

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
Introduction (5 min)	Bing Li, Ph.D., Associate Director for Science, Office of Bioequivalence (OB), Office of Generic Drugs (OGD), CDER, FDA	8:30 – 8:35 am
Opening Remarks (10 min)	Partha Roy, Ph.D., Office Director, Office of Bioequivalence (OB), Office of Generic Drugs (OGD), CDER, FDA	8:35 – 8:45 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	8:50 – 9:10 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	9:10 – 9:30 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	9:35 – 9:55 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	9:55 – 10:15 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	10:20 – 10:40 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	10:40 – 11:00 am

FDA/CDER Public Workshop:

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

Presentation 3 (20 min)	Common Quality Deficiencies in the Assessment of Topical Drug Products - Quality Perspectives – Qiuxi Fan, Ph.D. , Pharmaceutical Scientist, Unit 1, Division I, Office of Pharmaceutical Quality Assessment I, OPQ, CDER, FDA	11:00 – 11:20 am
Q&A/Panel Discussion Moderator: Christina Lee (5 mins), Bing Li, and Priyanka Ghosh,		
Panelists in addition to speakers: <ul style="list-style-type: none"> • 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 		11:25 – 12:00 noon