FDA/CDER Public Workshop:

Guidance Development and Regulatory Assessment of Generic Topical and Dermal Drug Products

October 03, 2024 | 8:30 AM – 12:00 PM

Agenda Item	Title/Presenter	Time
Opening Remarks (10 min)	**Partha Roy, Ph.D., Office Director, Office of Bioequivalence (OB), Office of Generic Drugs (OGD), CDER, FDA**	8:30 – 8:40 am
Section I: Development of PSG Recommendations for Topical Drug Products **Moderator: Priyanka Ghosh (5 mins)**		
Presentation 1 (20 min)	Product-specific Guidance for Complex Products: Proactive Research to Ensure Regulatory Readiness for Complex Generics - **Xiaomin Xu, Ph.D.**, Division Director, Office of Pharmaceutical Quality Research (OPQR), Office of Pharmaceutical Quality (OPQ), CDER, FDA	8:45 – 9:05 am
Presentation 2 (20 min)	Development and Status of Product-Specific Guidances for Topical Products - **Megan Kelchen, Ph.D.,** Senior Pharmacologist, Division of Therapeutic Performance I (DTP-I), Office of Research and Standards (ORS), OGD, CDER, FDA	9:05 – 9:20 am
Section II: *Topical Dermatologic Corticosteroids* **Moderator: Christina Lee (5 mins)**		
Presentation 1 (20 min)	Overview and Changes to the Guidance for Industry: Topical Dermatologic Corticosteroids – In Vivo Bioequivalence – **Ke Ren, Ph.D.,** Deputy Division Director, Division of Bioequivalence III (DBIII), OB, OGD, CDER, FDA	9:25 – 9:45 am
Presentation 2 (20 min)	ANDA Challenges Related to Vasoconstrictor Studies – **Kairui (Kevin) Feng, Ph.D.,** Division of Quantitative Methods and Modeling (DQMM), ORS, OGD, FDA	9:45 – 10:05 am
Section III: 3. Common Deficiencies in topical products **Moderator: Bing Li (5 mins)**		
Presentation 1 (20 min)	Considerations for In Vitro Release Test (IVRT) Data and Information Submitted in ANDAs – **Tian Ma, Ph.D.,** Lead Pharmacologist, Division of Bioequivalence I (DBI), OB, OGD, CDER, FDA	10:10 – 10:30 am
Presentation 2 (20 min)	Common Deficiencies for In Vitro Permeation Test (IVPT) Studies Submitted in ANDAs – **Allison Schafer, Ph.D.,** Senior Interdisciplinary Scientist, Division of Bioequivalence II (DBII), OB, OGD, CDER, FDA	10:30 – 10:50 am
Presentation 3 (20 min)	Common Quality Deficiencies in the Assessment of Topical Drug Products - Quality Perspectives – **Qiuxi Fan, Ph.D.,** Pharmaceutical	10:50 – 11:10 am

	Scientist, Unit 1, Division I, Office of Pharmaceutical Quality Assessment I, OPQ, CDER, FDA	
Q&A/Panel Discussion **Moderator: Bing Li (5 mins), Priyanka Ghosh, and Christina Lee**		
Panelists in addition to speakers: • **Utpal Munshi, Ph.D.,** Division Director, Division of Bioequivalence I, OB, OGD, CDER, FDA • **Sam Raney, M.S., Ph.D.,** Associate Director for Science and Chief Scientific Advisor, ORS, OGD, CDER, FDA • **Pahala Simamora, Ph.D.**, Division Director, Division of Product Quality Assessment II (DPQA II), OPQA II, OPQ, CDER, FDA		11:15 – 12:00 noon