



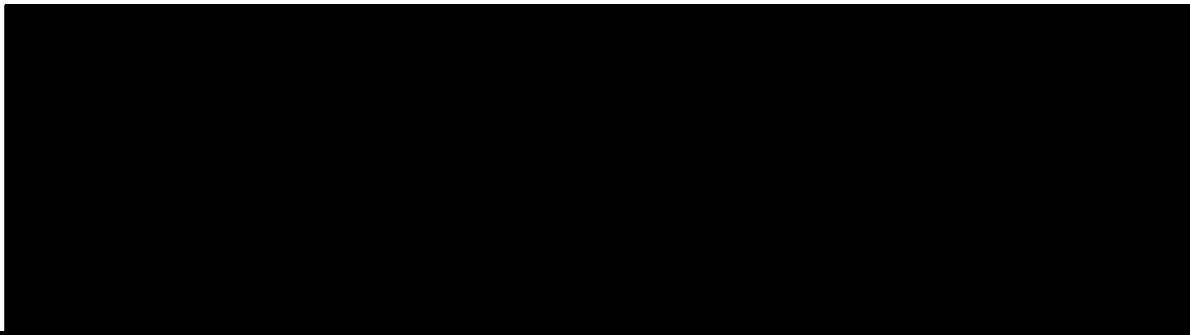
Fw: FDA request for information [SEC=UNCLASSIFIED]

InternationalGMP [REDACTED]
Sent by: Colleen Gill

19/09/2013 04:44 PM

The following information is requested from the FDA, 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.



[REDACTED] We would appreciate any information you can share with us on this site, including the EIR/483 letter and consequential correspondence with the site management.

Thank you and regards,

Colleen Gill

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