



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

SECTION 14 AND 14A NOTICE

On September 24 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 his consent to:

- (a) the supply of the following products by Ascent Pharma Pty Ltd, South Melbourne, VIC (“the Company”):
- salbutamol (as sulfate) (SALBUTAMOL-GA) 2.5 mg/2.5 mL inhalation solution ampoule [Aust R 199798]
 - salbutamol (as sulfate) (SALBUTAMOL-GA) 5 mg/2.5 mL inhalation solution ampoule [Aust R 199799]

That does not conform with paragraph 3(2)(b) of the Therapeutic Goods Order 69, in that the active ingredient is expressed as “salbutamol sulphate”, which is different to that of the Australian Approved Name, “salbutamol sulfate”.

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. The consent applies for:
 - Batches YW0052 and YW0123 of salbutamol (as sulfate) (SALBUTAMOL-GA) 2.5 mg/2.5 mL inhalation solution ampoule [Aust R 199798]
 - Batches YT0019 and YT0028 of salbutamol (as sulfate) (SALBUTAMOL-GA) 5 mg/2.5 mL inhalation solution ampoule [Aust R 199799]
2. The labels to which this consent applies are identical to those provided in correspondence from the Company dated July 30 2012, i.e. the labels which use “salbutamol sulphate” instead of the Australian Approved Name “salbutamol sulfate” in the expression of the active ingredient.
3. No other changes have been made to the products:
 - salbutamol (as sulfate) (SALBUTAMOL-GA) 2.5 mg/2.5 mL inhalation solution ampoule [Aust R 199798]
 - salbutamol (as sulfate) (SALBUTAMOL-GA) 5 mg/2.5 mL inhalation solution ampoule [Aust R 199799]