SCIENTIFIC PERSPECTIVE ON CYP- AND TRANSPORTER-BASED DRUG-DRUG INTERACTIONS:
IMPACT ON DRUG EXPOSURE/RESPONSE, LABELING AND CLINICAL DECISIONS
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Many factors affect drug exposure and response. Drug interactions are one key factor. CYP-based drug-drug interactions have been well evaluated in drug development and described in labeling. Transporter-based drug-drug interactions have been increasingly reported, as tools including pharmacogenomics become available. The impact of these interactions on drug exposure and/or clinical responses (both desirable and undesirable) is critical to evaluate during drug development and regulatory review. In addition, drug interactions in patients with other patient factors (e.g., genetics, age, organ dysfunctions) have been increasingly evaluated with the application of physiologically-based pharmacokinetic (PBPK) modeling. This presentation will review briefly examples of CYP- and transporter-based interactions that resulted in significant labeling languages for drugs (and therapeutic proteins) prior to- and post-marketing approval and the recent use of PBPK in evaluating these interactions in patients with various patient factors.

References:

Biography
Shiew-Mei Huang, PhD is currently Deputy Director, Office of Clinical Pharmacology, CDER, FDA. She received her B.S. in Pharmacy from National Taiwan University and her Ph.D. from University of Illinois, Medical Center. She has 15+ year drug development experience (Ortho pharmaceutical and Dupont-Merck) before joining the FDA in 1996. She has published over 100 peer-reviewed papers focusing on clinical pharmacology, drug metabolism/interactions and pharmacogenomics areas and received many awards, including FDA Outstanding Achievement Awards. Dr. Huang is an AAPS Fellow (American Association of Pharmaceutical Scientists) and a diplomate of the American Board of Clinical Pharmacology. She was the President (2009-2010) of the American Society for Clinical Pharmacology and Therapeutics.