



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

File No. 2000/065546  
Submission ID: OM-2009-01451-3

The Managing Director  
Sigma Pharmaceuticals Australia Pty Ltd  
Regulatory & Medical Affairs Dept  
Locked Bag 268  
CROYDON VIC 3136

**Attention: Frank da Silva**

Dear Sir/Madam

I refer to your application to vary the particulars of registration of **AMCAL BURN & BITE GEL tube AUST R 23681** in the Australian Register of Therapeutic Goods.

Approval is given for the introduction of a new graphic on the label as described in the application dated 22 December 2009 and as finalised with your e-mail correspondence dated 26 March 2009.

The following changes described in the application are noted:

- changes to manufacturing details,
- labelling changes involving colour, font and type size, and
- correction of the ARTG records with respect to the content of the active ingredient chlorhexidine gluconate (from 2.5 mg/g to 500 microgram/g) and update of excipient quantities as described in the application.

**Please note that only the requested changes (as above) have been assessed; no further review of the products or their labelling has been undertaken at this time.**

The Australian Register of Therapeutic Goods has been amended to reflect this approval. The TGA eBusiness Services website contains a printable updated Certificate of Registration for this good.

Yours faithfully

A handwritten signature in black ink, appearing to read 'Pradip', written over a horizontal line.

Pradip Adhikari  
Delegate of the Secretary  
OTC Medicines Section  
26 March 2010