Australian Government
Department of Health
Therapeutic Goods Administration

s22
Quality Assurance Manager
Slade Health Pty Ltd
14 Palmer Court Mount Waverley
Victoria 3149

Dear s22

Subject: Inspection announcement

I am writing to confirm our telephone conversation to announce the TGA inspection that is to take place at your 14 Palmer Court Mount Waverley facility, on the 28 – 30 June 2017 commencing at approximately 9:00am on the first day.

The purpose of the inspection is to establish compliance with the standard determined under the *Therapeutic Goods Act 1989*: the PIC/S Guide to Good Manufacturing Practice for medicinal products – 15 January 2009.

Additional information on the inspection process is available in the document TGA Guidance on licensing / certification inspections, which can be accessed from the TGA web site at http://www.tga.gov.au/industry/manuf-licensing-certification-02-process.htm.

On this occasion the inspection team will consist of two inspectors:
s22 (Lead Inspector)
s22

This inspection is now part of a firm schedule and will only be cancelled in exceptional circumstances. Please note that inspectors cannot accept any gifts in relation to the inspection.

The TGA's Manufacturing Quality Branch is working towards a 'paperless office environment' and consequently all correspondence relating the inspection will be done using electronic documents only. In the context of this, you are requested for any documents of which the inspection team wants to take a copy during the inspection as well as during the response and close out, to submit electronic copies only.

The final compliance rating following this inspection will be determined after review of your response/s to the inspection report. Information on the TGA's system to determine manufacturer compliance can be found on the TGA web site at http://www.tga.gov.au/industry/manuf-compliance-history.htm. Once the inspection is closed out, a letter will be sent to you to confirm close out, which will also advise on the final compliance rating. Subsequently, the compliance rating will be used as input to determine re-inspection frequency. Information on how this is done can be found on the TGA web site at http://www.tga.gov.au/industry/manuf-inspections-frequency.htm.

If there are any updates to the Site Master File previously forwarded, it would be appreciated if you could send them to me prior to the inspection date.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

(Signed electronically; contains no visible signature)

s22
Inspector
Manufacturing Quality Branch
08/06/2017
Tel: s22
E-mail: s22 @health.gov.au

Australian Government
Department of Health
Therapeutic Goods Administration

s22
Site Quality Director
Slade Health Pty Ltd
Unit11, 210 Robinson Road East
Geebung 4034
Brisbane

Dear s22,

Subject: Inspection announcement

I am writing to confirm our email correspondence to announce the TGA inspection that is to take place at your Robinson Road Geebung facility, on 13-16 June 2017, commencing at approximately 13.00 on the first day.

The purpose of the inspection is to establish compliance with the standard determined under the *Therapeutic Goods Act 1989*: the PIC/S Guide to Good Manufacturing Practice for medicinal products – 15 January 2009

Additional information on the inspection process is available in the document TGA Guidance on licensing / certification inspections, which can be accessed from the TGA web site at http://www.tga.gov.au/industry/manuf-licensing-certification-02-process.htm.

On this occasion the inspection team will consist of two inspectors:
s22

This inspection is now part of a firm schedule and will only be cancelled in exceptional circumstances. Please note that inspectors cannot accept any gifts in relation to the inspection.

The TGA's Manufacturing Quality Branch is working towards a 'paperless office environment' and consequently all correspondence relating the inspection will be done using electronic documents only. In the context of this, you are requested for any documents of which the inspection team wants to take a copy during the inspection as well as during the response and close out, to submit electronic copies only.

The final compliance rating following this inspection will be determined after review of your response/s to the inspection report. Information on the TGA's system to determine manufacturer compliance can be found on the TGA web site at http://www.tga.gov.au/industry/manuf-compliance-history.htm. Once the inspection is closed out, a letter will be sent to you to confirm close out, which will also advise on the final compliance rating. Subsequently, the compliance rating will be used as input to determine re-inspection frequency. Information on how this is done can be found on the TGA web site at http://www.tga.gov.au/industry/manuf-inspections-frequency.htm.

If there are any updates to the Site Master File previously forwarded, it would be appreciated if you could send them to me as soon as possible and prior to the inspection date.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

(Signed electronically; contains no visible signature)

s22
Senior Inspector
Manufacturing Quality Branch
25/05/2017
Tel: s22
E-mail: s22 @health.gov.au

Australian Government
Department of Health
Therapeutic Goods Administration

s22
Slade Health Pty Ltd (formerly mobiLife Pty Ltd)
6/18-20 Accolade Avenue,
Morisset NSW 2264

Dear s22,

Subject: Inspection announcement – MI-2016-LI-06329-1.

I am writing to confirm following our discussions earlier this week that the TGA inspection is to take place at your Morisset NSW facility, on 26th-28th February 2018 commencing at approximately 09:00am on the first day.

The purpose of the inspection is to establish compliance with the standard determined under the *Therapeutic Goods Act 1989*: the PIC/S Guide to Good Manufacturing Practice for medicinal products – 1 January 2017.

