

Expanding Generic Drug Access Through International Engagements

February 28, 2024, 9:00 – 11:30 am EDT

Welcome (5 min)	<p>Welcome and Overview</p> <p>Forest “Ray” Ford, Jr., <i>Captain</i>, United States Public Health Service <i>Pharmacist</i> Small Business and Industry Assistance (SBIA) Division of Drug Information (DDI) Office of Communications (OCOMM) Center for Drug Evaluation and Research (CDER) U.S. Food and Drug Administration (FDA)</p>	9:00 - 9:05 am
Talk 1 (20 min)	<p>Introduction to OGD’s Global Affairs and International Engagement</p> <p>Sarah Ibrahim, Ph.D. <i>Associate Director for Global Affairs</i> Office of Generic Drugs (OGD) CDER FDA</p>	9:05 - 9:25 am
Talk 2 (30 min)	<p>FDA and EMA’s Parallel Scientific Advice Pilot Program for Complex Generics/Hybrid Products</p> <p>Lei Zhang, Ph.D. <i>Deputy Director</i></p> <p>Caliop Sarago, M.S. <i>Lead Project Manager (Acting)</i> Office of Research and Standard (ORS) OGD CDER FDA</p>	9:25 – 9:55 am
Talk 3 (15 min)	<p>EMA and International Engagement for Generics Development</p> <p>Kevin Blake, M.D., Ph.D. <i>Senior Scientific Specialist Clinical Pharmacology</i> European Medicines Agency (EMA)</p>	9:55 – 10:10 am
Talk 4 (15 min)	<p>Use of Foreign Comparators in Bioequivalence Studies for Health Canada</p> <p>Scott Appleton, Ph.D., M.Sc. <i>Manager, Health Canada</i> Division of Biopharmaceutics Evaluation¹ Bureau of Pharmaceutical Sciences Pharmaceutical Drugs Directorate Health Products and Food Branch Health Canada</p>	10:10 - 10:25 am
Panel Discussion (30 min)	<p>Moderator: Sarah Ibrahim</p> <p>Panelists:</p> <ul style="list-style-type: none"> • Scott Appleton, Ph.D., M.Sc., <i>Manager</i>, Health Canada • Lisa Bercu, J.D., Senior Regulatory Counsel Office of Generic Drug Policy (OGDP) OGD CDER • Kevin Blake, M.D., Ph.D., <i>Senior Scientific Specialist Clinical Pharmacology</i>, EMA • Ashley Boam, M.S., <i>Director</i>, Office of Pharmaceutical Quality Policy (OPPQ) Office of Pharmaceutical Quality (OPQ) CDER • Robert Lionberger, PhD, <i>Director</i>, ORS OGD CDER • Hongling Zhang, PhD, <i>Division Director</i>, Division of Bioequivalence II, Office of Bioequivalence (OB) OGD CDER 	10:25 - 10:55 am
Speaker Q&A (30 min)	<p>Moderator: Forest “Ray” Ford, Jr.</p> <p>Speakers:</p> <ul style="list-style-type: none"> • Sarah Ibrahim, Lei Zhang, Caliop Sarago, Kevin Blake, and Scott Appleton 	10:55 - 11:25 am
Closing Remarks (5 min)	<p>Closing Remarks</p> <p>lilun Murphy, MD <i>Director, OGD CDER</i></p>	11:25 - 11:30 am