# Meeting of the Risk Communication Advisory Committee

March 5, 2018

FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, MD 20993

## AGENDA (DRAFT)

The Risk Communication Advisory Committee will discuss communicating risk information about fetal effects in product labeling according to the Pregnancy and Lactation Labeling Rule (PLLR), perception of risk and factors important to patients and prescribers, and societal factors that impact treatment decisions, to effectively assist patients and prescribers to make informed decisions about use of prescription drugs and vaccines in pregnancy.

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| 8:00 a.m. | Call to Order and Opening Remarks | **Susan J. Blalock, Ph.D., M.P.H.**<br>Chair<br>Risk Communication Advisory Committee |
| | Conflict of Interest Statement | **Lee Zwanziger, Ph.D.**<br>Designated Federal Officer<br>Risk Communication Advisory Committee<br>FDA |
| 8:10 a.m. | Opening Remarks | **Malcolm J. Bertoni, M.S.**<br>Associate Commissioner for Planning and Director of the Office of Planning<br>Office of the Commissioner<br>FDA |

**FDA PRESENTATIONS**

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| 8:15 a.m. | Welcome / Opening Remarks | Division of Pediatric and Maternal Health<br>Office of Drug Evaluation IV<br>Office of New Drugs<br>Center for Drug Evaluation and Research<br>FDA |
| | | Division of Bone, Reproductive, and Urologic Products<br>Office of Drug Evaluation III<br>Office of New Drugs<br>Center for Drug Evaluation and Research<br>FDA |

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| 8:30 a.m. | Pregnancy and Lactation Labeling Rule: History and Background | Division of Pediatric and Maternal Health<br>Office of Drug Evaluation IV<br>Office of New Drugs<br>Center for Drug Evaluation and Research<br>FDA |
| 8:50 a.m. | Labeling Revision Process | Division of Pediatric and Maternal Health<br>Office of Drug Evaluation IV<br>Office of New Drugs<br>Center for Drug Evaluation and Research<br>FDA |

**GUEST SPEAKER PRESENTATIONS**

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|---|---|---|
| 9:10 a.m. | Physicians' Perspective of the New Pregnancy and Lactation Labeling: Survey Results | **Jennifer A. Namazy, M.D.** |
| 9:30 a.m. | Break | |
| 9:45 a.m. | Communicating Risk in an Environment of Uncertainty | **Michael F. Greene, M.D.** |
| 10:15 a.m. | Prescribing for Pregnant Patients: Progress Report | **Katherine L. Wisner, M.D., M.S.** |
| 10:45 a.m. | Communication: Advisory Committee on Immunization Practices (ACIP) Recommendations and Vaccine Uptake by Pregnant Women | **Laura E. Riley, M.D.** |
| 11:15 a.m. | Communicating Teratogen Information Effectively: The Teratogen Information Service Perspective | **Beth Conover, APRH, CGC** |
| 11:45 a.m. | Lunch | |

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| 12:45 p.m. | Open Public Hearing | |
| 1:45 p.m. | A Patient Perspective: Pregnancy and Lactation Labeling Rule - A Modern Day Medical X Factor | **Jamie Zahlaway Belsito** |
| 2:15 p.m. | Pregnancy and Lactation Labeling: A Law and Ethics Perspective | **Kayte Spector-Bagdady, J.D., MBioethics** |
| 2:45 p.m. | Pregnancy and Lactation Labeling Rule (PLLR) from an Industry Perspective | **Traci J. Lee, Pharm.D.** |
| 3:15 p.m. | Break | |
| 3:30 p.m. | Clarifying Questions | |
| 4:00 p.m. | Charge to Committee/Committee Discussion | |
| 5:00 p.m. | Adjournment | **Susan J. Blalock, Ph.D., M.P.H.**<br>Chair<br>Risk Communication Advisory Committee |



**U.S. Food and Drug Administration**
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