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August 11, 2000

BY FACSIMILE/CONFIRMATION COPY BY MAIL

Dockets Management Branch
U.S. Food and Drug Administration
5630 Fishers 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 July 18, 2000 Federal Register announcement for the above-referenced public meeting held on August 2, 2000, states that interested parties may submit written comments until September 1, 2000. The purpose of this letter is to request a 60-day extension of the comment deadline, until October 31, 2000. A 60-day extension is justified for the following reasons.

The August 2, day-long public meeting focused on complicated and controversial issues concerning the interpretation and application of FDA's proposed regulatory framework for human tissue to a wide range of bone allografts used for spinal and other orthopedic reconstruction and repair. According to the agency's proposal, as confirmed by FDA officials' presentations at the meeting, the failure of a bone allograft to satisfy the proposed "minimal manipulation" and "homologous use" criteria would subject that allograft to an increased level of FDA regulation, including costly and time-consuming premarket clearance or approval requirements. In opening remarks, FDA officials solicited input on how to resolve the perceived ambiguities noted in comment submissions to date

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and institute a sensible regulatory scheme that is no more burdensome than necessary to address valid public health concerns.

Not counting FDA officials, more than 20 speakers gave presentations. The majority of speakers voiced strong objection to the lack of clarity and illogic of the proposed "kick-up" criteria as applied to bone allografts. Several speakers outlined alternative approaches to be further developed in written comments to the agency after the meeting. Following the presentations, FDA officials acknowledged a need to revisit the proposed definitional criteria and consider alternatives.

Extension of the deadline for written comments is necessary to allow interested parties adequate time to develop and submit proposed alternative approaches for consideration by FDA which incorporate and respond to the multitude of questions asked by the agency and the views presented at the meeting. Given the rapid pace of the meeting, its length, and the broad range of issues discussed, it would be difficult for interested parties to submit responsive comments or alternatives without reviewing the meeting transcript. We are informed that the transcript will not be available to the public until August 16 at the earliest. Thus, the present comment deadline of September 1 would leave interested parties roughly two weeks in which to review the transcript and prepare and submit their comments. Two weeks simply is not enough time for this important topic.

In addition, many interested parties who attended the meeting, but did not make a presentation, may wish to address or expand upon certain matters discussed. Following each set of speaker presentations, for example, FDA officials primarily directed their questions to the speakers and not to members of the general audience. Audience members thus had significantly less opportunity to respond to agency questions. Like the speakers who offered to submit alternatives, members of the audience need time to review the meeting transcript and respond to questions and comments they did not have an opportunity to address during the meeting.

Finally, many interested parties may not have been able to attend the August 2 public meeting. For these individuals also, adequate time to review the transcript is essential. Without the transcript, they simply cannot comment on the issues discussed at the meeting.

At the conclusion of the meeting, FDA officials acknowledged the need for additional consideration of the proposed approach. Moreover, the agency has allowed a second comment period for its September 1999 proposed rule addressing donor suitability, and has stated in its proposed rulemaking that all three parts of its proposed regulatory framework will be promulgated simultaneously as one final rule. The third part of FDA's

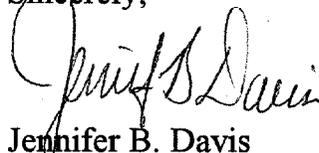
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proposed framework addressing "good tissue practices" has yet to be published. There is therefore no reason to believe that a 60-day extension of the comment period for the August 2 public meeting would unduly or detrimentally delay FDA's rulemaking. Indeed, receiving the more comprehensive comments that a 60-day extension would allow to be submitted would help the agency in refining its proposed regulatory framework.

For the foregoing reasons, we request that the comment deadline for the August 2 public meeting be extended until October 31, 2000.

Sincerely,



Jennifer B. Davis

JBD/tee

cc: Kathryn C. Zoon, Ph.D.
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