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December 17, 1999

Document Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

RE: Docket #97N-484S

Dear Sirs:

In reference to docket #97N-484S, I am writing to comment upon the FDA's encroachment on the use of allograft materials which has been a part of orthopaedics since its onset.

I am very concerned that this infringement and concern on the FDA's part is unwarranted and certainly unnecessary. I have been using allograft materials, both of a structural and non-structural nature, in restorative orthopaedic surgery for greater than 20 years. These materials allow orthopaedists to manage complex injuries and can be used as either allograft bone substitutes or as structural components. Certainly the use of femoral allografts has been widely used, as well as fibular allografts in multiple areas of restorative orthopaedic surgery.

I think that it is, at this time, unclear in my mind what the impetus for evaluation is. This is certainly something that has been a long-held standard and has an extremely long track record, and is, I feel, out of the purview of the FDA.

Sincerely *John Brugman*

Signature stamped  
to avoid delay in mailing

John L. Brugman, M.D.  
JLB/cec

97N 484S

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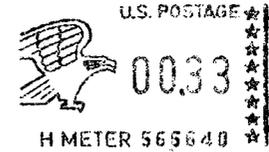


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