FDA Regulatory Education for Industry (REdI) Conference: Prescription Drug Labeling - Challenges and Issues

Agenda

Day 1: Tuesday, November 3, 2015	
7:15 AM	Registration Opens
8:20-8:30 AM	Welcome Brenda Stodart, Pharm.D., Captain, United States Public Health Service Program Director, Small Business and Industry Assistance, Division of Drug Information, Office of Communications, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)
8:30-9:00 AM	Meeting Objectives, Labeling Resources for Industry, and Understanding CDER's Labeling Review Process Eric Brodsky, M.D. Associate Director, Labeling Development Team, Office of New Drugs, CDER, FDA
9:00-10:30 AM Session #1	Challenges and Issues With the Indications and Usage, Dosage and Administration, and Clinical Studies Sections of Labeling Farrokh Sohrabi, M.D. (moderator) Labeling Reviewer, Labeling Development Team, Office of New Drugs, CDER, FDA Eric Brodsky, M.D. (presenter: 50 minutes) Associate Director, Labeling Development Team, Office of New Drugs, CDER, FDA *Abstract: This presentation will discuss frequently encountered labeling development issues in the INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION, and CLINICAL STUDIES sections of labeling and will include examples of how these labeling issues were resolved.* Dora Cohen (presenter: 15 minutes) Executive Director, Global Labeling, Global Regulatory Affairs and Safety, Amgen *Abstract: The presentation provides the industry perspective on the INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION, and CLINICAL STUDIES sections of US labeling for prescription drug and biological products. There will be a brief review of the FDA labeling regulations and guidance documents for these sections followed by a discussion on some common challenges in preparing these sections throughout the product lifecycle.* Panel Discussion with Farrokh Sohrabi, Eric Brodsky, Ann Marie Trentacosti, and Dora Cohen (25 minutes)
10:30-10:45 AM	**BREAK**
10:45-noon Session #2	Challenges and Issues With Safety-Related Information in the Prescribing Information Farrokh Sohrabi, M.D. (moderator) Labeling Reviewer, Labeling Development Team, Office of New Drugs, CDER, FDA Ann Marie Trentacosti, M.D. (presenter: 35 minutes) Medical Lead, Labeling Development Team, Office of New Drugs, CDER, FDA *Abstract: This presentation will discuss frequently encountered labeling development issues with risk information and/or risk management information in the BOXED WARNING, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and the ADVERSE REACTIONS sections of labeling.*

Day 1: Tuesday, November 3, 2015	
	Jacqueline Kline (presenter: 20 minutes) Eisai Inc. *Abstract: The presentation provides the industry perspective on some of the challenges associated with safety-related information in the prescribing information from a pre- and post-approval perspective. Pre-approval discussion points will include how the Common Technical Document supports prescribing information and challenges around determining adverse reactions for a product. Post-approval discussion points will include challenges around the approval of "Changes Being Effected" and prior approval labeling supplements, as well as class labeling changes and their impact on a Company Core Data Sheet.* Panel Discussion with Farrokh Sohrabi, Ann Marie Trentacosti, Eric Brodsky, and Jacqueline Kline (20 minutes)
noon -1:15 PM	**LUNCH - Optional pay on own, networking opportunity**
1:15-2:30 PM Session #3	Challenges of Drug Interaction Information in Labeling Strategies for Enhancing Quality, Utility, and Clarity in Drug Interaction Labeling: A Regulatory Perspective Joseph A. Grillo, Pharm.D. (presenter: 35 minutes) also moderator Associate Director of Labeling and Health Communication, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA *Abstract: This presentation will discuss content and format for the three key areas in labeling that contain drug interaction information [i.e., the DRUG INTERACTIONS section (Section 7), the CLINICAL PHARMACOLOGY section (Section 12), and the DOSAGE AND ADMINISTRATION section (Section 2)]. Strategies to enhance clarity and readability including text formatting and attributes, as well as the use of tables and figures will be presented with examples.* Julie Retzinger, RN, MBA (presenter: 20 minutes) Senior Director Regulatory Affairs, Vertex Pharmaceuticals Inc. *Abstract: The motivation for this presentation is to share with the audience a labeling case study. This case study will give an industry perspective to the Dosage and Administration, Drug Interactions, and the Clinical Pharmacology sections of the USPI.* Panel Discussion with Joe Grillo (moderator) and Julie Retzinger (presenter: 20 minutes)
2:30-2:45 PM	**BREAK**
2:45-4:15 PM Session #4	Patient Labeling and Patient Counseling Information Section in the Prescribing Information LaShawn Griffiths, MSHS-PH, BSN, RN (moderator) Associate Director for Patient Labeling Division of Medical Policy Programs, Office of Medical Policy Initiatives, Office of Medical Policy, CDER, FDA Developing the Patient Counseling Information Section of Labeling Iris Masucci, Pharm.D. (presenter: 20 minutes) Office of Medical Policy, CDER, FDA *Abstract: This presentation will discuss the recently published (December 2014) Patient Counseling Information Section of Labeling guidance that is intended to assist application holders in developing the PATIENT COUNSELING INFORMATION section of labeling.* Patient Labeling Team Updates

