

Re: Request for Information [SEC=UNCLASSIFIED] □

Doug Fenwick to: [REDACTED]

29/10/2013 01:52 PM

Cc: [REDACTED] "internationalgmp@ [REDACTED]"

"Michael.Carland [REDACTED]", [REDACTED]

Great thanks [REDACTED]

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**From:** Doug.Fenwick [REDACTED] [mailto:Doug.Fenwick [REDACTED]]

**Sent:** Monday, October 28, 2013 05:53 PM Eastern Standard Time

**Cc:** Michael.Carland [REDACTED] <Michael.Carland [REDACTED]>; [REDACTED]  
internationalgmp [REDACTED] <internationalgmp [REDACTED]>

**Subject:** Request for Information [SEC=UNCLASSIFIED]

The following information is provided to you, in accordance with the cooperation arrangements and confidentiality undertakings exchanged between the TGA and the US FDA 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.

Hi [REDACTED]

Hope you are both well.

We understand you recently completed an inspection of [REDACTED]

[REDACTED] We would very much appreciate being provided with a copy of the 483 letter issued to at the completion of this inspection.

Many thanks

Kind regards

**Doug Fenwick** B. Pharm, MBA  
Head of Office (Acting)  
Office of Manufacturing Quality  
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Department of Health

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