

**Butler, Jennie C**

**From:** Robert Nerem [robert.nerem@ibb.gatech.edu]  
**Sent:** Wednesday, June 12, 2002 10:30 AM  
**To:** FDADockets@oc.fda.gov  
**Cc:** ombuds@oc.fda.gov  
**Subject:** Fwd: Request to speak

In an earlier e-mail I requested the opportunity to speak at the June 24 public hearing on Part 15 Combination Products Containing Cellular Components as announced in the May 14 Federal Register. This e-mail is attached below.

The purpose of this e-mail is to update my request. Specifically I am asking to speak for 20 minutes. My comments will be based on my experience in tissue engineering and will cover the following.

1. The needs of the tissue engineering industry and the patients to be served.
2. A summary of the recently held Medical Technology Leadership Forum hosted by my institution which focused on "Defining a Regulatory Process for Combination Products."
3. The unique nature of combination products and the fact that they are not simply combinations.
4. Two examples illustrating the complexity of combination products.

Bob Nerem

>Date: Tue, 28 May 2002 12:14:27 -0400  
>To: FDADockets@oc.fda.gov  
>From: Robert Nerem <robert.nerem@ibb.gatech.edu>  
>Subject: Request to speak  
>  
>I would like to speak at the June 24, 2002 public hearing on Part 15  
>Combination Products Containing Cellular Components as announced in the  
>May 14 Federal Registrar.  
>  
>I am making this request as a member of the FDA Science Board and as  
>the  
>director of a major federally-funded tissue engineering center.  
>  
>Please advise as to whether there is anything else I need to do and how  
>much time I will be allocated.  
>  
>

Bob Nerem

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