FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (ACPS-CP) Meeting
Bethesda North Marriott Hotel and Conference Center
White Oak Room, 5701 Marinelli Road, Bethesda, Maryland
September 25, 2013

QUESTIONS TO THE COMMITTEE

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1. **DISCUSSION:** Please discuss the following with regard to format of drug interaction study results presentation in prescription drug labeling:

   a) The level of detail on study design and study results

   b) The advantages and disadvantages of presenting the drug interaction study results in a forest plot versus a table versus a narrative

2. **DISCUSSION:** How do you recommend that complex drug-drug interaction (DDI) information be presented in prescription drug labeling? Examples of complex DDI information include:

   a) DDIs that differ between poor metabolizers and extensive metabolizers if the drug is metabolized by a polymorphic enzyme

   b) DDIs that change over time

   c) DDIs that differ depending on organ impairment (kidney or liver)

   d) DDIs in patients who take three or more drugs, but DDIs were evaluated in pairs

3. **DISCUSSION:** Some DDIs can be predicted based on *in vitro* studies, other *in vivo* studies, and *in silico* analyses. In those situations, what information about predicted DDIs should be included in prescription drug labeling? Should the labeling list all potential interactions or a subset (based on drug class, likelihood of co-administration, or severity of interaction)?

4. **DISCUSSION:** What statements about the management of drug interactions are most useful? Least useful?

5. **DISCUSSION:** Under what circumstances should DDI results from the literature be included in the prescription drug labeling? Please discuss the factors that should be considered to determine whether literature reported DDI results are included in the labeling qualitatively (general description of the DDI) or quantitatively (the quantitative information may be used for dosage adjustment).