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August 16, 2000

Docket Number 00N-1380
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Request for an Extension to File Written Comments--Human Bone Allograft Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction Repair (FDA Public Meeting August 2, 2000)

Dear Dockets Management Branch:

This letter respectfully requests a 60-day extension to the comment period in regard to the above-referenced public meeting. In the Federal Register, FDA requested that written comments be submitted by September 1, 2000. However, we request that FDA extend this time frame to file written comments until **October 31, 2000** to allow the public adequate time to review and comment on the public hearing transcript, which has not yet been made available.

Due to the importance of the issues discussed at the public meeting, we believe that an extension is appropriate to allow interested parties the time to provide meaningful comments on the matters discussed at the meeting. Indeed, the matters discussed at the meeting present significant regulatory consequences to the tissue industry, physicians, and patients alike.

During the day-long public meeting, numerous speakers and FDA representatives gave presentations on a number of complicated issues involving FDA's proposed regulatory scheme for bone allografts used for construction and repair. At the beginning of the meeting, FDA specifically solicited input from interested parties on the ambiguities in FDA's proposed definitions for "minimal manipulation" and "homologous use." An extension of the written comment period is crucial to allowing interested parties to review the hearing transcript, conduct research into the issues discussed at the meeting, and develop well-reasoned comments to submit to FDA.

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The extension will benefit FDA because more parties will have had an opportunity to carefully review the important issues discussed at the public hearing and then submit well-reasoned comments to FDA. In addition, a 60-day extension will not unduly delay FDA's proposed rulemaking--FDA has yet to publish the third portion of FDA's proposed regulatory framework addressing good tissue practices.

In sum, we respectfully request that FDA extend the deadline for filing written comments on the public meeting until October 31, 2000.

Sincerely,

Ed Basile /aw

Edward M. Basile

Ashley Whitesides

Ashley Whitesides

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