



Noel Fraser to: [REDACTED]

22/02/2014 12:14 PM

Cc: [REDACTED] "InternationalGMP" [REDACTED], [REDACTED]

Dear [REDACTED]

Thank you for the update.

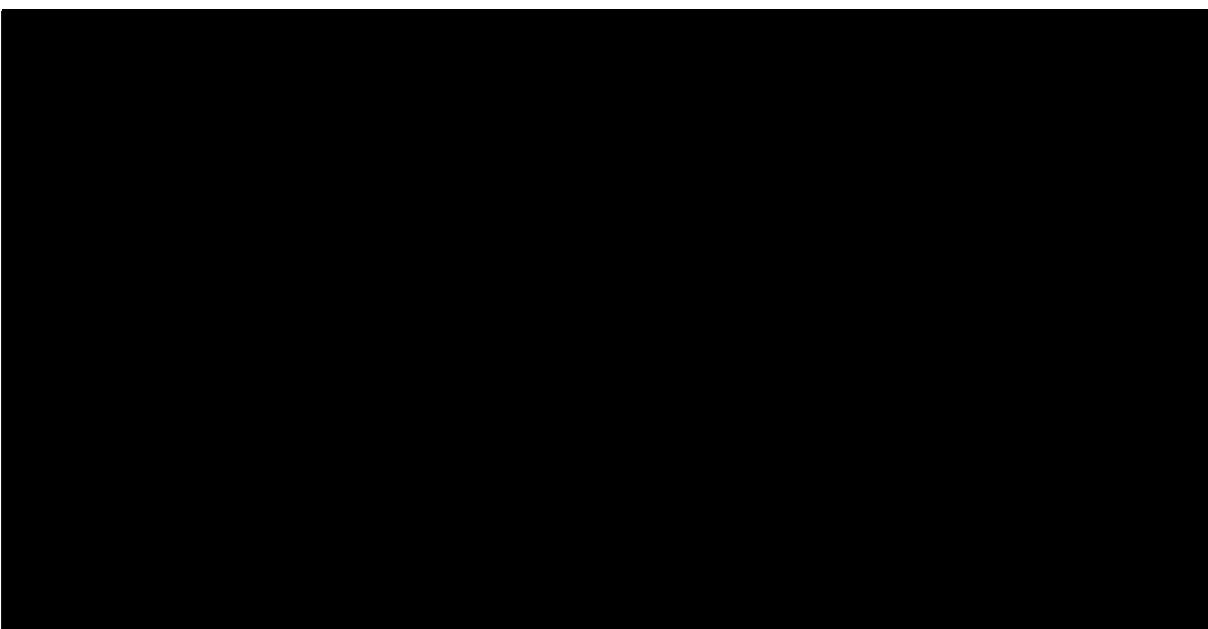
Based on your earlier advice, and [REDACTED] as a preparatory measure we have already reviewed the status of the products being supplied to Australia, thank you. I will convey the latest development to TGA management.

Your assistance is very much acknowledged and greatly appreciated.

Kind regards,
Noel.

Noel Fraser
Inspection Group Manager, Compliance.
Office of Manufacturing Quality | Monitoring & Compliance Group
Phone: +61 3 8626 4302 | Email: noel.fraser [REDACTED]

Therapeutic Goods Administration | Department of Health.
Level 8, 595 Collins St . Melbourne, Victoria,
Australia. 3000



From: Noel.Fraser [mailto:[Noel.Fraser](mailto>Noel.Fraser)]
Sent: 21 February 2014 09:48
Cc: [REDACTED] InternationalGMP [REDACTED]; [REDACTED]
Subject: RE: Request for information [REDACTED] India. [SEC=UNCLASSIFIED]

Dear [REDACTED]

Further to your 31 January email, are you able to update us on any further developments, and in particular if MHRA has issued or will be issuing, a "statement of serious GMP non-compliance" ?

Thank you and kind regards.

Noel.

Noel Fraser
Inspection Group Manager, Compliance.
Office of Manufacturing Quality | Monitoring & Compliance Group
Phone: +61 3 8626 4302 | Email: noel.fraser [REDACTED]

Therapeutic Goods Administration | Department of Health.
Level 8, 595 Collins St . Melbourne, Victoria,
Australia. 3000
[REDACTED]

From: Noel Fraser/TGA/Health
To: [REDACTED]
Cc: [REDACTED] "InternationalGMP [REDACTED]" <[InternationalGMP \[REDACTED\]](mailto:InternationalGMP [REDACTED])>,
[REDACTED]
Date: 01/02/2014 03:11 PM
Subject: RE: Request for information [REDACTED] India. [SEC=UNCLASSIFIED]

Dear [REDACTED]

