INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

STRENGTHENING CORE ELEMENTS OF REGULATORY SYSTEMS IN DEVELOPING COUNTRIES

MARCH 2-3, 2011

MEETING AGENDA

Keck Building
500 Fifth Street NW
Washington, DC 20001

Day 1 Goals:

1) Introduce the National Academies' study process
2) Discuss bias and conflict-of-interest
3) Fully understand this study's statement of task
4) Learn about the capacity and priorities of the FDA

DAY ONE: WEDNESDAY, MARCH 2, 2011
The Keck Building, Room 109

SESSION 1 - CLOSED
IOM COMMITTEE PROCESS AND CHARGE TO COMMITTEE

Objectives: To review the National Academies' study process that includes a bias and conflict-of-interest discussion; to discuss the role of the committee in addressing the statement of task; and to ensure the committee understands their statement of task.

SESSION 2- OPEN
QUESTIONS ON STATEMENT OF TASK

11:10 – 11:30	Project Timeline and Statement of Task Sponsor Representative Introductions **Jim Riviere**, Committee Chair
11:30 – 12:15	Questions to Sponsor **Mary Lou Valdez**, Associate Commissioner for International Programs, FDA **Kate Bond**, Associate Director for Technical Cooperation/Capacity-Building, FDA
12:15	Lunch

SESSION 3- OPEN
THE FDA PERSPECTIVE

Objective: To learn about the FDA's current capacity and its international work.

12:45	Welcome the Public and Introduce Commissioner Hamburg **Jim Riviere**, Committee Chair
12:45 – 1:05	Keynote Address: Why is this study important to the FDA? **Margaret Hamburg,** Commissioner, FDA
1:05 – 1:25	**Questions**

1:25 – 2:30	What is the capacity of the FDA Centers? What are the key issues they face in international work? **Deb Autor**, Director, Office of Compliance, FDA Center for Drug Evaluation and Research **Karen Midthun**, Director, FDA Center for Biologics Evaluation and Research **Lillian Gill,** Senior Associate Director, FDA Center for Devices and Radiological Health **Don Kraemer**, Acting Deputy Director for Operations, FDA Center for Food Safety and Applied Nutrition
2:30 – 2:50	How is the FDA already working to build regulatory systems abroad? **Mac Lumpkin**, FDA Deputy Commissioners for International Programs
2:50 – 3:20	Panel discussion with presenters **Jane Henney**, Moderator
3:20 – 3:35	Break

SESSION 4 - OPEN
CORE ELEMENTS OF REGULATORY SYSTEMS

Objective: To identify the core elements of regulatory systems in developing countries and what gaps exist in these systems.

3:35 – 4:00	Core Elements of Medical Device Regulatory Systems in Developing Countries **Michael Gropp**, Vice President, Global Regulatory Strategy, Medtronic **Greg Kalbaugh**, Director and Counsel, US Chamber of Commerce, US-India Business Council
4:00 – 4:25	Core Elements of Food Regulatory Systems in Developing Countries **Ernesto Enriquez**, Ministry of Health, Mexico **Paul B. Young**, Director, Chemical Analysis Operations, Waters Corporation
4:25 – 4:55	Core Elements of Drug and Biologics Regulatory Systems in Developing Countries **Jose Luis Di Fabio,** Area Manager, PAHO **Ekopimo Okon Ibia**, Director and US Regulatory Policy Lead, Global Regulatory Strategy, Policy, and Safety, Merck & Co., Inc.
4:55 – 5:45	What are the gaps in the systems? A panel discussion with presenters **Martha Brumfield**, Moderator
5:45	**Adjourn**

DAY TWO: THURSDAY, MARCH 3, 2011
The Keck Building, Room 110

Day 2 Goals:

1) Learn about existing recommendations and the obstacles to implementing them
2) Make a strategy for how to tackle the statement of task
3) Discuss how to structure the final report
4) Begin considering possible recommendation topics

SESSION 5 - CLOSED
REACTIONS TO PRESENTATIONS AND PLANNING TRAVEL

Objective: To discuss the presentations and plan the travel meetings.

SESSION 6 - OPEN
EXISTING RECOMMENDATIONS AND OBSTACLES TO IMPLEMENTATION

Objective: To learn what recommendations have already been made to strengthen regulatory systems and what obstacles exist to implementing these recommendations.

10:10 – 10:30	The Global Harmonization Task Force **Michael Gropp**, Vice President, Global Regulatory Strategy, Medtronic
10:30 – 10:50	Promoting the Quality of Medicines **Patrick Lukulay**, Director, Promoting the Quality of Medicines Program, US Pharmacopeia
10:50 – 11:10	Capacity Building and the Partnership Training Institute Network **Paul B. Young**, Director, Chemical Analysis Operations, Waters Corporation
11:10 – 11:30	The Global Food Safety Initiative **Mike Robach**, Vice President Corporate Food Safety and Regulatory Affairs, Cargill
11:30 – 11:50	The International Medical Products Anti-Counterfeiting Taskforce **Howard Zucker**, Senior Advisor, Division of Global Health & Human Rights, Massachusetts General Hospital
11:50 –12:30	Lunch
12:30 – 1:15	What prevents implementing recommendations? A panel discussion with presenters **Tom Bollyky**, Moderator

SESSION 7 – CLOSED
DISCUSSION AND STRATEGY FOR THE WAY FORWARD

Objective: To review the previous session, begin discussing recommendations, and give feedback on the meeting.