Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

SECTION 14 AND 14A NOTICE

On October 18 2012, the delegate of the Secretary of the Department of Health and Ageing for the purposes of subsection 14 and 14A of the *Therapeutic Goods Act 1989* ("the Act") gave her consent to:

a) The supply of the product fluoxetine (as hydrochloride) (AUSCAP ASPEN) 20 mg capsules [Aust R 190676] by Generic Health Pty, Camberwell, Vic ("the Company")

   That does not conform with paragraph 4 of the Therapeutic Goods Order (TGO) 69 in that the name of the active ingredient is expressed differently on the carton labels to the approved version.

Pursuant to subsection 15(1) of the Act, the consent given by the delegate of the Secretary as described above is subject to the following conditions:

1. This consent applies for a period of 6 months.

2. No other changes have been made to the product fluoxetine (as hydrochloride) (AUSCAP ASPEN) 20 mg capsules [Aust R 190676].

3. This consent applies only to batches B200E2004 and B200E2005, which are packed in cartons expressing the proportion of active ingredient as 'Fluoxetine hydrochloride capsules' rather than 'Fluoxetine (as hydrochloride) capsules'. All future batches must be packed in cartons that express the active as 'Fluoxetine (as hydrochloride)', and as such will comply completely with TGO 69 and TGA approved artwork.

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