Date: December 15, 2010

To: Office of Device Authorisation
Therapeutic Goods Administration
PO Box 100
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From: Kristina Hall
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RTI Biologics, Inc.
11621 Research Circle
Alachua, Florida 32615
United States of America

Re: Comments on the "Reforms in the Medical Devices Regulatory Framework Discussion Paper"

To Whom It May Concern:

We appreciate the opportunity to comment on the proposed reforms and trust that the following comments will be helpful. RTI Biologics, Inc. (RTI) is the leading provider of sterile biological implants for surgeries around the world with a commitment to advancing science, safety and innovation. RTI prepares human donated tissue and bovine tissue for transplantation through extensive testing and screening, precision shaping and proprietary, validated sterilization processes. These allograft and xenograft implants are used in orthopedic, dental, hernia and other specialty surgeries.

Thank you for your attention concerning our comments.

Sincerely,

Kristina K. Hall
Regulatory Affairs Associate

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RTI Comments

Section	Proposal Header	Proposal	RTI Comment
2C(i)	*Recognition of third party assessment bodies*	*Pg 19: Confidence building for EU Notified Bodies designated under the MRA*	We are generally supportive of EU-Australia MRA confidence building with designated Notified Bodies under the MRA. We believe this will strengthen the utility of the MRA, and benefit both European manufacturers and the Australian public.
3(i)	*Amending the way a kind of device is included on the ARTG*	*Pg 22: As new models become available, sponsors will be required to submit an application to vary the existing ARTG record to add a new model of that kind of device. This new model would undergo assessment if the kind of device is Class IIb or above, and if it meets the requirements for supply, will be added to the ARTG...Cost Implications: The assessment of the subsequent variations of devices will result in increased regulatory costs for pre-market assessment...*	We recommend the costs associated with "assessment of the subsequent variations" be designated in a manner appropriate for the assessment required. For example, the expense associated with adding a model number or trade name to the ARTG record would be less expensive than an assessment of more significant device variations.
4	*Publication of device product information on the TGA Website*	*Pg 26: Establishment of similar publications* [to the public information for US FDA medical devices and/or Australia medicines] *for medical devices...Specific issues which need to be addressed include:* • *The types or classes of devices which should be included in such a scheme:* - *Only higher risk classification devices such as Class III and AIMD;* - *All medical devices including lower risk classification devices;* - *All higher risk medical devices, and 'more interesting' lower risk devices where the technology is new or innovative for example;* • *The information which should be included when published, including the depth of that information;* • *Responsibility for authorship of the information (i.e. the manufacturer or the TGA);* • *Responsibility for ensuring information is up to date;*	▪ We are generally supportive of posting product summary information regarding safety and effectiveness on the TGA website for solely higher risk classification devices, such as Class III and AIMD. ▪ We recommend this information to be authored by the manufacturer. If authored by TGA, the manufacturer should be allowed to review the information prior to publication. This will ensure that proprietary information is duly protected. ▪ We recommend TGA establish a system for which this information can be updated in a timely manner as required by the manufacturer. Further, information to be published should not be required or posted until such a system is established. ▪ We strongly recommend against posting device labeling on the TGA website. We believe it could be detrimental to the public health if device labeling from a source other than the labeling accompanying the product is utilized in medical device application.

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Section	Proposal Header	Proposal	RTI Comment
4	*Publication of device product information on the TGA Website*	*Pg 26: Establishment of similar publications* [to FDA medical devices and Australia medicines] *for medical devices...Specific issues which need to be addressed include:* • *Whether to publish, or not, information relating to rejected applications:* - *Should all rejections be published, including lower risk classifications such as Class I and IIa;* - *The information which should be released if the application is rejected;* - *The reasons for rejection*	We strongly recommend against disclosure of when an application is rejected. Disclosure could be extremely detrimental to companies attempting to provide safe and effective products to the public. An application could be withdrawn or abandoned for a number of reasons, including lack of funding. In turn, TGA's concerns of safety would be left unresolved. Disclosure of this information would provide competitors with ammunition for slandering their competition, and facilitate a false negative public perception of a sponsor and/or company. A later approved or cleared new product or new use for an existing product, by means of a resubmission, would also be negatively impacted by this disclosure.

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