FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC)
March 28-29, 2023

AGENDA

The committees will discuss proposed changes to the iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) requirements to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of isotretinoin oral capsules for patients.

Day 1: Tuesday, March 28, 2023

10:00 a.m.	Call to Order	**Vincent Lo Re III, MD, MSCE** Chairperson, DSaRM
10:10 a.m.	Introduction of the Committee	**Philip Bautista, PharmD, MPH** Designated Federal Officer, DSaRM
	Conflict of Interest Statement	
10:15 a.m.	FDA Opening Remarks	**Cynthia LaCivita, PharmD** Director, Division of Risk Management (DRM) Office of Medication Error Prevention and Risk Management (OMEPRM) Office of Surveillance and Epidemiology (OSE) CDER, FDA
10:30 a.m.	Isotretinoin Background & Regulatory History	**Roselyn E. Epps, MD, FAAP, FAAD** Clinical Reviewer Division of Dermatology and Dentistry Office of Immunology and Inflammation Office of New Drugs (OND), CDER, FDA
11:00 a.m.	Overview of the iPLEDGE REMS	**James Shamp** VP of Data Intelligence and Program Analytics United BioSource Corporation (UBC)
	IPMG Overview of Pregnancy Registry	**Sara Ephross, PhD** Senior Director, Epidemiology Syneos Health
11:45 a.m.	Contraception and Pregnancy Testing Requirements to Prevent Exposure in Pregnancy	**Wenjie Sun, MD, FACOG** Clinical Reviewer Division of Pediatrics and Maternal Health Office of Rare Diseases, Pediatrics, Urologic, and Reproductive Medicine OND, CDER, FDA

AGENDA (cont.)

12:00 p.m.	IPMG Modifications to iPLEDGE REMS Program	**Gregory P. Wedin, PharmD** Pharmacovigilance and Risk Management Director Upsher-Smith Laboratories, LLC
12:30 p.m.	Clarifying Question to Presenters	
1:00 p.m.	**LUNCH**	
1:30 p.m.	Potential Modifications to the iPLEDGE REMS	**Lindsey Crist, PharmD, BCPS** Risk Management Analyst DRM, OMEPRM, CDER, FDA
2:30 p.m.	Clarifying Question to Presenters	
4:00 p.m.	**ADJOURNMENT OF DAY 1**	

Day 2: Wednesday, March 29, 2023

10:00 a.m.	Call to Order	**Vincent Lo Re III, MD, MSCE** Chairperson, DSaRM
10:05 a.m.	Introduction of the Committee	**Philip Bautista, PharmD, MPH** Designated Federal Officer, DSaRM
10:10 a.m.	FDA Opening Remarks	**Cynthia LaCivita, PharmD** Director, Division of Risk Management (DRM) Office of Medication Error Prevention and Risk Management (OMEPRM) Office of Surveillance and Epidemiology (OSE) CDER, FDA
10:30 a.m.	**OPEN PUBLIC HEARING**	
12:00 p.m.	**LUNCH**	
12:30 p.m.	Questions to the Committee/Committee Discussion	
3:30 p.m.	**ADJOURNMENT OF DAY 2**	