

s22

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**From:** s22  
**Sent:** Friday, 20 May 2022 11:20 AM  
**To:** s22  
**Subject:** RE: Attn. s22 (TGA Reference: D22-5324844): Edgewell Personal Care Australia Pty Ltd [SEC=OFFICIAL]  
**Attachments:** CONFIDENTIAL Root Cause Summary dated 20 May 2022.pdf; Attachment 1 - TGA Notice of Compliance Test Failure dated 9 December 2021.pdf; Attachment 2 - EPC's 2 week, 6 week and Final Reports.pdf; CONFIDENTIAL Attachment 3 - Supplier's Investigation.pdf

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Dear s22,

Attached is Edgewell Personal Care Pty Ltd's Root Cause Analysis report and supporting documents.

Please let me know if you require any further information.

Kind regards,

s22

s22

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**From:** s22 s22 @health.gov.au>  
**Sent:** Tuesday, 10 May 2022 3:28 PM  
**To:** s22  
**Subject:** RE: Attn. s22 (TGA Reference: D22-5324844): Edgewell Personal Care Australia Pty Ltd [SEC=OFFICIAL]

Dear s22,

Thank you for the prompt response to the request, the extension of 5 extra days is reasonable.

Kind regards

s22

s22  
Principal Chemist  
Chemistry  
Laboratories Branch

Phone: s22  
Email: s22@health.gov.au

**Therapeutic Goods Administration**  
Department of Health  
PO Box 100  
Woden ACT 2606 Australia  
[www.tga.gov.au](http://www.tga.gov.au)

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Building a stronger,  
healthier country  
Yesterday  
today and  
tomorrow

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From: s22 >  
Sent: Tuesday, 10 May 2022 2:57 PM  
To: s22@health.gov.au >  
Subject: Attn. s22 (TGA Reference: D22-5324844): Edgewell Personal Care Australia Pty Ltd

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Dear Sir

We act for Edgewell Personal Care Australia Pty Ltd (**EPC**).

Our client has received the TGA's Notice under s 31(2) of the *Therapeutic Goods Act 1989* - Requirement to provide information or documents dated 3 May 2022 (**Notice**) and is preparing its response. As the root cause report documents obtained from EPC's manufacturer comprise proprietary information relating to products other than those supplied in Australia, further time is required to respond to the Notice.

In the circumstances our client requests a further 5 working days to allow it to respond to the Notice, by **20 May 2022**. Can you please advise by return email if the TGA does not consider this short extension to be reasonable?

Kind regards

s22  
[Redacted signature block]

s22

[Redacted]

[Redacted]

[Redacted]