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APPLICATION NUMBER:

206073Orig1s000

SUMMARY REVIEW

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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)
Division Director	Jean-Marc Guettier
Statistical Reviewer	Jennifer Clark
Clinical Pharmacology Reviewer	Suryanarayana Sista
Pharmacology/Toxicology Reviewer	David Carlson
Chemistry, Manufacturing and Controls	Joseph Leginus and Kareen Riviere
Project Manager	Callie Cappel-Lynch

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