

Joint Meeting of the Peripheral and Central Nervous System  
Drugs Advisory Committee and the  
Psychopharmacologic Drugs Advisory Committee

July 10, 2008

Sheraton Washington North Hotel  
Beltsville, Maryland

## Questions

- 1) Does the Committee agree with the Agency's overall finding of an increase in suicidality for the 11 AEDs analyzed?
- 2) Does the Committee agree with the Agency's conclusion that the finding of increased suicidality should apply to each of the drugs included in the analyses, despite the observation that the estimate of the Odds Ratio for 3 of the drugs was below 1? If not, to which drugs should the conclusion apply?
- 3) Does the Committee agree with the Agency's conclusion that the finding should apply to all currently approved chronically administered AEDs, including those not part of the analyses?
- 4) Does the Committee agree with the Agency's plan to require a Boxed warning for all AEDs?  
If not, does the Committee want to offer guidance on other approaches to communicating this information?
- 5) Does the Committee agree with the Agency's plan to require a Medication Guide?  
If not, does the Committee want to offer guidance on other approaches to communicating this information?