

From: Jenkins, John K  
Sent: Wednesday, January 10, 2007 5:13 PM  
To: CDER-OND-110-ALL; CDER-OND-120-ALL; CDER-OND-130-ALL  
Cc: Kweder, Sandra L; Jenkins, John K  
Subject: Today's ODE1 All Hands Meeting

Folks

I wanted to thank each of you who attended today's meeting for your participation and in particular your candor in expressing your concerns about the pressures you are facing every day as you try to do the best job possible in meeting our important public health mission. Hearing the perspectives directly from review staff is exactly the purpose of these meetings and your feedback today was very important for me to hear. I agree that the competing pressures, workload, and goals we face today are daunting and that we don't have nearly enough staffing and resources to do our work to the level we strive for as stewards of the public health. I advocate for you in many venues to seek additional resources and to pressure sponsors to do a better job in preparing their submissions for our review. I plan to continue to do that and will redouble my efforts. In the short term we all need to be mindful of the need to triage and prioritize our work with a focus on those issues that are most important to the public health. We clearly cannot do all that we are being asked to do and must learn to make the tough calls on when we have to say "no" to lower priority work. I would reiterate that while PDUFA goals are important and we must continue to attempt to meet our goals to the best of our ability, safety and public health are our top priorities.

Thanks again for your feedback. As I said in the meeting, if you have additional questions, comments, or suggestions please send them to me by e-mail. I look forward to coming back to meet with you in July.

John

John K. Jenkins, M.D.  
Director, Office of New Drugs  
10903 New Hampshire Avenue  
Bldg #22, Room 6304  
Silver Spring, MD 20993  
301-796-0700  
301-796-9856 (fax)  
NOTE, New E-mail Address: john.jenkins@fda.hhs.gov