

Submission for changes to:

Draft AUSTRALIAN CODE OF GOOD MANUFACTURING PRACTICE HUMAN BLOOD AND BLOOD COMPONENTS, HUMAN TISSUES AND HUMAN CELLULAR THERAPIES

New Zealand Heart valve Bank

11 February 2010

INTRODUCTION

Product Standards are to be established separately which will set out specifications addressing product safety and efficacy. Manufactuirers will be required to develop TechnicalStandards Files for product groups to demonstrate that these standards are met

Please supply an example/template of a Technical Standards File