Update to the PAC: Atypical Antipsychotics in the Pediatric Population

Judith U. Cope, MD, MPH
Office of Pediatric Therapeutics
OC, FDA

Pediatric Advisory Committee (PAC) Meeting
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Outline

- Background: November 18, 2008 PAC

- FDA Division of Psychiatry Products:
  Overview of June 2009 Psychopharmacologic Drug Advisory Committee Meeting

- NICHD/NIH Working Group:
  Update by BPCA Atypical Antipsychotics Working Group

- FDA Division of Epidemiology/OSE:
  Drug Use of Atypical Antipsychotics by Pediatric Age Subgroups

- FDA Office of Pediatric Therapeutics:
  Clinical Summary of Pediatric Metabolic AERS Reports
Background
11/2008 PAC Safety Reporting: Olanzapine & Risperidone

PAC recommendations:
• Additional follow-up regarding
  – Pediatric use of atypical antipsychotics with attention to age & indication
  – Metabolic syndrome, growth, sexual maturation and hyperprolactinemia
  – Extrapyramidal side effects in the pediatric population
• Studies, which may be collaboratively developed with NIH, on long-term effects of atypical antipsychotics in the pediatric population
• Evaluation of this drug class & concomitant drug use
• Delay any labeling recommendations until additional information is provided