

## New Insights for Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products

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The FDA's Center for Drug Evaluation and Research, Office of Generic Drugs (OGD), Office of Research and Standards, Division of Therapeutic Performance has made strides in new approaches that demonstrate therapeutic equivalence for locally-acting orally-inhaled and nasal drug products (OINDPs), and in the development of tools for assessing generic OINDPS that benefit industry and the FDA.

The ability to establish bioequivalence is a cornerstone of demonstrating therapeutic equivalence for generic OINDPs. For traditional systemically-acting drugs, establishing bioequivalence is accomplished by using a typical pharmacokinetic (PK) approach that demonstrates equivalence in systemic plasma concentrations of the test product to its reference product. However, demonstrating therapeutic equivalence for locally-acting OINDPs presents a unique challenge, because the traditional PK approach used for systemically acting drugs is not directly applicable to OINDPs. Since the Generic Drug User Fee Amendments (GDUFA) were enacted, the FDA has published 39 product-specific guidances on OINDPs that include a combination of in vivo and in vitro bioequivalence studies.

To design products that meet bioequivalence standards, the generic industry needs tools that can direct product development toward bioequivalent products. Performance of OINDPs has been difficult to predict because of a lack of understanding of the complex interactions between active and inactive ingredients, device design and characteristics, and stability across the life of the product. Moreover, there has not been a clear in vitro to in vivo correlation with predictive methodologies to determine regional deposition and local availability of these products. We recognize that accelerating the path to establishing bioequivalence of these products is critical to further development.

The GDUFA Regulatory Science Research Program in OGD has advanced the FDA's understanding of the critical product attributes relevant for in vivo performance of OINDPs and has led to the development of assessment tools beneficial to both industry and the FDA. Multiple external and internal research projects were initiated or completed under the GDUFA Regulatory Science Research Program, and the outcomes from these research studies have provided valuable insights about the factors that influence the performance of OINDPs.

To facilitate public discussion and evaluation of these new methods for characterizing and demonstrating therapeutic equivalence of OINDPs, the FDA is hosting a public workshop, [New Insights for Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products](#). The discussion will include areas in which these methods may significantly contribute to generic product development, regulatory understanding and understanding of inherent scientific challenges.

The workshop will provide a public venue to share the agency's experience with the utility of novel analytical tools for generic OINDP product and bioequivalence assessments. At the workshop, we will also gather input from the public on analytical methods and procedures applied in the development and review of Abbreviated New Drug Applications (ANDAs) for OINDPs.

The workshop will be held on the FDA's White Oak campus in Silver Spring, Maryland, on January 9, 2018. The workshop will also be available via webcast for those who cannot attend in person. Further information will be posted to the meeting [webpage](#) as it becomes available.