Version 6 – Updated June 3, 2020

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AGENDA

All times are Eastern (EDT, UTC-4)

Tuesday, June 9, 2020

8:40 - 8:50: Administrative Announcements — **Jeff Kelly**

8:50 – 9:00

Welcome

Brenda Stodart
CAPT, USPHS
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM) | CDER

9:00 - 9:30

Keynote

Gerald Dal Pan
Director
Office of Surveillance and Epidemiology (OSE)

9:30 - 10:00

Process for Reviewing Nonproprietary Name Suffix for Biological Products

This session will describe how CDER evaluates and designates nonproprietary name suffixes for biological products

Lubna Merchant
Deputy Director
Office of Medication Error Prevention and Risk Management (OMEPRM) | OSE

10:00 - 10:15: BREAK

10:15 - 11:15

Best Practices for Proprietary Name(PN) Design

This session describes the best practices for the development of PN; Rx and OTC updates.

Danielle Harris
Deputy Director
Division of Medication Error Prevention and Analysis (DMEPA)
OMEPRM | OSE

Tuesday, June 9, 2020

11:15 - 12:15 PM: LUNCH BREAK

12:15 - 1:10 PM

Preventing Medication Errors: Designing User Interfaces to Prevent Medication Errors

This session describes general principles of human factors engineering and optimization of user interfaces (e.g., product design, labels, labeling) to minimize medication errors.

Lolita White
Team Leader
DMEPA | OMEPRM | OSE

1:10 - 1:55

Preventing Medication Errors: Lessons Learned from Postmarket Safety Surveillance

This presentation will cover the general principles of medication error reporting and analysis; and describe assessment of reports to determine type of medication errors, root causes, and contributing factors.

Ashleigh Lowery
Team Leader
DMEPA | OMEPRM | OSE

1:55 - 2:10: BREAK

2:10 - 2:55 PM

Division of Risk Management: Overview of Review Activities

This session will describe the role of Division of Risk Management (DRM) in the application review process, from pre-market to post-market.

Cynthia LaCivita
Director
DRM | OSE

Jacqueline Sheppard
DRM | OSE

2:55 - 3:40

REMS Integration Initiatives

The goal of this session is to describe the ongoing REMS integration initiatives, including NCPDP's new script standard, REMS SPL and REMS Web Portal.

Gita Toyserkani
Associate Director for Research and Strategic Initiatives
DRM | OSE

3:40 - 4:25

Development of Shared System REMS and Implications of the Appropriations Act

This session describes considerations in the design and implementation of a shared system REMS; understand the implications of the new law.

Elaine Lippmann
Senior Regulatory Counsel
Office of Regulatory Policy (ORP)

Laura Zendel
Team Leader
DRM | OSE

4:25: ADJOURN

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Wednesday, June 10, 2020

8:45 - 8:50: Administrative Announcements — **Jeff Kelly**

8:50 - 9:00

Welcome

Forest "Ray" Ford, Jr.
CAPT | USPHS
DDI | OCOMM

9:00 - 9:40

Considerations for REMS Surveys and Assessments: Planning and Reporting

This session describes lessons learned from the survey methodology guidance and understand FDA's current thinking on REMS evaluations.

Doris Auth
Associate Director
Division of Risk Management (DRM) | OSE

Shelly Harris
Team Leader
DRM | OSE

9:40 - 10:20

FAERS Overview

This session will describe FAERS data content, ICSR submission process, and public access to data through the FAERS Dashboard.

Suranjan De
Deputy Director
Regulatory Science Staff (RSS) | OSE

10:20 - 10:35: BREAK

10:35 - 11:15

IND Digital Reporting Overview

This session will discuss the new digital IND ICSR reporting to FAERS, with data quality considerations.

Meredith Chuk
Associate Director for Safety
Office of Oncologic Diseases
Office of New Drugs (OND)

11:15 - 11:40

Combination Products: Reporting Device Information and Malfunctions

This session will discuss ICSR reporting to FAERS for combination products including device malfunction issues.

Melissa Burns
Senior Program Manager
Office of Combination Products (OCP)
Office of Clinical Policy and Programs (OCPP)
Office of the Commissioner (OC)

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Wednesday, June 10, 2020

11:40 - 12:40 PM: LUNCH BREAK

12:40 - 1:15

ICSR Data Quality of Coding - Products, Adverse Events and Medication Errors

This session will present cases to illustrate quality in coding of suspect products, adverse events and medication errors.

Sonja Brajovic
Team Lead

Manish Kalaria
MedDRA Coordinator

RSS | OSE

1:15 - 2:20

Postmarket Safety Surveillance

Postmarket Safety Surveillance Principles, Tools, and Methods
This presentation describes the risk-based principles, available tools, and methods for postmarket safety surveillance.

Eileen Wu
Associate Director
Division of Pharmacovigilance I (DPV1)
Office of Pharmacovigilance and Epidemiology (OPE)
OSE

Using Benefit-Risk to Inform Decision Making in the Postmarket Setting
This presentation provides the fundamentals of benefit-risk assessment in the drug regulatory context, with an introduction to the FDA's Benefit-Risk Framework and its implementation into postmarketing processes.

Judith Zander
Director
OPE | OSE

2:20 - 2:35: BREAK

2:35 - 3:35

FDA's Sentinel Initative

FDA's Sentinel Initiative
This presentation will provide an overview of FDA's Sentinel Initiative, including the Active Post-market Risk Identification and Analysis System (ARIA) and its application.

Danijela Stojanovic
LCDR | USPHS
Epidemiologist
RSS | OSE

Implementation of Signal Detection Capabilities in the Sentinel System
This presentation will describe the motivation and approach towards building signal identification capabilities in Sentinel.

Monica Muñoz
CDR | USPHS
Deputy Director
DPV1 | OSE

3:35 PM: ADJOURN

For updates and additional information, please visit www.FDA.gov/CDERSBIA

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