# DRAFT Program Overview DRAFT

| | Monday<br>September 25, 2006 | Tuesday<br>September 26, 2006 | Wednesday<br>September 27, 2006 | Thursday<br>September 28, 2006 |
|---|---|---|---|---|
| | **Day One: Overview** | **Day Two: Application Review** | **Day Three: Good Clinical Practice and Good Manufacturing Practices** | **Day Four: Generic Drugs and Pharmacovigilance** |
| ***Morning Session*** | Drug Review Process<br><br>Critical Points in the Life Cycle of a Drug | Good Guidance Practices<br><br>Good Review Practices | Good Clinical Practices<br><br>Human Subject Protection Activities and Bioresearch Monitoring | Review of Generic Drug Applications |
| | ***Lunch is on your own*** | ***Lunch is on your own*** | ***Lunch is on your own*** | ***Lunch is on your own*** |
| ***Afternoon Session*** | Types of Submissions<br><br>Review Disciplines | Special Interest Review Areas<br><br>Botanicals<br>Pediatrics<br>Orphan Drugs | Good Manufacturing Practices<br><br>Compliance Activities | Pharmocovigilance<br><br>Drug Safety Initiatives |

***The CDER Forum will be offered in Rockville, Maryland***