following conditions:

1. The consent applies to batch number BR961 only;
2. The product complies with all other aspects of the *Therapeutic Goods Order No. 69 – General requirements for medicine label;*
3. The product labels include the name and address of the previous sponsor Shering-Plough Pty Ltd; and
4. Merck Sharp & Dohme (Australia) Pty Limited have arranged for any contacts made in relation to the above products to the Shering-Plough Pty Ltd address to be re-directed to the address of the current sponsor.

(Signed by)

Mayada Kayali

Delegate of the Secretary

Office of Medicines Authorisation

19 April 2013