Day 1: Tuesday, November 3, 2015	
	Nathan Caulk, MS, BSN, RN, LT, USPHS (presenter: 15 minutes) Patient Labeling Reviewer, Division of Medical Policy Programs, Office of Medical Policy Initiatives, Office of Medical Policy, CDER, FDA *Abstract: Patients who take prescription medications rely on accurate and easily understood medication information. This presentation will provide an update on current Patient Labeling Team activities and challenges, including an update on formatting for existing forms of patient labeling.* Patient Medication Information Elisabeth Walther, Pharm.D., JD (presenter: 15 minutes) Division of Medical Policy Programs, Office of Medical Policy Initiatives, Office of Medical Policy, CDER, FDA *Abstract: FDA is considering the development of a new form of patient information called Patient Medication Information (PMI). This presentation will discuss an overview of PMI related meetings, a brief description of an experimental study of patient information prototypes, and a proposed framework for PMI.* Patient Medication Information Amy Ebel, BS, Pharm.D. (presenter: 20 minutes) Director, Global Regulatory Affairs Labeling, GlaxoSmithKline *Abstract: Pharmaceutical companies submit for review different types of patient labeling including patient information leaflets, medication guides, and instructions for use. This presentation will describe very briefly labeling development within GSK and challenges in the creation or revision of patient labeling from an industry perspective.* Panel Discussion with LaShawn Griffiths, Iris Masucci, Nathan Caulk, Elisabeth Walther, and Amy Ebel (20 minutes)
4:15-4:30 PM	Closing Brenda Stodart, Pharm.D. Captain, USPHS Program Director, CDER SBIA, DDI, OCOMM, CDER, FDA

Day 2: Wednesday November 4, 2015	
7:15 AM	Registration Opens
8:20-8:35 AM	Welcome Brenda Stodart, Pharm.D. Captain, USPHS Program Director, Small Business and Industry Assistance, Division of Drug Information, Office of Communications, CDER, FDA
8:35-10:00 AM Session #5	Pregnancy and Lactation Labeling Rule (PLLR) Labeling PLLR Overview Jeanine Best, MSN, RN (presenter: 20 minutes) and also moderator Labeling Reviewer, Labeling Development Team, Office of New Drugs, CDER, FDA *Abstract: This presentation will focus on an overview of the Pregnancy and Lactation Labeling Rule which took effect June 30, 2015.* PLLR: Implementation and Challenges Tamara Johnson, M.D., MS (presenter: 20 minutes) Maternal Health Team Leader, Division of Pediatric and Maternal Health, Office of New Drugs, CDER, FDA