Additional information on the inspection process is available in the document TGA Guidance on licensing / certification inspections, which can be accessed from the TGA web site at http://www.tga.gov.au/industry/manuf-licensing-certification-02-process.htm.

On this occasion the inspection team will consist of inspectors:

s22 and s22

This inspection is now part of a firm schedule and will only be cancelled in exceptional circumstances. Please note that inspectors cannot accept any gifts in relation to the inspection.

The TGA's Office of Manufacturing Quality is working towards a 'paperless office environment' and consequently all correspondence relating the inspection will be done using electronic documents only. In the context of this, you are requested for any documents of which the inspection team wants to take a copy during the inspection as well as during the response and close out, to submit electronic copies only.

The final compliance rating following this inspection will be determined after review of your response/s to the inspection report. Information on the TGA's system to determine manufacturer compliance can be found on the TGA web site at http://www.tga.gov.au/industry/manuf-compliance-history.htm. Once the inspection is closed out, a letter will be sent to you to confirm close out, which will also advise on the final compliance rating. Subsequently, the compliance rating will be used as input to determine re-inspection frequency. Information on how this is done can be found on the TGA web site at http://www.tga.gov.au/industry/manuf-inspections-frequency.htm.

If there are any updates to Site Master File previously forwarded, it would be appreciated if you could send it to me as soon as possible and prior to the inspection date.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

(Signed electronically; contains no visible signature)

s22
GMP Inspector
Manufacturing Quality Branch
Date: 1st February 2018

Tel: s22
Mobile: s22
E-mail: s22 @health.gov.au

Australian Government
Department of Health
Therapeutic Goods Administration

s22
Slade Health Pty Ltd
Level 1, 2 Woodland Way
Mount Kuring-Gai
NSW 2080

Dear s22,

Subject: Inspection announcement – Slade Health Pty Ltd

I am writing to confirm our telephone conversation to announce the TGA inspection that is to take place at your Mt Kuring-Gai facility, on 9-11 April 2018, commencing at approximately 9am on the first day.

The purpose of the inspection is to establish compliance with the standard determined under the *Therapeutic Goods Act 1989*: the PIC/S Guide to Good Manufacturing Practice for medicinal products – 01 January 2017.

Additional information on the inspection process is available in the document TGA Guidance on licensing / certification inspections, which can be accessed from the TGA web site at http://www.tga.gov.au/industry/manuf-licensing-certification-02-process.htm.

On this occasion the inspection team will consist of 2 inspectors and 1 observer:

s22 – Lead Inspector
s22 - Inspector
s22 - Observer

This inspection is now part of a firm schedule and will only be cancelled in exceptional circumstances.

The TGA's Manufacturing Quality Branch is working towards a 'paperless office environment' and consequently all correspondence relating the inspection will be done using electronic documents only. In the context of this, please provide any documents requested as electronic copies only.

To assist you in preparation for the inspection, the TGA website includes information on the inspection procedures and reporting processes that will apply to this inspection. Please see the information provided at the links available at: https://www.tga.gov.au/book-page/licensing-and-certification-process. Please consider in your inspection preparation that:

- The inspectors will require access to an area appropriate for working with a desk and chair
- You should be prepared to provide the inspection team with site safety and security procedures including any required personal protective equipment such as high visibility vests, clean room garments, eye or hearing protection (if required).
- If there are any known health risks relating to manufacturing operations at your site (such as the manufacture of cytotoxics) please provide information regarding these risks and their controls to the Lead Inspector.
- As per Australian Government requirements, inspectors cannot accept any gifts in relation to the inspection.

The final compliance rating following this inspection will be determined after review of your response/s to the inspection report. Information on the TGA's system to determine manufacturer compliance can be found on the TGA web site at http://www.tga.gov.au/industry/manuf-compliance-history.htm. Once the inspection is closed out, a report will be sent to you to confirm close out, which will also advise on the final compliance rating. Subsequently, the compliance rating will be used as input to determine re-inspection frequency. Information on how this is done can be found on the TGA web site at http://www.tga.gov.au/industry/manuf-inspections-frequency.htm.

If there are any updates to the Site Master File previously forwarded, it would be appreciated if you could send them to me as soon as possible and prior to the inspection date. A request for documents to be provided prior to and during the inspection is attached in the email accompanying this letter. It would be appreciated if you could send them to me as soon as possible and at least one week prior to the inspection date.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

(Signed electronically; contains no visible signature)

s22
Lead Inspector
Manufacturing Quality Branch
26 March 2018

Tel: s22
E-mail: s22 @health.gov.au

Australian Government
Department of Health
Therapeutic Goods Administration

s22 : National Quality Manager.
Slade Health P/L
2 Woodland Way,
Mount Kuring-gai
NSW 2080

Dear s2,

Subject: Inspection announcement

I am writing to confirm our telephone conversation to announce the TGA inspection that is to take place at your Unit 11 / 210 Robinson Road East GEEBUNG QLD facility, during Tuesday 07 – Friday 10 May 2019 commencing at approximately 13.00 on the first day. The inspection duration will be the equivalent of three days.

