



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

Vanessa Thomas  
Aspen Pharmacare Australia Pty Ltd  
34-36 Chandos Street  
ST LEONARDS NSW 2065

Sponsor Client ID: 32728

**GMP Clearance Application MI-2011-CL-10459-3 Notification.**

Please be advised that GMP Clearance is approved for the following manufacturer:

Beltapharm SPA  
Via Stelvio 66  
Cusano Milano  
Italy

Manufacturer Client ID: 51019

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Cream	Registered Therapeutic Good	Finished Product Manufacture

This Clearance remains current until 03/06/2014 unless otherwise revoked.

This clearance has been issued with an additional six months to allow re-certification and application activities to be completed before expiry. You are advised to submit a new electronic GMP Clearance application with updated GMP evidence not less than three months prior to the expiry date to avoid delays in the registration/listing of new products and maintain products on the Australian Register of Therapeutic Goods (ARTG). Expired GMP Clearance could result in affected product(s) being removed from the ARTG.

This Clearance letter should be used only for future listing/registration of the product types specified above.

For further information please refer to the Therapeutic Goods Administration website:  
<http://www.tga.gov.au/industry/manuf.htm> Alternatively you may contact the undersigned.

Yours sincerely

Colleen Trotter  
GMP Clearance Unit  
Office of Manufacturing Quality  
Monitoring and Compliance Group  
Therapeutic Goods Administration  
20/12/2011