From: [redacted] [redacted]
Sent: 21 May 2008 16:45
To: Ebenezer Tetteh
Cc: Helen Chung; Jeremy Powell; Meindert Boysen; Natalie Bemrose; [redacted]; [redacted]
Subject: RE: ACD - Febuxostat for hyperuricaemia

Dear Ebenezer,

Thanks for the draft ACD.

There appears to be a few discrepancies in section 3 of the draft ACD.

1. In section 3.2 it states that ' in the APEX, FACT and EXCEL trials, colchicine.. It is not clear why reference to the EXCEL trial is made in this section as it is discussed in section 3.3. and was provided as supplementary evidence only.

3. In section 3.3. it states 'Although summaries of the clinical evidence from the respective trials were provided by the manufacturer, the main evidence in support of the clinical effectiveness of febuxostat was based on pooled data from the FACT, APEX and TM-00-004 trials'. This statement is incorrect. A pooled analysis of the FACT and APEX trial (using [patient level data) was presented by the manufacturer, only. The TMX-00-004 trial(not TM-00-004 as in ACD) was excluded (no reason given) from the pooled analysis.

There may be other minor descrepancies but I have not had time to go through the full draft ACD.

Best wishes

[redacted]