



**Australian Government**

**Department of Health and Ageing**  
Therapeutic Goods Administration

**THERAPEUTIC GOODS ACT 1989**

**SECTION 14 AND 14A NOTICE**

On October 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 Generic Health Pty Ltd, Camberwell, VIC (“the Company”):
- olanzapine (as benzoate) (OLANZAPINE GENERICHEALTH) 2.5 mg tablet blister pack [Aust R 152124]
  - olanzapine (as benzoate) (OLANZAPINE GENERICHEALTH) 5 mg tablet blister pack [Aust R 152167]
  - olanzapine (as benzoate) (OLANZAPINE GENERICHEALTH) 7.5 mg tablet blister pack [Aust R 152168]
  - olanzapine (as benzoate) (OLANZAPINE GENERICHEALTH) 10 mg tablet blister pack [Aust R 152169]
  - olanzapine (as benzoate) (STADA OLANZAPINE) 2.5 mg tablet blister pack [Aust R 152170]
  - olanzapine (as benzoate) (STADA OLANZAPINE) 5 mg tablet blister pack [Aust R 152171]
  - olanzapine (as benzoate) (STADA OLANZAPINE) 7.5 mg tablet blister pack [Aust R 152172]
  - olanzapine (as benzoate) (STADA OLANZAPINE) 10 mg tablet blister pack [Aust R 152123]
  - olanzapine (as benzoate) (OLANZATABS) 2.5 mg tablet blister pack [Aust R 152174]
  - olanzapine (as benzoate) (OLANZATABS) 5 mg tablet blister pack [Aust R 152175]
  - olanzapine (as benzoate) (OLANZATABS) 7.5 mg tablet blister pack [Aust R 152176]
  - olanzapine (as benzoate) (OLANZATABS) 10 mg tablet blister pack [Aust R 152177]

That do not conform with the United States Pharmacopoeia 35 monograph for Olanzapine Tablets in that the products listed above do not comply with the acceptance criterion for Olanzapine related compound B in the Organic Impurities test.

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 acceptance criteria to be applied to “Olanzapine related compound B” in the product specifications is not more than 0.15% at release and not more than 0.5% at expiry for the following products:
  - olanzapine (as benzoate) (OLANZAPINE GENERICHEALTH) 2.5 mg tablet blister pack [Aust R 152124]
  - olanzapine (as benzoate) (OLANZAPINE GENERICHEALTH) 5 mg tablet blister pack [Aust R 152167]
  - olanzapine (as benzoate) (OLANZAPINE GENERICHEALTH) 7.5 mg tablet blister pack [Aust R 152168]
  - olanzapine (as benzoate) (OLANZAPINE GENERICHEALTH) 10 mg tablet blister pack [Aust R 152169]
  - olanzapine (as benzoate) (STADA OLANZAPINE) 2.5 mg tablet blister pack [Aust R 152170]
  - olanzapine (as benzoate) (STADA OLANZAPINE) 5 mg tablet blister pack [Aust R 152171]
  - olanzapine (as benzoate) (STADA OLANZAPINE) 7.5 mg tablet blister pack [Aust R 152172]
  - olanzapine (as benzoate) (STADA OLANZAPINE) 10 mg tablet blister pack [Aust R 152123]
  - olanzapine (as benzoate) (OLANZATABS) 2.5 mg tablet blister pack [Aust R 152174]
  - olanzapine (as benzoate) (OLANZATABS) 5 mg tablet blister pack [Aust R 152175]
  - olanzapine (as benzoate) (OLANZATABS) 7.5 mg tablet blister pack [Aust R 152176]
  - olanzapine (as benzoate) (OLANZATABS) 10 mg tablet blister pack [Aust R 152177]
  
2. The test method to be used is method QC.NUS.OPN.bza.tab.002.C/2.