

## Dear Open Public Hearing (OPH) Speakers:

We have had many requests by individuals and organizations to participate in the September 6 advisory committee meeting. We have established the following guidelines for you to follow as you plan your statement.

1. Your comments must be limited to 5 minutes or less. This will be timed with a "Stop Light" to maintain time equality among all the speakers. The "Stop Light" will show green for the first four minutes and turn yellow for the fifth minute. At the five minute point the light will turn red. If you are still speaking at the end of your five minutes the Chair will interrupt you and thank you for your presentation.
2. We will have reserved seating. When you come to the meeting you need to sign in at the front desk. Please ask the people at the front desk where those seats are. There will be one chair for you. The OPH is in the afternoon - you are more than welcome to move to another seat after the OPH ends.
3. Please start your talk with a full disclosure on potential conflict of interest issues which are related to the issues of this meeting:
  - a. If your presentation and/or related expenses have been or will be covered by a manufacturer of a COPD Drug.
  - b. If you have ever been an investigator for any company that produces a COPD Drug.
  - c. If you have ever consulted on the development or analysis of COPD Drugs.
  - d. If you were an investigator or consultant on COPD Drugs.
  - e. If your organization (beyond your own answers to the above) receives pharmaceutical monies (please describe very briefly)
  - f. If there is any other way that you may be conflicted.
4. Submit in writing (e-mail to [Topperk@cderr.fda.gov](mailto:Topperk@cderr.fda.gov)) your **complete** statement that you wish to present by September 1, 2002. **All PowerPoint presentations must be forwarded to Kimberly by the deadline. Presentations not in by the due date will be handed out to the committee but will not be projected at the meeting.**
5. All statements will be posted on our web site: <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> Click on the year 2002 and go to the CDER meeting for Pulmonary-Allergy Drugs. The comments will be posted with the transcript and all PP presentations will be posted 10 days after the meeting.
6. You no longer need to bring copies for the head table. We will print up the material you submit to us for the committee's review.
7. If you have any questions, please call Kimberly Topper at 301-827-7001