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

Arthritis Advisory Committee (AAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
July 13, 2016

DRAFT QUESTIONS

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1. **DISCUSSION:** Please discuss whether the evidence from analytical studies supports a demonstration that GP2015 is highly similar to US-licensed Enbrel, notwithstanding minor differences in clinically inactive components.

2. **DISCUSSION:** Please discuss whether the evidence supports a demonstration that there are no clinically meaningful differences between GP2015 and US-licensed Enbrel in the studied condition of use (plaque psoriasis (PsO)).

3. **DISCUSSION:** Please discuss whether the totality of the data provides adequate scientific justification to support a demonstration of no clinically meaningful differences between GP2015 and US-licensed Enbrel for the following additional indications for which US-licensed Enbrel is licensed:
   - Rheumatoid Arthritis (RA)
   - Juvenile Idiopathic Arthritis (JIA)
   - Psoriatic Arthritis (PsA)
   - Ankylosing Spondylitis (AS)

   If not, please state the specific concerns and what additional information would be needed to support such a demonstration. Please discuss by indication if relevant.

4. **VOTE:** Does the totality of the evidence support licensure of GP2015 as a biosimilar to US-licensed Enbrel for the following indications for which US-licensed Enbrel is currently licensed and for which Sandoz is seeking licensure (RA, JIA, AS, PsA, PsO)?

   Please explain the reason for your vote.