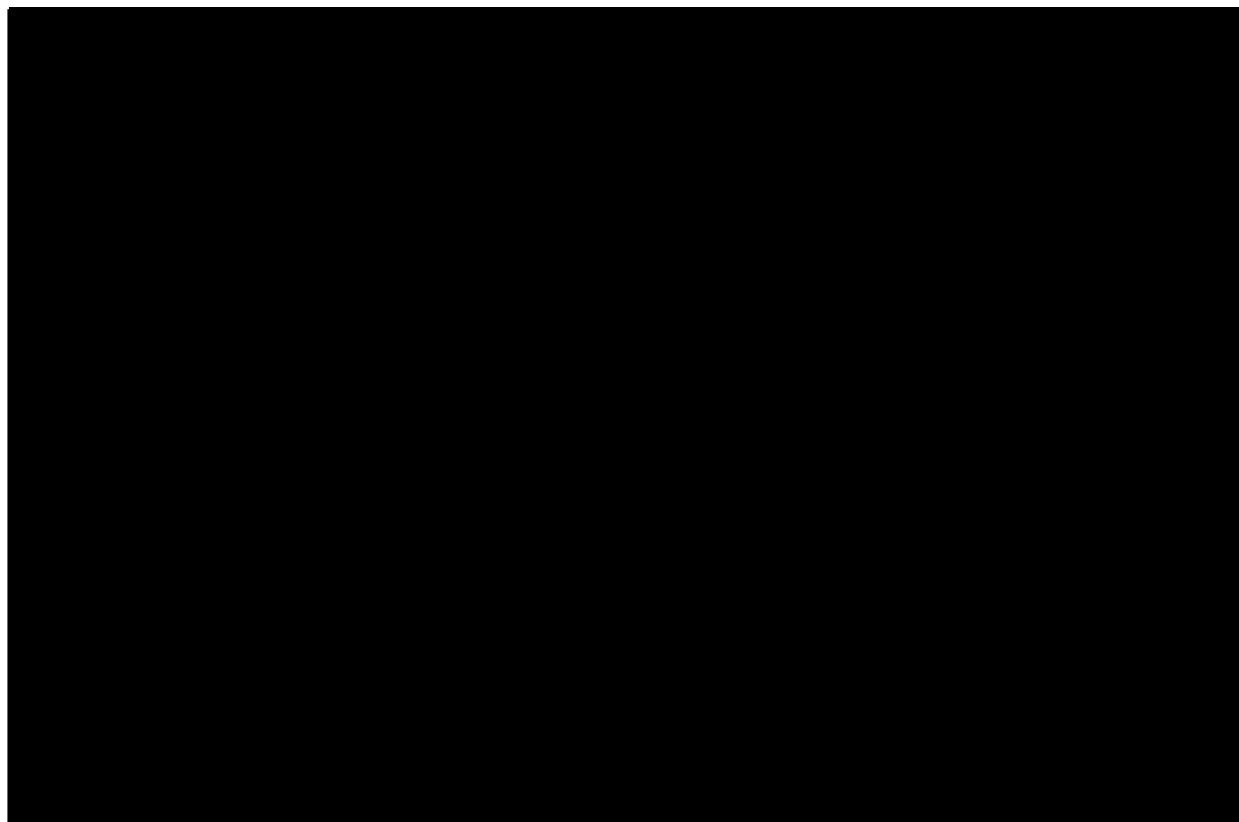
Thank you for advising us of these latest developments

We would greatly appreciate being kept informed of ongoing developments, particularly should MHRA indeed decide to issue a statement of serious GMP, leading to cessation of supply from [REDACTED]

Kind regards,
Noel.

Noel Fraser
Inspection Group Manager, Compliance.
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Phone: +61 3 8626 4302 | Email: [noel.fraser@\[REDACTED\]](mailto:noel.fraser@[REDACTED])

Therapeutic Goods Administration | Department of Health.
Level 8, 595 Collins St . Melbourne, Victoria,
Australia. 3000



From: [Noel.Fraser@\[REDACTED\]](mailto>Noel.Fraser@[REDACTED])
Sent: 31 December 2013 00:10
To: [REDACTED]
Cc: [REDACTED]
[InternationalGMP@\[REDACTED\]](#); [REDACTED]
Subject: RE: Request for information [REDACTED] India. [SEC=UNCLASSIFIED]

Dear [REDACTED]

Thank you for the update, it's most helpful.

I appreciate your undertaking to provide TGA with the report (when available) and to inform us of the IAG decision(s) regarding any Regulatory actions.

Thank you and kind regards,

Best wishes for 2014.

Noel.

Noel Fraser
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Phone: +61 3 8626 4302 | Email: [noel.fraser@\[REDACTED\]](mailto:noel.fraser@[REDACTED])

Therapeutic Goods Administration | Department of Health.
Level 8, 595 Collins St . Melbourne, Victoria,
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[REDACTED]

From: Noel.Fraser [mailto:[Noel.Fraser](mailto>Noel.Fraser)]
Sent: 20 December 2013 02:01
To: [REDACTED]
Cc: [REDACTED] [InternationalGMP](#) [REDACTED]
Subject: RE: Request for information [REDACTED] India. [SEC=UNCLASSIFIED]

Dear [REDACTED]

