

7 February 2011

Biological Science Section
Office of Scientific Evaluation
Therapeutic Goods Administration

Email: biologicals_consultation@tga.gov.au

Dear Madam / Sir,

Re: Submission for Consultation Documents:

- **Therapeutic Goods Order – Standards for minimizing infectious disease transmission via therapeutic goods that are human blood components, human tissues and human cellular therapy products**
- **Therapeutic Goods Order – Standards for human cardiovascular tissue**
- **Therapeutic Goods Order – Standards for human musculoskeletal tissue**
- **Therapeutic Goods Order – Standards for human ocular tissue**
- **Therapeutic Goods Order – Standards for human skin; and**
- **Therapeutic Goods Order – General requirements for the labelling of biologicals**

Thank you for your email of 8 December 2010 regarding the above.

Under section 6 (5), of the *General requirements for the labelling of biologicals* report, it is the opinion of the College that the following parts of this section should be mandatory information on the product label and not as an accompanying document:

- (e) description of biological
- (f) expiry date
- (g) storage conditions
- (h) size, volume, weight or concentration (as applicable)
- (i) international units (if applicable)

Please do not hesitate to contact me on 02 8356 5830 or email, debra@rcpa.edu.au if you wish to discuss the submission.

Yours sincerely,



Dr Debra Graves
Chief Executive Officer