Queensland Government

Queensland **Health**

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Our Ref: respcov.doc
Date: February 12, 2009

Blood & Tissues Unit
Standards & Code of GMP
Office of Devices Blood and Tissues
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

By email: biologicals_consultation@tga.gov.au

Dear Sir

The Queensland Bone Bank (QBB) participated in the ATBF sponsored workshop on the proposed Code of Good Manufacturing Process for Blood & Tissue and the related proposed Therapeutic Goods Orders. QBB is supportive of the submission made by ATBF on behalf of its members.

Unfortunately, the workshop was unable to address all of the items in every section in detail. Attached is our submission regarding a particular provision within the Standards for Musculoskeletal Tissue.

We would also advise that the Medical Director of the Queensland Bone Bank (Dr David Morgan) is also preparing a submission addressing a particular aspect of the collection of potential Donor information.

QBB wishes to express its appreciation to the TGA for enabling an opportunity to comment on these very important draft documents. QBB recognizes the need and value of the Code and the corresponding proposed Therapeutic Goods Orders and looks forward to working cooperatively with the TGA.

Yours sincerely

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Comments to Draft Therapeutic goods order no. xx – Standards for banked human musculoskeletal tissue

7. General Requirements

6. A musculoskeletal tissue that is to be transported to the manufacturing facility must be

(a) sampled using a representative and validated sampling technique to collect surface micro-organisms for bioburden determination, prior to packaging;

We interpret this clause as referring to initial sampling at retrieval. In the case of the Living Donor program, this would oblige this activity to occur at Theatre. There should be provision for the tissue bank to perform a test at the bank rather than having it performed in theatre, using a superior sampling method. We request that this requirement is reconsidered.

We do not understand why this is a requirement if the tissue undergoes further processing and a terminal, validated test. There should be provision for this initial sample to be an indicator only (e.g. a swab test which most know cannot be validated as a reliable sampling method) when it does not determine product release.

Queensland Bone Bank
February 2010