Standardizing and Evaluating
Risk Evaluation and Mitigation Strategies (REMS)
Public Meeting

July 25 - 26, 2013

FDA White Oak Great Room
Building 31, Room 1503
10903 New Hampshire Avenue
Silver Spring, MD 20993

Meeting Website:
http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm351029.htm

July 25, 2013

8:30 – 9:00 am **Opening Remarks/Overview of REMS**
Theresa Toigo, R.Ph., M.B.A.
Associate Director for Drug Safety Operations
Center for Drug Evaluation and Research

9:00 – 9:30 am **Standardizing REMS**
Adam Kroetsch, M.S.
Operations Research Analyst, Office of Program and Strategic Analysis
Office of Strategic Programs
Center for Drug Evaluation and Research

9:30 – 9:45 am **Prescriber-Directed Tools in REMS**
Kate Oswell, M.A.
Health Communications Analyst, Division of Risk Management
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

9:45 – 10:00 am **Patient-Directed Tools in REMS**
Anahita Tavakoli, M.A.
Health Communications Analyst, Division of Risk Management
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

10:00 – 10:15 am **Dispensers and Dispensing Settings in REMS**

Megan Moncur, M.S.
Regulatory Health Policy Analyst, Division of Risk Management
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

10:15 – 10:30 am **Break**

General Standardization Speaker Section 1

10:30 – 10:40 am
Sarah A. Spurgeon, *Pharmaceutical Research and Manufacturers of America (PhRMA*)
10:40 – 10:50 am
Andrew Emmett, *Biotechnology Industry Organization (BIO)*
10:50 – 11:00 am
Paul Sheehan, *Celgene Corporation*
11:00 – 11:10 am
Jeff Fetterman, *ParagonRx*
11:10 – 11:20 am
JoAnn Stubbings, B.S.Pharm., M.H. C.A., *University of Illinois at Chicago*
11:20 – 11:30 am
Paul Brown, *National Research Center for Women and Families*
11:30-11:40 am
Phyllis Greenberger, MSW, *Society for Women's Health Research*

11:40 – 11:50 am **FDA Questions**

11:50 am – 12:45 pm **Lunch**

General Standardization Speaker Section 2

12:45 - 12:55 pm
Gary Appio, Pharm.D., M.B.A., *Novartis Pharmaceuticals Corporation*
12:55 -1:05 pm
Jim Devita, *CVS Caremark*
1:05 – 1:15 pm
Stephen A. Goldman, M.D., F.A.P.M., *Stephen A. Goldman Consulting Services, L.L.C.*
1:15 – 1:25 pm
Paul Seligman, *Amgen*
1:25 – 1:35 pm
Brian J. Malkin, *Partner, Frommer Lawrence & Haug, L.L.P.*
1:35 – 1:45 pm
Bill Martin, Express Scripts

1:45 – 1:55 pm **FDA Questions**

Prescriber & Patient Directed Tools Speaker Section

1:55 – 2:05 pm
Ann Karty, **M.D., F.A.A.F.P.,** *American Academy of Family Physicians*
2:05 – 2:15 pm
Murray Kopelow, M.D., *Accreditation Council for Continuing Medical Education*
2:15 -2:25 pm
Andrew Kolodny, M.D., *Physicians for Responsible Opioid Prescribing*
2:25 – 2:35 pm
Natalie O'Donnell, B.S.N., R.N., *United BioSource Corporation*

2:35 – 2:45 pm **FDA Questions**

2:45 – 3:00 pm **Break**

REMS Tools in Dispensing Settings Speaker Section

3:00 – 3:10 pm
Kevin Nicholson, R.Ph., J.D., *National Association of Chain Drug Stores*
3:10 – 3:20 pm
Stacie Maass, B.S.Pharm., J.D., *American Pharmacists Association*
3:20 – 3:30 pm
Carolyn Ha, Pharm.D., *National Community Pharmacists Association*
3:30 – 3:40 pm
David Chen, R.Ph., M.B.A., *American Society of Health-System Pharmacists*
3:40 – 3:50 pm
Mary Jo Carden, R.Ph., J.D., *Academy of Managed Care Pharmacy*
3:50 – 4:00 pm
Lindsey R. Kelly, Pharm.D., M.S., *University of Michigan Health System*
4:00 – 4:10 pm
Katie Stabi, Pharm.D., B.C.P.S., *Cleveland Clinic*

4:10 – 4:20 pm **FDA Questions**

4:20 – 4:30 pm **Concluding Remarks**
Theresa Toigo, R.Ph., M.B.A.

July 26, 2013

8:30 – 8:45 am **Opening Remarks**
Theresa Toigo, R.Ph., M.B.A., FDA

Standardization Projects Speaker Section

8:45 – 8:55 am
Gerald K. McEvoy, Pharm.D., *National Council for Prescription Drug Programs (NCPDP)*
8:55 – 9:05 am
C. Douglas Monroe, R.Ph., M.S., *Kaiser Permanente*
9:05 – 9:15 am
Yola Moride, Ph.D., F.I.S.P.E., *Université de Montréal*
9:15 – 9:25 am
Marie Link, Pharm.D., *REMS Logic, L.L.C.*
9:25 – 9:35 am
Catherine Sigler, D.V.M., M.P.H., Ph.D., *United BioSource Corporation*
9:35 – 9:45 am
Frank Gallo, *Pharmaceutical Product Development, L.L.C. (PPD)*
9:45 – 9:55 am
Madalina Chirieac, M.D., M.P.H., Biogen Idec, Inc.
9:55 – 10:05 am
Rebekah L. Hanson, Pharm.D., B.C.P.S., B.C.A.C.P., *University of Illinois at Chicago*