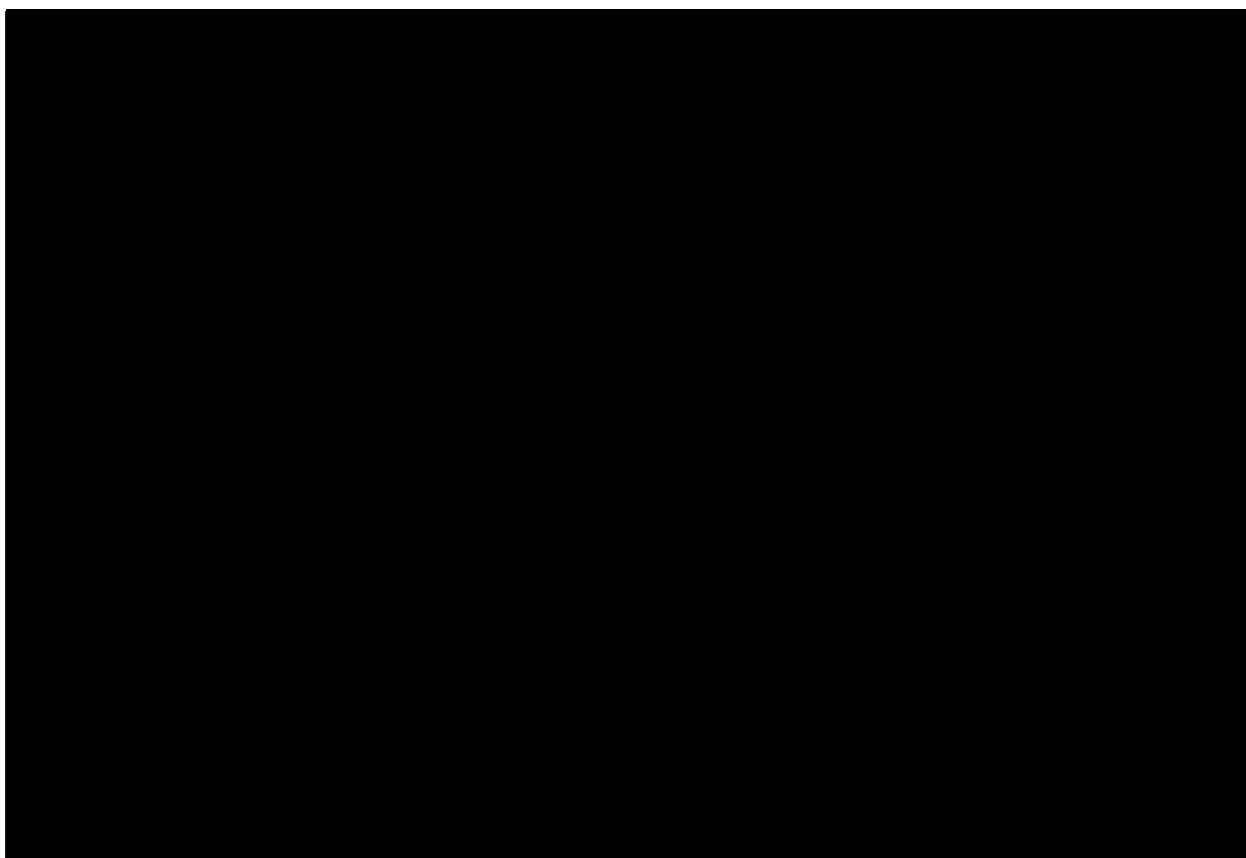
Thank you for your earlier response to Colleen.

Further to your email, I was wondering if there had been any developments to this matter, including as applicable, (1) the results of the regulatory action meeting you referenced and (2) The structured response with report ?

Thank you and kind regards,
Noel.

Noel Fraser
Inspection Group Manager, Compliance.
Office of Manufacturing Quality | Monitoring & Compliance Group
Phone: +61 3 8626 4302 | Email: noel.fraser [REDACTED]

Therapeutic Goods Administration | Department of Health.
Level 8, 595 Collins St . Melbourne, Victoria,
Australia. 3000
[REDACTED]



From: Colleen.Gill [mailto:Colleen.Gill] **On Behalf Of**
InternationalGMP [mailto:InternationalGMP]
Sent: 21 November 2013 01:24
[REDACTED] **Noel.Fraser** [REDACTED]
Subject: Request for information [REDACTED] India. [SEC=UNCLASSIFIED]

[REDACTED]
An Australian sponsor has contacted the TGA following the receipt of a MHRA report issued to [REDACTED] indicating serious deficiencies. They have forwarded a copy of this report to the TGA.

In accordance with the cooperative arrangements for the Exchange of Information between the TGA and the MHRA relating to GMP inspections; and to assist TGA's understanding of the MHRA findings and resulting actions relating to [REDACTED] we would like to request a copy of the complete inspection report and any other relevant information relating to this site.

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

Alternatively or additionally a teleconference including yourself, the inspectors involved and the TGA could be organised if an open dialogue would better convey your findings and outcomes.

Please contact myself or Noel Fraser (noel.fraser) to arrange.

Thank you in advance for your assistance.

Kind Regards

Colleen Gill on behalf of

International GMP
Office of Manufacturing Quality

Phone: 02 6232 8156
Fax: 02 6232 8426
Email: internationalgmp [REDACTED]

Therapeutic Goods Administration
Department of Health
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