



RE: TGA request for information on [REDACTED]

[SEC=UNCLASSIFIED] 

InternationalGMP to: [REDACTED]

Sent by: Joyce Lopez

17/08/2012 09:16 AM

Dear [REDACTED]

Thank you for the report and close out letter.

As this matter is with our inspection managers at the moment, I will be in touch again should they require anything further.

Kind Regards

Joyce

Office of Manufacturing Quality (OMQ) / Therapeutic Goods Administration (TGA) / Department of Health and Ageing /Location: 136 Narrabundah Lane Symonston CANBERRA 2609 AUSTRALIA / Postal Address: PO Box 100 WODEN ACT 2606/ Tel: + 61 (0) 2 6232 8813/ Fax: + 61 (0) 2 6232 8426

[REDACTED]

-----Original Message-----

From: Joyce.Lopez [mailto:Joyce.Lopez] On Behalf Of InternationalGMP
Sent: 14 August 2012 01:38
To: [REDACTED]
Cc: Michelle.Richens [REDACTED]; Draçana.Milic [REDACTED]; Mark.Dickson [REDACTED]; Doug.Ferwick [REDACTED]
Subject: TGA request for information on [REDACTED]
[REDACTED] [SEC=UNCLASSIFIED]

The following information is provided to you in accordance with Section III of the Medicinal Products GMP Inspection Annex of the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and Australia and is released under Section 61(5) of the Therapeutic Goods Act 1989. The material is confidential

non-public information and must not be disclosed to third parties without TGA's prior written agreement.

Dear [REDACTED]

The TGA understands that the MHRA recently inspected the following facility:

[REDACTED]

In accordance with the cooperative arrangements for the exchange of information between the TGA and the MHRA relating to GMP inspections, we would like to request a copy of the latest inspection report for this site.

It would be much appreciated if this information could be sent to us as soon as possible.

Thank you.

Kind Regards
Joyce Lopez
Office of Manufacturing Quality (OMQ) / Therapeutic Goods Administration (TGA) / Department of Health and Ageing / Location: 136 Narrabundah Lane Symonston CANBERRA 2600 AUSTRALIA / Postal Address: PO Box 100 WODEN ACT 2606/ Tel: + 61 (0) 2 6232 8813/ Fax: + 61 (0) 2 6232 8426

[REDACTED]

