

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)
PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE
Hilton Hotel, the Maryland Ballroom, Silver Spring, Maryland
8:00 a.m. – 5:00 p.m.
December 13, 2006

Final Questions and Charge to the Committee

1. Does the committee feel that there is need to alter the current labeling of antidepressant drugs to include extension to young adult age?

2. Should the suggested label change be extended into the black box?

Charge to the Committee

Please discuss the findings from FDA's meta-analysis on antidepressants and suicidality in adult patients and comment both on the findings and on our general plans for labeling changes to reflect this new information. We would also encourage you to discuss possible research strategies to better understand the apparent risk of suicidality with antidepressant use in younger patients.