Day 2: Wednesday November 4, 2015	
	PLLR Christina Bucci-Rechtweg, M.D. (presenter 25 minutes) Global Head, Pediatrics & Maternal Health Policy, Drug Regulatory Affairs, Novartis Pharmaceuticals. Panel Discussion with Jeanine Best (moderator), Tamara Johnson, Melissa Tassinari, and Christina Bucci-Rechtweg (20 minutes)
10:00-10:15 AM	**BREAK**
10:15-11:45 AM Session #6	Carton and Container Labeling Danielle Harris, Pharm.D., BCPS (moderator) Lead Pharmacist, Division of Medication Error Prevention and Analysis, Office of Medication Error Prevention and Risk Management, Office of Surveillance and Epidemiology, CDER, FDA Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors for Drug Products Tingting Gao, Pharm.D. (presenter: 20 minutes) Safety Evaluator, Division of Medication Error Prevention and Analysis, Office of Medication Error Prevention and Risk Management, Office of Surveillance and Epidemiology, CDER, FDA *Abstract: This presentation will discuss strategies and recommendations for ensuring that critical elements of container labels and carton labeling are designed to reduce or eliminate medication errors and to promote safe dispensing, administration, and use of drug products.* Common Deficiencies in Container Label and Carton Labeling for Biological Products Jibril Abdus-Samad, Pharm.D., LT USPHS (presenter: 20 minutes) Labeling Reviewer, Office of Biotechnology Products, Office of Pharmaceutical Quality, CDER, FDA *Abstract: This presentation will discuss common deficiencies in container labels and carton labeling for biological products. The presentation will focus on the display of proper names, dosage forms, strength, route of administration, and manufacturer information on container labels and carton labeling.* Carton and Container Labeling Varsha Mehta (presenter: 20 minutes) Associate Director, US Labeling, Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation *Abstract: This presentation will discuss the challenges and recommendations specific to industry experience in BLA and NDA container and carton labeling. It will focus on hands-on approach to developing the labeling design, content, product specific information, and patient's/physician's instructions for container and carton labeling.* Panel Discussion with Tingting Gao, Jibril Abdus-Samad, and Varsha Mehta (30 minutes)
11:45 AM-1:00 PM	**LUNCH - Optional pay on own, networking opportunity**
1:00-2:15 PM Session #7	Prescribing Information Potpourri Eric Brodsky, M.D. (moderator) Associate Director, Labeling Development Team, Office of New Drugs, CDER, FDA Ann Marie Trentacosti, M.D. Medical Lead, Labeling Development Team, Office of New Drugs, CDER, FDA FDA presentations (50 minutes) *Abstract: The FDA presentations will discuss a potpourri of labeling challenges including developing the Highlights of Prescribing Information, distributing specific population information throughout the*

Day 2: Wednesday November 4, 2015	
	labeling, and other labeling issues; and will provide examples of how these labeling issues were resolved. Panel Discussion with Ann Marie Trentacosti and Eric Brodsky (25 minutes)
2:15-2:30 PM	BREAK
2:30-4:00 PM Session #8	Drug Labeling and Its Impact on Promotion Jean-Ah Kang, Pharm.D. (moderator) Special Assistant to the Director, Office of Prescription Drug Promotion, Office of Medical Policy, OMP, CDER, FDA Aline Moukhtara, RN, MPH (presenter: 20 minutes) CDR, USPHS Regulatory Review Officer, Division I, Office of Prescription Drug Promotion, Office of Medical Policy, CDER, FDA Elaine Hu Cunningham, Pharm.D., RAC (presenter: 20 minutes) CDR, USPHS Senior Advisor for Evidence Review, Division I, Office of Prescription Drug Promotion, Office of Medical Policy, CDER, FDA *Abstract: The FDA presentations will describe OPDP's role in labeling review, discuss the impact of labeling on promotion, and provide illustrative enforcement examples.* Dolores Shank-Samiec, M.S. (presenter: 30 minutes) Director, Office of Promotion and Advertising Review, Merck & Co., Inc. *Abstract: This presentation will cover the need to 'start with the end in mind' so that desired promotional claims can be built into the development program and into physician and patient labeling.* Panel Discussion with Jean-Ah Kang, Elaine Hu Cunningham, Aline Moukhtara and Dolores Shank-Samiec (20 minutes)
4:00-4:15 PM	Closing Remarks