

**From:** [REDACTED]  
**To:** [REDACTED]  
**Subject:** RE: TGA Application DV-2015-DR-03198-1; BIRMINGHAM HIP Resurfacing Acetabular Cup [SEC=UNCLASSIFIED]  
**Date:** Friday, 19 June 2015 10:23:27 AM  
**Attachments:** [image001.png](#)

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Dear [REDACTED]

I am writing regarding your email dated 18 June 2015 requiring an extension of the period specified in the notice requesting information relevant for the audit of the application DV-2015-DR-03198-1.

On 21 May 2015, on behalf of [REDACTED], delegate of the Secretary of the Department of Health, I advised you under section 41FH of the *Therapeutic Goods Act 1989* that your application DV-2014-DR-03198-1 had been selected for audit. Also in the notice (the **selection notice**), you were required to provide information relevant to the audit within the period specified in the notice. The date specified in the notice was **22 June 2015**.

You stated in your email that "We have applied to the AOANJRR for the ad hoc report for the BHR System but it has not yet issued. Accordingly, I would be grateful if you could please grant an extension of time within which to respond to the s.41FH notices above."

I have considered the above and, on behalf of [REDACTED], delegate of the Secretary for the purposes of section 41FH of the Act, I am informing you that a decision to amend the selection notice dated 21 May 2015, in order to vary the period specified for response in the notice. The revised date is **COB, Thursday, 17 July 2015 (AEDT)**.

Kind Regards

[REDACTED]

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**From:** [REDACTED] **On Behalf Of** Devices  
**Sent:** Friday, 19 June 2015 8:50 AM  
**To:** [REDACTED]  
**Subject:** FW: TGA Application DV-2014-DR-19876-1; BIRMINGHAM HIP Resurfacing Femoral Head [SEC=UNCLASSIFIED]

Hi [REDACTED]

Please see email below relating to TGA Application DV-2014-DR-19876-1

**Kind Regards**

**Medical Devices Information Unit**  
 Devices Authorisation Branch  
 Therapeutic Goods Administration

Phone: 1 800 141 144

Fax: [REDACTED]

Email: [devices@tga.gov.au](mailto:devices@tga.gov.au)

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



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**From:** [REDACTED]  
**Sent:** Thursday, 18 June 2015 5:01 PM  
**To:** Devices  
**Subject:** FW: TGA Application DV-2014-DR-19876-1; BIRMINGHAM HIP Resurfacing Femoral Head [SEC=UNCLASSIFIED]

Dear [REDACTED]

We have applied to the AOANJRR for the ad hoc report for the BHR System but it has not yet issued. Accordingly, I would be grateful if you could please grant an extension of time within which to respond to the s.41FH notices above.

Regards

[REDACTED]

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**From:** [REDACTED]  
**Sent:** Thursday, 21 May 2015 2:24 PM  
**To:** [REDACTED]  
**Subject:** TGA Application DV-2014-DR-19876-1; BIRMINGHAM HIP Resurfacing Femoral Head [SEC=UNCLASSIFIED]

Dear [REDACTED]

I refer to your application DV-2014-DR-19876-1; BIRMINGHAM HIP Resurfacing Femoral Head.

I am writing to request additional information under Section 41FH of the *Therapeutic Goods Act 1989*. Please note that I require your response by **22 June 2015** to continue with your application. If no response is received regarding this request for information the application will lapse (section 41FK(a) of the Act).

Please find the notice under section 41FH of Act requesting further information.

**Please note: Directions on how to respond to the s41FH notice is included in the letter attached. Please do not reply or provide any response to this notice to this email account as it will not be actioned. Please direct all enquiries to [devices@tga.gov.au](mailto:devices@tga.gov.au)**

Regards



  
Departmental Officer  
Devices Application & Verification  
Devices Authorisation Branch  
Phone: 1 800 141 144  
Email: 

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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