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Dr. Tannaz Ramezanli is a pharmacologist within the Office of Research and Standard (ORS) at Office of Generic Drugs (OGD) at the U.S. FDA. She specializes in topical and transdermal products. She is responsible for the development of product-specific bioequivalence guidances, reviewing and responding to controlled correspondences, citizen petitions, and Pre-ANDA meeting packages. She also serves as Project Officer for multiple regulatory science research initiatives related to development of bioequivalence standards for complex topical drug products through FDA-funded collaborations with research institutions around the world. She received her Ph.D. in Pharmaceutical Sciences from Rutgers University and her Pharm.D. from Tehran University of Medical Sciences.

PRESENTATION: Development of Efficient Bioequivalence Approaches for Topical Dermatological Drug Products

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Topical dermatological drug products are often complex in multiple ways (e.g. complex route of administration, complex dosage form) and there are unique considerations impacting bioequivalence (BE) of these drug products. Under Generic Drug User Fee Amendments (GDUFA), the Agency has funded multiple research initiatives to support the development of efficient alternative BE approaches for topical dermatological drug products, as part of an effort to facilitate generic drug development and enhance patient access to these topical products. This presentation is an overview of different strategies that are developed/under investigation to evaluate the BE of prospective generic products in more efficient and sensitive ways.