

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
Phone: [REDACTED]

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 GSD 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

[REDACTED]
[REDACTED]
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.

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free. [attachment "RR13-047

Submission.pdf" deleted by [REDACTED]/TGA/Health] [attachment "Submission

paper for sexual activity based deferrals 02 May.pdf" deleted by [REDACTED]

[REDACTED]/TGA/Health]