



Australian Government

Department of Health
Therapeutic Goods Administration

File Reference: ##/#####
Sent by email

The Regulatory Affairs Manager

Sponsor Name

Sponsor Address

Suburb State Postcode

Email: <Enter recipient's email address – this must come from eBS - check with Sponsor to make sure it is accurate>

Dear Title Surname,

NOTICE OF COMPLIANCE TEST PASS

Notice under Part 5, reg 29 of the *Therapeutic Goods Regulations 1990* informing [Sponsor Name] of the testing results of 'device or medicine name' from the Australian Register of Therapeutic Goods entry [ARTG number].

If not an official sample (taken by an Authorised Officer or supplied under s28 (5)[h] or s41 FN(2) of the *Therapeutic Goods Act 1989*) delete the above [#delete this note]

ARTG Number: ARTG number
Product Name: From the ARTG
Intended Purpose: (If medical device, otherwise delete) From the ARTG
Device Class: (If medical device, otherwise delete) xxx
Batch Number: xxx
Expiry Date: xxx
TGA Sample Number: xxx

A sample of the above mentioned product was recently tested by the TGA Laboratories as part of routine surveillance of products on the Australian market / as a result of a problem reported in relation to the medicine/medical device on [#insert date] / as a result of a complaint investigation on (insert date).

The enclosed Certificate of Official Analyst – official samples/Certificate of Analysis / Laboratory Report indicates that the above mentioned product complies with list the standards or parts of the standard as appropriate. [#optional – The labelling relating to the goods and the packaging of the goods was also examined and found to comply with the labelling, packaging and other requirements applicable to the goods, including [# insert as applicable, including any relevant TGOs, e.g., 69 (General requirements for labels for medicines), 91 (Standard for labels of prescription and related medicines) and 92 (Standard for labels of non-prescription medicines)]

No further action is required.

Please note that samples of batch ***** will be stored under controlled conditions for end

of shelf life testing. Results of this testing will be forwarded to you on completion of testing. [#optional]

Please note that outcomes of laboratory testing are published on the TGA Database of Laboratory Testing Results <http://www.tga.gov.au/ws-labs-index>.

Yours Sincerely,

Signed electronically by

[name]

[position]

[section]

Laboratories Branch

Email: name@health.gov.au

[date]

Sent by email