PDUFA VI Public Meeting on Electronic Submissions and Data Standards

April 12, 2022

9:00 – 9:10 am **Welcome and Opening Remarks***

Ron Fitzmartin
Sr. Informatics Advisor
Data Standards Branch,
CBER, FDA

Topic 1

9:10 – 9:50 am **IT Modernization in Action - 2022**

Vid Desai
Chief Information Officer,
FDA

Industry Comment

Public Comment

Topic 2

9:50 – 10:20 am **Electronic Submissions Gateway**

Lowell Marshall
IT Program Manager, ESG
Enterprise Applications Branch,
ODT, FDA

Industry Comment

Public Comment

Topic 3

10:20 – 11:00 am **PQ/CMC Data Standards**

Norman Schmuff
Associate Director
Office of Pharmaceutical Manufacturing Assessment,
CDER, FDA

Industry Comment

Public Comment

11:00 – 11:10 am **Break**

Topic 4

11:10 – 11:40 am **Identification of Medicinal Products (IDMP)**

TJ Chen
Program Lead, IDMP
Office of Strategic Programs,
CDER, FDA

Industry Comment

Public Comment

Topic 5

11:40 – 12:20 pm **IND Safety Reporting**

Suranjan De
Deputy Director, Regulatory Science Staff
Office of Surveillance and Epidemiology,
CDER, FDA

Industry Comment

Public Comment

12:20 – 12:40 pm **Break**

Topic 6

12:40 – 1:20 pm **eCTD**

Mark Gray
Senior Program Manager
Data Standards Branch,
CBER, FDA

Industry Comment

Public Comment

Topic 7

1:20 – 2:00 pm **Technical Rejection of Study Data**

Heather Crandall
DDMSS, OBI
Office of Strategic Programs,
CDER, FDA

Industry Comment

Public Comment

2:00 pm **Meeting Adjourned**

*Please note that the meeting will progress to the next topic at the scheduled time or when the speakers have finished a topic and there are no further comments.

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