10:05 – 10:30 am **FDA Questions**

10:30 – 10:45 am **Break**

10:45 – 11:30 am **Standardization Open Public Hearing**

11:30 – 11:45 am **REMS Assessments: A Summary of FDA's Experiences and Challenges**

Mary Willy, Ph.D.
Associate Director, Division of Risk Management
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology

11:45 am – 12:15 pm **Building a Framework for Future REMS Assessments**

Gary Slatko, M.D.
Director, Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology

12:15 – 1:15 pm **Lunch**

General Evaluation Speaker Section

1:15 – 1:25 pm
Sarah A. Spurgeon, *Pharmaceutical Research and Manufacturers of America (PhRMA)*
1:25 – 1:35 pm
Meredith Y. Smith, Ph.D., M.P.A., *AbbVie, Inc.*
1:35 – 1:45 pm
Gretchen S. Dieck, Ph.D., *United BioSource Corporation*
1:45 – 1:55 pm
Mark DeLuca, M.H.S.E. candidate, *Lehigh University and ParagonRx International, L.L.C.*
M. Kris Srinivasan, M.D., M.B.A., M.H.S.E., *ParagonRx International, L.L.C.*
1:55 – 2:05 pm
Ruth S. Day, Ph.D., *Duke University*
2:05 – 2:15 pm
Sidney M. Wolfe, M.D., *Public Citizen*
2:15 – 2:25 pm
Juliane K. Mills, M.S., M.P.H., *United BioSource Corporation*

2:25 – 2:40 pm	**FDA Questions**
2:40 – 3:00 pm	**Break**
3:00 – 4:00 pm	**Evaluation Open Public Hearing**
4:00 – 4:20 pm ***Gary Slatko, M.D., FDA***	**Meeting Summary**
4:20 – 4:30 pm ***Theresa Toigo, R.Ph., M.B.A., FDA***	**Closing and Adjournment**

FDA Panelists	
CDR Chardae Araojo, Pharm.D., M.S.	Deputy Director, Office of Medical Policy Initiatives Office of Medical Policy Center for Drug Evaluation and Research U.S. Food and Drug Administration
Doris Auth, Pharm.D.	Lead Pharmacist, Division of Risk Management Office of Medication Error Prevention and Risk Management Office of Surveillance and Epidemiology Center for Drug Evaluation and Research U.S. Food and Drug Administration
Michie Hunt, Ph.D., M.B.A.	Program Analyst, Office of Executive Programs Center for Drug Evaluation and Research U.S. Food and Drug Administration
Mwango Kashoki, M.D., M.P.H.	Associate Director for Safety, Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration
Adam Kroetsch, M.S.	Operations Research Analyst, Office of Program and Strategic Analysis Office of Strategic Programs Center for Drug Evaluation and Research U.S. Food and Drug Administration
Elaine Lippmann, J.D.	Regulatory Counsel, Division of Regulatory Policy II Office of Regulatory Policy Center for Drug Evaluation and Research U.S. Food and Drug Administration
Claudia Manzo, Pharm.D.	Director, Division of Risk Management Office of Medication Error Prevention and Risk Management Office of Surveillance and Epidemiology Center for Drug Evaluation and Research U.S. Food and Drug Administration
Megan Moncur, M.S.	Regulatory Health Policy Analyst, Division of Risk Management Office of Medication Error Prevention and Risk Management Office of Surveillance and Epidemiology Center for Drug Evaluation and Research U.S. Food and Drug Administration
Kate Oswell, M.A.	Health Communications Analyst, Division of Risk Management Office of Medication Error Prevention and Risk Management Office of Surveillance and Epidemiology Center for Drug Evaluation and Research U.S. Food and Drug Administration
Kevin Prohaska, D.O., M.P.H.	Captain, U.S. Public Health Service Corps Director/Medical Officer, Division of Safety Compliance Office of Scientific Investigations Office of Compliance Center for Drug Evaluation and Research U.S. Food and Drug Administration
Gary Slatko, M.D.	Director, Office of Medication Error Prevention and Risk Management Office of Surveillance and Epidemiology Center for Drug Evaluation and Research U.S. Food and Drug Administration

Ana Tavakoli, M.A.	Health Communications Analyst, Division of Risk Management Office of Medication Error Prevention and Risk Management Office of Surveillance and Epidemiology Center for Drug Evaluation and Research U.S. Food and Drug Administration
Theresa Toigo, R.Ph., M.B.A.	Associate Director for Drug Safety Operations, Center for Drug Evaluation and Research U.S. Food and Drug Administration
Marcia Britt Williams, Ph.D.	CAPT, U.S. Public Health Service Team Leader, REMS Compliance Team Division of Safety Compliance Office of Scientific Investigations Office of Compliance Center for Drug Evaluation and Research U.S. Food and Drug Administration
Mary Willy, Ph.D.	Associate Director, Division of Risk Management Office of Medication Error Prevention and Risk Management Office of Surveillance and Epidemiology Center for Drug Evaluation and Research U.S. Food and Drug Administration