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RESEARCH**

*APPLICATION NUMBER:*

**206073Orig1s000**

**SUMMARY REVIEW**

NDA-206073  
Sponsor: Boehringer Ingelheim  
SD-1, eCTD-0000  
Received: January 29, 2014  
Primary Safety Review/CDTL  
Reviewer: William H. Chong

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## CLINICAL REVIEW/CROSS-DISCIPLINE TEAM LEADER REVIEW

Application NDA-206073  
Supporting Document Number SD-1  
  
Submission Receipt Date January 29, 2014  
PDUFA Goal Date January 30, 2015  
Division Division of Metabolism and Endocrinology  
Products

Reviewer William H. Chong  
Review Completion Date January 29, 2015

Generic name Empagliflozin/Linagliptin  
Trade name GLYXAMBI  
Therapeutic class Fixed dose combination of a sodium dependent  
glucose cotransporter-2 inhibitor and a  
dipeptidyl peptidase-4 inhibitor  
Applicant Boehringer Ingelheim  
Priority designation Standard

Formulation Tablet  
Dosing regimen Empagliflozin 10 mg/Linagliptin 5 mg  
Empagliflozin 25 mg/Linagliptin 5 mg  
Indication Type 2 diabetes mellitus  
Intended population Adults with type 2 diabetes mellitus

Related INDs/NDAs IND-108388 (Empagliflozin/Linagliptin);  
NDA-201280 (Linagliptin); NDA-204629  
(Empagliflozin)

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