The purpose of the inspection is to establish compliance with the standard determined under the *Therapeutic Goods Act 1989*: the PIC/S Guide to Good Manufacturing Practice for medicinal products – 01 January 2017..

To assist you in preparation for the inspection, the TGA website includes information on the inspection procedures and reporting processes that will apply to this inspection. Please see the information provided at the links available at: https://www.tga.gov.au/book-page/licensing-and-certification-process. Please consider in your inspection preparation that:

- The inspectors will require access to an area appropriate for working with a desk and chair
- You should be prepared to provide the inspection team with site safety and security procedures including any required personal protective equipment such as high visibility vests, clean room garments, eye or hearing protection (if required).

On this occasion the inspection team will consist of 2 inspector/s:

Lead inspector: s22
Inspector: s22

The scope of the inspection is as per the current licence.

This inspection is now part of a firm schedule and will only be cancelled in exceptional circumstances.

The TGA's Manufacturing Quality Branch is working towards a 'paperless office environment' and consequently all correspondence relating the inspection will be done using electronic documents only. In the context of this, please provide any documents requested as electronic copies only.

The final compliance rating following this inspection will be determined after review of your response/s to the inspection report. Information on the TGA's system to determine manufacturer compliance can be found on the TGA web site at http://www.tga.gov.au/industry/manuf-compliance-history.htm. Once the inspection is closed out, a letter will be sent to you to confirm close out, which will also advise on the final compliance rating. Subsequently, the compliance rating will be used as input to determine re-inspection frequency. Information on how this is done can be found on the TGA web site at http://www.tga.gov.au/industry/manuf-inspections-frequency.htm.

Thank you for providing the current version of the SMF. Subject to its review, I anticipate – in the near term - submitting a separate request for documents to be provided prior to, and/or during, the inspection.

If there are any known health risks (such as the manufacture of cytotoxics) at your facility these should be information on the appropriate containment at your site included in the documentation.

Please note that it is an Australian Government requirement that inspectors cannot accept any gifts in relation to the inspection.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

(Signed electronically; contains no visible signature)

s22
Lead Inspector
Manufacturing Quality Branch

Date 29 April 2019.
Tel: s22
E-mail: s22 @health.gov.au

Australian Government
Department of Health
Therapeutic Goods Administration

s22 : National Quality Manager.
Slade Health P/L
2 Woodland Way,
Mount Kuring-gai
NSW 2080

Dear s2,

Subject: Inspection announcement

I am writing to confirm our telephone conversation to announce the TGA inspection that is to take place at your 14 Palmer Court MOUNT WAVERLEY VIC facility, during 19-21 June 2019 commencing at approximately 09.00 on the first day. The inspection duration will be three days.

The purpose of the inspection is to establish compliance with the standard determined under the *Therapeutic Goods Act 1989* i.e. the PIC/S Guide to Good Manufacturing Practice for medicinal products – 01 January 2017.

To assist you in preparation for the inspection, the TGA website includes information on the inspection procedures and reporting processes that will apply to this inspection. Please see the information provided at the links available at: https://www.tga.gov.au/book-page/licensing-and-certification-process. Please consider in your inspection preparation that:

- The inspectors will require access to an area appropriate for working with a desk and chair
- You should be prepared to provide the inspection team with site safety and security procedures including any required personal protective equipment such as high visibility vests, clean room garments, eye or hearing protection (if required).

On this occasion the inspection team will consist of two inspector/s:

Lead inspector: s22
Inspector: s22

The scope of the inspection is as per the current licence.

This inspection is now part of a firm schedule and will only be cancelled in exceptional circumstances.

The TGA's Manufacturing Quality Branch is working towards a 'paperless office environment' and consequently all correspondence relating the inspection will be done using electronic documents only. In the context of this, please provide any documents requested as electronic copies only.

The final compliance rating following this inspection will be determined after review of your response/s to the inspection report. Information on the TGA's system to determine manufacturer compliance can be found on the TGA web site at http://www.tga.gov.au/industry/manuf-compliance-history.htm. Once the inspection is closed out, a letter will be sent to you to confirm close out, which will also advise on the final compliance rating. Subsequently, the compliance rating will be used as input to determine re-inspection frequency. Information on how this is done can be found on the TGA web site at http://www.tga.gov.au/industry/manuf-inspections-frequency.htm.

If there are any updates to the Site Master File previously forwarded, it would be appreciated if you could send them to me as soon as possible and prior to the inspection date.

Subject to the review of the aforementioned Site Master File, I anticipate (in the near term) submitting a separate request for documents to be provided prior to, and/or during, the inspection.

If there are any known health risks (such as the manufacture of cytotoxics) at your facility these should be information on the appropriate containment at your site included in the documentation.

Please note that it is an Australian Government requirement that inspectors cannot accept any gifts in relation to the inspection.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

(Signed electronically; contains no visible signature)

s22
Lead Inspector
Manufacturing Quality Branch

Date 29 April 2019
Tel: s22
E-mail: s22 @health.gov.au