

Dear [REDACTED],

TGA would like to acknowledge receipt of this variation and confirm that it is currently under review by TGA. Due to the complex nature of the requested change we would like to inform the Blood Service that a decision is not expected to be made for some time. TGA will keep you informed of progress with the review and may request additional information regarding the change as the review process progresses.

At this time it is expected that a discussion paper will be submitted to the Advisory Committee for Biologicals for their consideration at their next meeting, currently scheduled for 19th September 2013.

Sincerely

[REDACTED]

[REDACTED]  
Principal Evaluator  
Cell & Tissue Therapy Unit  
Biological Science Section  
Office of Scientific Evaluation  
Market Authorisation Group  
Therapeutic Goods Administration  
PO Box 100, Woden ACT 2606

E-mail: [REDACTED]@tga.gov.au  
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From: [REDACTED]@redcrossblood.org.au>  
To: [REDACTED]@tga.gov.au" <[REDACTED]@tga.gov.au>  
Cc: [REDACTED]@tga.gov.au" <[REDACTED]@tga.gov.au>,  
[REDACTED] <[REDACTED]@redcrossblood.org.au>, "(AUS) Regulatory Affairs"  
<DL-RegulatoryAffairs@redcrossblood.org.au>  
Date: 09/05/2013 11:44 AM  
Subject: Submission for proposed changes to the GSBD for Sexual Activity-Based Deferrals (Blood Service Ref: RR13-047 )

Dear [REDACTED],

Further to my letter of 26 April 2013 detailing the review of the Guidelines for the Selection of Blood Donors (GSBD), please find attached the submission for proposed changes to the GSBD in relation to sexual activity-based deferrals.

A copy will also be sent by post, including a copy of the references.

Regards

Regulatory Affairs Associate  
Australian Red Cross Blood Service  
Level 1, 69 Walters Drive  
Osborne Park WA 6017  
P: [REDACTED] I F: 08 6213 5949 I M: [REDACTED]  
Roll up your sleeves and give blood.  
Call 13 14 95 or visit [donateblood.com.au](http://donateblood.com.au)  
Facebook | Twitter | YouTube  
P Please consider the environment before

#### E-mail Disclaimer:

Any personal information in this e-mail must be handled in accordance with the provisions of the Privacy Act 1988 [Cth]. The information contained in the e-mail may be confidential and if the person receiving the e-mail is not the intended recipient they should immediately advise Australian Red Cross Blood Service by e-mail response to the Blood Service sender and then deal with the e-mail as directed by the Blood Service. The views expressed in the e-mail are those of the individual sender unless otherwise stated to be the views of the Blood Service. No warranties are provided that the e-mail is computer virus or other defect free. [attachment "RR13-047 Submission.pdf" deleted by ██████████ /TGA/Health] [attachment "Submission paper for sexual activity based deferrals 02 May.pdf" deleted by ██████████]

[REDACTED]/TGA/Health]