

US-EU High-level Regulatory Cooperation Forum
Conference on Best Cooperative Practices and Regulatory Work Plans
May 3, 2006

Hosted by the U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
John Eisenberg Room, 8th floor HHH Building
Washington, D.C.

Morning session is a Government Discussion (informal, interactive roundtables) followed by an afternoon session with Interested Parties

9:00-9:30am Arrivals/Coffee

9:30-9:35 Welcome

William R. Steiger, PhD.
Special Assistant to the Secretary for International Affairs, HHS

9:35-9:45 Opening Remarks

The Honorable C. Boyden Gray, Ambassador, U.S. Mission to the EU
The Honorable Heinz Zourek, Director General, DG Enterprise and Industry

Regulatory Cooperation: Best Cooperative Practices

9:45-11:00 “Model” US-EC regulatory dialogues – what works well and why?

Highlight benefits from specific cooperative dialogues and discuss experiences with specific regulatory cooperation tools (e.g., confidentiality arrangements, expert exchanges, training); linkage to good regulatory practices

Open Roundtable Discussion introduced by:

Murray Lumpkin, M.D., Deputy Commissioner, U.S. Food and Drug Administration/HHS
Hal Stratton, Chairman, U.S. Consumer Product Safety Commission
Robert Shotton, Director, DG Health and Consumer Affairs
Georgette Lalis, Director, DG Enterprise and Industry

11:00-11:30 Presentation/Discussion of draft Best Cooperative Practices

Open Discussion introduced by:

Jim Sanford, Deputy Assistant U.S. Trade Representative, USTR
Jan Frydman, Deputy Head of Unit, DG Enterprise and Industry

11:30-11:40 Break

US and EC Regulatory Work Plans: Future Cooperation

11:40-12:50 Future Cooperation – discussion on prospective new topics for US-EU regulatory cooperation

How do we create our work plans? Discussion opened by:

Don Arbuckle, Acting Administrator, OIRA, OMB
Alexander Italianer, Deputy Chef de Cabinet for EC President Barroso

Identification/Validation of new topics for cooperation:

Sectoral dialogues -- Discussion opened by:

Georgette Lalis, Director, DG Enterprise and Industry
Murray Lumpkin, M.D., Deputy Commissioner, FDA/HHS
and relevant speakers for other possible sectors/projects

Horizontal OMB-EC Dialogue -- Discussion opened by:

Don Arbuckle, Acting Administrator, OIRA, OMB
Gert-Jan Koopman, Director, DG Enterprise and Industry

12:50-1:00 Closing Remarks/Conclusions

Andrew C. von Eschenbach, M.D., Acting Commissioner, FDA/HHS or
Murray Lumpkin, M.D., Deputy Commissioner, FDA/HHS
Heinz Zourek, Director General, DG Enterprise and Industry

1:00-2:15 Buffet Lunch – Great Hall, 1st floor

Brief informal remarks by The Honorable Alex M. Azar II, HHS Deputy Secretary and Michael Fruhmann of the Austrian Federal Chancellery

2:30-4:00 Interested Parties Session – John Eisenberg Room, 8th floor

Briefing on Government discussions and opportunity for stakeholder input

Led by:

Murray Lumpkin, M.D., Deputy Commissioner, FDA/HHS
Heinz Zourek, Director General, DG Enterprise and Industry

Forum Coordinators: US: Jim Sanford, Deputy Assistant U.S. Trade Representative, USTR
EC: Jan Frydman, Deputy Head of Unit, DG ENTR
Antti Karhunen, Principal Administrator, DG ENTR