[redacted]

From: Colleen.Gill[redacted][mailto:Colleen.Gill[redacted]] **On Behalf Of** InternationalGMP[redacted]
Sent: 17 July 2013 07:35
To: [redacted]

Dear [redacted]

The following information is requested from you in accordance with the cooperation arrangements and confidentiality undertakings exchanged between the TGA and the EDQM under Section 61(5) of the Therapeutic Goods Act 1989. The material will be treated as confidential non-public information and will not be disclosed to third parties without prior written agreement.

Please can you forward the inspection report of [redacted] India. which they inspected in [redacted].
Please can you confirm the actual address of the site at which the inspection was conducted, we have another similar address on our system [redacted]
We would like to differentiate between the two.

Thank you in advance and kind Regards

Colleen
Office of Manufacturing Quality
Phone: 02 6232 8156
Fax: 02 6232 8426
Email: internationalgmp[redacted]

Therapeutic Goods Administration
Department of Health and Ageing
PO Box 100
Woden ACT 2606
www.tga.gov.au

From August 2012, the Office of Manufacturing Quality is using the term 'inspect' instead of 'audit' to describe its core regulatory activities.

[redacted]