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August 22, 2000 1309 00 AUG 25 08:07

Facsimile
Confirmation copy by Mail

Docket Management Branch
U.S. Food and Drug Administration
5630 Fisher Lane
Room 1061 (HFA-305)
Rockville, Maryland 20852

Re: FDA Docket No. 00N-1380: Human Bone Allograft: Manipulation and
Homologous Use in Spine and Other Orthopedic Reconstruction and Repair;
Public Meeting -

Request for Extension of Comment Period

Dear Sir or Madam:

The Federal Register notice listed above noted that interested parties may submit written comments until September 1, 2000. Regeneration Technologies, Inc. (RTI) is requesting a sixty (60) - day extension of the comment deadline, until October 31, 2000. Our request for extension is based on the following reasons.

The lengthy August 2, 2000 meeting covered complicated and controversial issues. The interpretation of the FDA's proposed regulations for allograft tissue, including allograft used in the spine and other orthopaedic procedures, were discussed by the FDA and by representatives of tissue banking, donor families, and recipients. The FDA's proposed regulation uses bump up criteria such as minimal manipulation and homologous use, which would subject allografts to an increased level of FDA regulation, including premarket approval requirements.

It was very apparent that the majority of speakers feel there is lack of clarity in the definitions and that use of the proposed criteria for bumping up an allograft would produce illogical results. At the end of the meeting, the FDA acknowledged the need to revisit the definitions and even the possibility of removing the minimal manipulation and homologous use criteria.

RTI stated we would submit written comments offering alternatives to the current definitions and criteria for bumping up an allograft. In order to provide a well thought out solution incorporating and responding to views expressed during the meeting, RTI needs time to review the official transcript of the meeting, which was only recently made available to the public on August 16, 2000. The current comment deadline of September 1, 2000 does not afford RTI enough time to prepare a thorough and complete document.

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RTI also notes that there are interested parties other than RTI, both who attended and could not attend the meeting, who will require additional time to comment on this critical topic.

RTI agrees with the FDA's regulations in 21 CFR Part 1270 and believes these regulations have improved public health by setting minimal standards for donor screening and testing which all Tissue and Eye Banks must meet. RTI looks forward to working with the FDA in developing new definitions and appropriate additional regulations that make sense for allograft tissue.

For the reasons cited above, RTI requests an extension of the comment period for the August 2 public meeting until October 31, 2000. We appreciate your consideration of this request.

Most Respectfully,

A handwritten signature in cursive script, appearing to read "Robert M. Clark", is written over the typed name and title.

Robert M. Clark
Regulatory Affairs Manager