Over the years, the US Food and Drug Administration's Center for Drug Evaluation and Research (CDER) has been privileged to host many of our international colleagues interested in learning about our drug review process.

CDER desires to continue to be responsive to requests from our international colleagues.

The CDER Forum for International Regulators will allow CDER review staff to efficiently provide information about the US drug regulatory processes in an organized and integrated manner. During this program CDER will explain the role of CDER as well as the science, technology, regulations and processes used to do our work.

There is no registration fee for this program. However, attendees are responsible for their own travel expenses. The program will be offered in Rockville, Maryland.

USFDA is a transparent agency.

Information about CDER can be found at: www.fda.gov/cder

The following learning modules:

- *Drug Review and Related Activities in the United States*
- *Field Investigators: Adverse Drug Effects (ADE) Investigators (2000)*
- *The FDA Process for Approving Generic Drugs*

can be accessed online at:
www.fda.gov/cder/learn/CDERLearn/default.htm

For more information contact:

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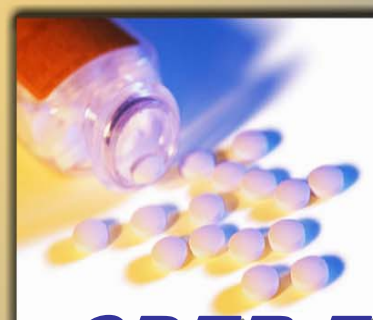

CDER Forum for International Drug Regulatory Authorities

September
25th – 28th
2006

Rockville, Maryland

DRAFT Program Overview DRAFT

	Monday September 25, 2006	Tuesday September 26, 2006	Wednesday September 27, 2006	Thursday 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 Critical Points in the Life Cycle of a Drug	Good Guidance Practices Good Review Practices	Good Clinical Practices 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 Review Disciplines	Special Interest Review Areas Botanicals Pediatrics Orphan Drugs	Good Manufacturing Practices Compliance Activities	Pharmocovigilance Drug Safety Initiatives

The CDER Forum will be offered in Rockville, Maryland