Labels Without Categories:
A Workshop on FDA's Pregnancy and Lactation Labeling Rule

Abstract: The recently finalized Pregnancy Labeling and Lactation Labeling Rule changes the organization of the current Pregnancy and Nursing Mothers section of the US package insert of prescription drugs. The labeling changes will require omission of the current letter categories and reformatting of the sections with inclusion of clinically relevant human and animal data. The labeling changes are significant in that they now require written risk summaries of available safety data; as well as clinical prescribing considerations, including background rates of malformations, and the hazards of untreated disease states for successful pregnancy outcome. The rule covers new drug approvals as well as drugs approved from June 2001. This rule goes into effect June 30, 2015. In response to these changes in prescription drug labeling, the HESI Developmental and Reproductive Toxicology (DART) Technical committee is sponsoring a two-day workshop on this topic. This workshop aims to:

1) provide a forum to discuss the impact of the PLLR;
2) train relevant industry professionals on how to write labels according to the new rule;
3) provide feedback to the US FDA.

WORKSHOP AGENDA

WEDNESDAY, MAY 20

7:30am – 9:00am Registration & Continental Breakfast

Day 1 – Morning Session

9:00am – 9:10am **Welcome and Workshop Objectives**
Susan Laffan (GlaxoSmithKline)

9:10am – 9:50am **Introduction to the Pregnancy and Lactation Labeling Rule**
Melissa Tassinari (US Food and Drug Administration, Center for Drug Evaluation and Research)

9:50am – 10:15am **Clinical Use of Labels**
Shari Lusskin (Icahn School of Medicine, Mount Sinai Medical Center)

10:15am – 10:30am Break

10:30am – 11:00am **Writing Risk Summaries – Human, Animal & Pharmacologic**
Mary Ellen McNerney (Bristol-Myers Squibb)

11:00am – 11:30am **Using Animal Data to Communicate Human Risk**
Tacey White (Exponent)

Day 1 – Afternoon Session

11:35am – 11:45am **Explanation of Breakout Session Logistics, Structure, and Expectations**
Susan Laffan (GlaxoSmithKline)

11:45am – 12:00pm Break for Working Lunch

12:00pm – 2:00pm **Breakout Session 1 – "New Label" Case Studies: Animal and Pharmacology Data Only**

2:00pm – 2:15pm Break

2:15pm – 3:00pm **Report from Breakout Session 1**

3:00pm – 3:45pm	**Clinical Considerations** *Anthony Scialli (Reproductive Toxicology Center)*
3:45pm – 5:00pm	**Breakout Session 2 – Populating the Clinical Considerations Section**
5:00pm – 5:45pm	**Report from Breakout Session 2 / Close for Day**
5:45pm	Cocktail Reception

THURSDAY, MAY 21

6:45am – 8:00am Continental Breakfast

Day 2 – Sunrise Session (optional)

7:00am – 7:45am	**European Perspective on Drug Labeling Without Categories** *Jan Willem van der Laan (Medicines Evaluations Board, The Netherlands)*

Day 2 – Morning Session

8:00am – 8:05am	**Recap of Day 1/Overview of Day 2**
8:05am – 8:50am	**Incorporating Clinical Information into the Label** *Janet Hardy (The ECC Population Health Group LLC, University of South Florida)*
8:50am – 10:30am	**Breakout Session 3 – Writing Risk Summary with Clinical Data, "Revising a Label"**
10:30am – 10:45am	Break
10:45am – 11:30am	**Report from Breakout Session 3**
11:30am – 11:45pm	**New Technologies to Collect Pregnancy and Lactation Data** *Diego Wyszynski (Boehringer Ingelheim)*
11:45am – 12:30pm	Lunch

Day 2 – Afternoon Session

12:30pm – 1:00pm	**Section 8.3 – Females and Males of Reproductive Potential** *Lynnda Reid (US Food and Drug Administration, Center for Drug Evaluation and Research)*
1:00pm – 2:15pm	**Breakout Session 4 – Case Studies for Writing Content for Section 8.3**
2:15pm – 2:30pm	Break
2:30pm – 3:15pm	**Report from Breakout Session 4**
3:15pm – 4:00pm	**Group Discussion (lessons learned, concerns, considerations, requests for clarity) & Concluding Remarks**