



RE: Urgent TGA inquiry - information on the [REDACTED] site
[SEC=UNCLASSIFIED] [REDACTED]

Robert Spence [REDACTED]

20/09/2013 03:23 PM

Cc: Doug.Fenwick, [REDACTED] Michael Carland, Hung Dang,
Noel Fraser

Dear [REDACTED]

Thank you. But could I stretch the friendship and get the September 2012 EIR for the facility which appears to have the bulk of the issues.

Thanks in advance.

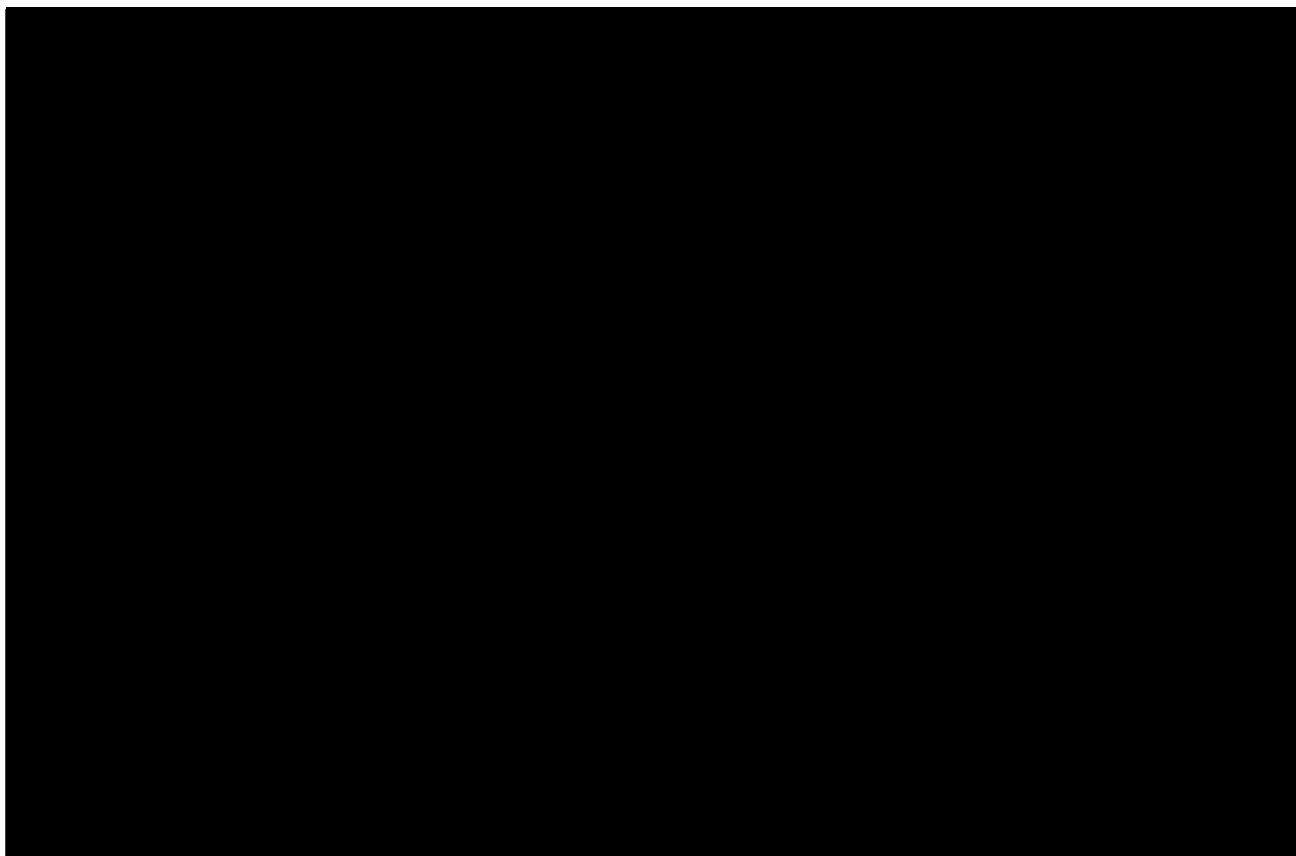
Rob Spence
Projects and Planning Officer
Office of Manufacturing Quality

