Risk Management Guidances Training

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Course Content

- Welcome, Introductions, and Background
- Review of Industry Guidances:
  - Premarketing Risk Assessment
  - Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment
  - Development and Use of Risk Minimization Action Plans
- Questions and Answers

Background

- *"By the end of Fiscal Year 2004, CDER and CBER will jointly develop final guidance documents that address good risk assessment, risk management, and pharmacovigilance practices."*

  - Section VIII, PDUFA III goals letter October 1, 2002

Guidance Development

- Concept Papers
  - Public meetings/comments (through April 30, 2003)
- Draft Guidances
  - Published in *Federal Register* May 5, 2004
  - Public comments (through July 6, 2004)
- Final Guidances
  - Published March 24, 2005

Impact

- October 1, 2002-September 13, 2005
  - Reviewed 82 Risk Management Plans/Risk Minimization Action Plans (RiskMAPs)
    - 23 for PDUFA III products
    - 10 involved more than standard labeling, including postmarketing pharmacovigilance plans and targeted educational campaigns
  - Reviewed 3 peri-approval RiskMAPs

Other Initiatives

- A CDER MaPP on Risk Management Plan Activities in OND and ODS was developed and subsequently finalized on September 8, 2005
- OND/ODS Process Improvement Team