

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**206073Orig1s000**

**STATISTICAL REVIEW(S)**



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Translational Sciences  
Office of Biostatistics

## STATISTICAL REVIEW AND EVALUATION

### CLINICAL STUDIES

**NDA/BLA #:** NDA 206073  
**Supplement #:** Original-1  
**Drug Name:** Empagliflozin (BI 10773)/linagliptin (BI 1356)  
**Indication(s):** Type II Diabetes Mellitus  
**Applicant:** Boehringer Ingelheim  
**Date(s):** Stamp Date: January 30, 2014  
User Fee Goal Date: January 31, 2014

**Review Priority:** Standard

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