CDER Forum for International Drug Regulatory Authorities

September 25-28, 2006

CDER's International Program

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CDER Forum for International Drug Regulatory Authorities

Thank you for coming and WELCOME!

Overview

	Monday	Tuesday	Wednesday	Thursday
	Applications and Review	Application Review	Compliance	Pharmocovigilance and Generic Drugs
Morning Sessions	Welcome and Introduction Role of CDER	Good Guidance Practices Good Review Practices	Good Clinical Practice Good Manufacturing Practice Compliance	Drug Safety Drug Marketing
	Lunch is on your own	*Lunch is on your own*	*Lunch is on your own*	*Lunch is on your own*

International Program Leveraging Activities

- **WHO**
  - Consultations and review of documents
  - Members of Technical Committees
- **PAHO**
  - Pan American Network for Drug Regulatory Harmonization
  - Lead for GMP and BA/BE Working Group and member of Drug Registration Working Group
- **ICH**
  - Publication of ICH Guidances
    - Current focus is implementation of CTD
  - Global Cooperation Group- Regional Harmonization Initiatives
- **PEPFAR**
  - President's Emergency Plan for AIDs Relief

International Program Leveraging Activities

- International visitors/training requests
  - Coordinated with the agency's Office of International Programs
  - Prioritization of requests
    - Kept to a minimum so won't disrupt the review process and burden review staff
    - Confidentiality issues of concern
  - **CDER Forum for International Drug Regulatory Authorities**

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CDER Forum September 2005

CDER Forum for International Drug Regulatory Authorities

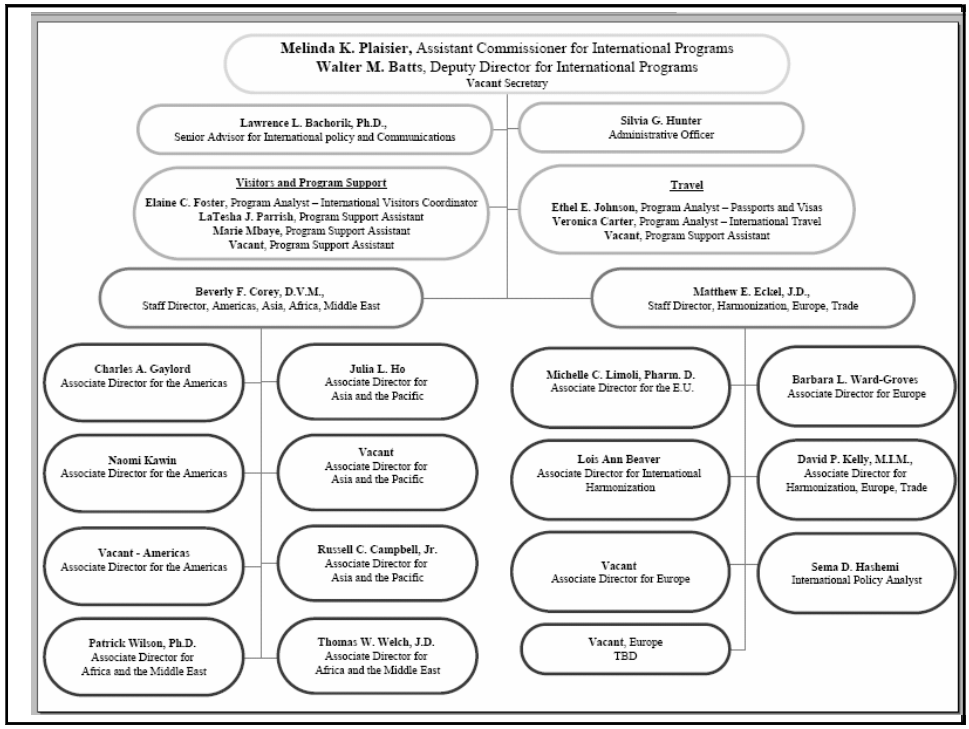
CDER Forum March 2006

CDER Forum for International Drug Regulatory Authorities

CDER Forum for International Drug Regulatory Authorities

FDA's International Program

- Office of International Programs
  - Melinda Plaisier, Assistant Commissioner
    - Walter Batts, Deputy Director
  - Africa, Middle East, Asia/Pacific, Americas
    - Bev Corey, Staff Director
  - Europe/Eurasia
    - Matt Eckel, Staff Director
- FDA's International Working Group (IWG)
  - Composed of OIP and Center representatives



Introductions International Colleagues

- Please share …
  - Your Name
  - Your Country
  - Your Position
  - Key areas of interest in CDER Forum topics