Questions and Issues
November 4, 2002
PDAC

Clozaril® (clozapine, Novartis Pharmaceuticals Corporation)

Issues for which FDA would like committee discussion and feedback:

1. Potential bias in referral of events to the safety monitoring board
2. Claim focusing on suicidality in schizophrenia or schizoaffective disorder
3. Expansion of Clozaril claim beyond treatment resistant schizophrenia
4. Interpretation of the InterSePT study with regard to olanzapine
5. Adequacy of a single randomized controlled trial to support suicidality claim
6. Adequacy of "suicidality" outcome in the InterSePT study

Question for which FDA would like a committee vote:

Do the data from the InterSePT Study, along with other data provided in this NDA supplement, provide a sufficient basis for a new claim involving suicidality in schizophrenia and schizoaffective disorder [Note: Part of the challenge to the committee is to articulate what the new claim should be.]?