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RESEARCH**

*APPLICATION NUMBER:*

**204629Orig1s000**

**OFFICE DIRECTOR MEMO**

## Summary Basis for Regulatory Action

<b>Date</b>	August 1, 2014
<b>From</b>	Curtis J Rosebraugh, MD, MPH Director, Office of Drug Evaluation II
<b>Subject</b>	Summary Review
<b>NDA/BLA #</b> <b>Supp #</b>	204629
<b>Applicant Name</b>	Boehringer Ingelheim Pharmaceuticals Inc.
<b>Proprietary / Established (USAN) Names</b>	Jardiance Empagliflozin
<b>Dosage Forms / Strength</b>	10 and 25 mg tablets
<b>Proposed Indication(s)</b>	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
<b>Action:</b>	<i>Approval</i>

### 1. Introduction and Discussion

This will be a brief summary of the basis for the regulatory action regarding empagliflozin and the reader should review the action package for more detail. During the first review cycle, the safety and efficacy of empagliflozin were established that would allow marketing. However, deficiencies were identified at the manufacturing site which led to a Complete Response (CR) action on March 4, 2014.

These deficiencies have now been satisfactorily resolved. Therefore this application should receive an Approval action.

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/s/  
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CURTIS J ROSEBRAUGH  
08/01/2014