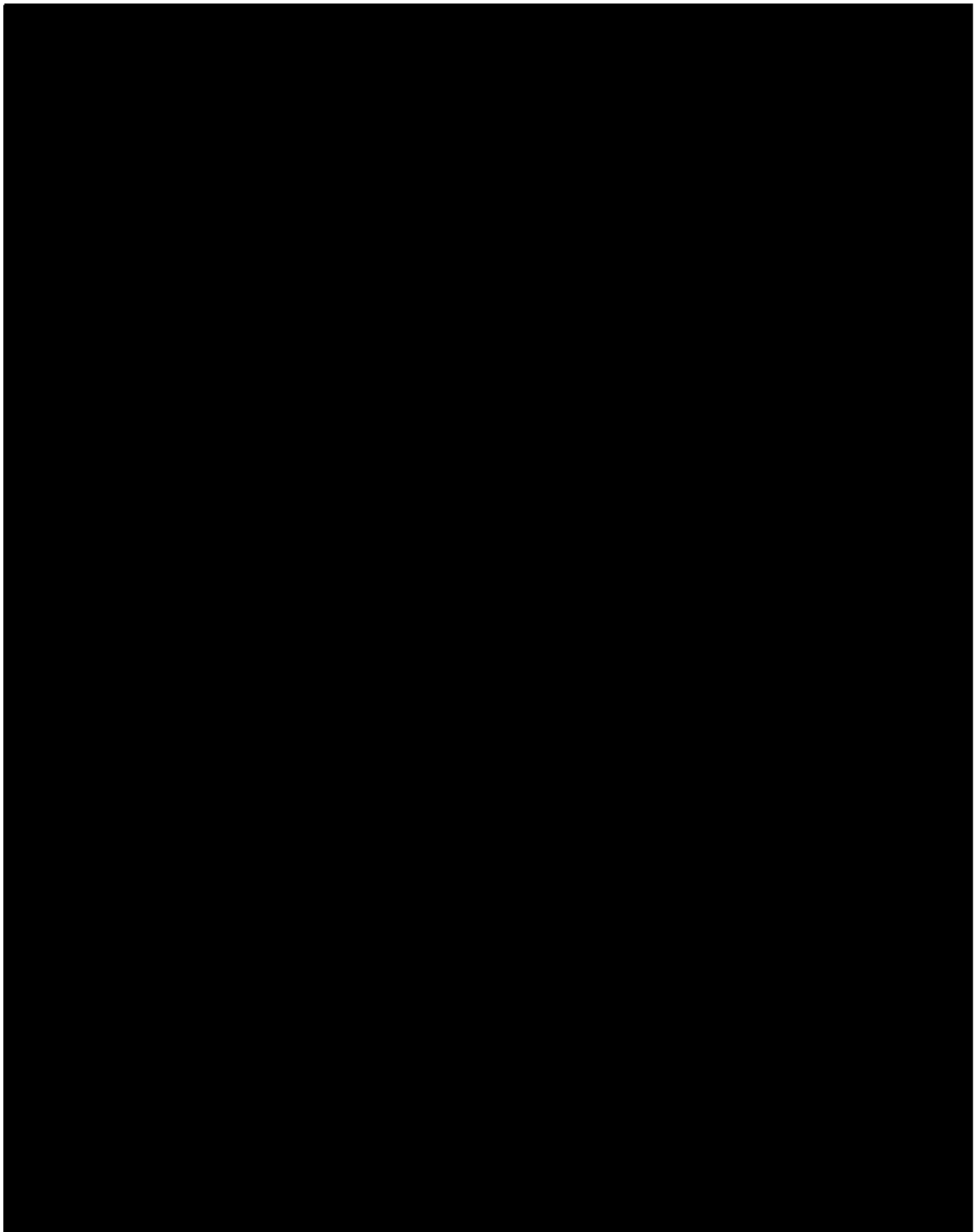
Phone: 02 6232 8752

email: robert.spence [REDACTED]

Therapeutic Goods Administration
Department of Health and Ageing
PO Box 100
Woden ACT 2606

www.tga.gov.au





From: Doug.Fenwick [mailto:Doug.Fenwick]
Sent: Thursday, September 19, 2013 7:41 PM
To:
Cc: Michael.Carland; Michelle.Richens;
Robert.Spence;
Subject: Re: Urgent TGA inquiry - information on the site [SEC=UNCLASSIFIED]
Importance: High

Hi [REDACTED]

I would really appreciate an early response on this, even if partial.

Thanks

Regards

Doug Fenwick B. Pharm, MBA
Head of Office (Acting)
Office of Manufacturing Quality
Therapeutic Goods Administration
Department of Health and Ageing

Phone: 02 9865 9304
Fax: 02 6203 1526
Email: doug.fenwick@tga.gov.au [REDACTED]

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



From: Robert Spence/TGA/Health

To: [REDACTED]

Cc: Doug Fenwick/TGA/Health [REDACTED] Michael Carland/TGA/Health [REDACTED] Michelle Richens/TGA/Health [REDACTED]

Date: 19/09/2013 10:16 AM

Subject: Urgent TGA inquiry - information on the [REDACTED] site [SEC=UNCLASSIFIED]

Dear FDA Colleagues

I am an associate of both Doug Fenwick and Anton Norder holding the position in TGA's Office of Manufacturing Quality of Projects and Planning Officer. In that capacity, I need to follow up on the media release at

[REDACTED] and
[REDACTED] outlining concerns
with [REDACTED].

To allow us to better understand the situation with [REDACTED] and address some of the queries we are receiving, could I ask for a response on the following points as a urgent matter:

1. We have two [REDACTED] manufacturing sites on the TGA books that reference the [REDACTED] suburb. I need to firstly confirm that the location of the site in question is [REDACTED]

[REDACTED] Please confirm that this is correct site address. Of course our strategy for dealing with the matter centres on having the correct site in the

cross hairs. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Please contact me immediately if any points above need clarification or additional information.

Any information provided by your agency will be retained in confidence, in accordance with the cooperation arrangements and confidentiality undertakings exchanged between the TGA and the US FDA. The material is confidential non-public information and will not be disclosed to third parties without your agency's prior written agreement.

Thank you in advance.

Rob Spence
Projects and Planning Officer
Office of Manufacturing Quality

Phone: 02 6232 8752

email: [robert.spence](mailto:robert.spence@tga.gov.au) [REDACTED]

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[REDACTED]