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*APPLICATION NUMBER:*

**208026Orig1s000**

**PHARMACOLOGY REVIEW(S)**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

**PHARMACOLOGY/TOXICOLOGY NDA REVIEW AND EVALUATION**

**Application number:** 208026  
**Supporting document/s:** SDN-1  
**Applicant's letter date  
(CDER Stamp Date):** July 27, 2015  
**Product:** Linagliptin/metformin XR FDC  
**Indication:** Type 2 diabetes mellitus  
**Applicant:** Boehringer Ingelheim Pharmaceuticals, Inc.  
**Review Division:** Metabolism and Endocrinology Products  
**Reviewer:** David B. Carlson, Ph.D.  
**Supervisor/Team Leader:** Todd Bourcier, Ph.D.  
**Division Director:** Jean-Marc Guettier, M.D.  
**Project Manager:** Richard Whitehead, M.S.  
**Review Completion Date:** 4/20/16

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**Review Notes and Abbreviations/Key**

Some of the sponsor's tables and figures from the electronic NDA submission have been included and cited in this review. All drug-related trends are discussed in relation to concurrent vehicle control groups in each study unless otherwise noted.

**Key:** Linagliptin (LINA); Metformin HCl extended release (metformin XR, aka metformin ER); fixed-dose combination (FDC), once daily dosing (QD); mg/kg (mg/kg/day); MRHD (maximum recommended human dose); IR (immediate release), XR (extended release); polyethylene oxide (PEO), polyethylene glycol (PEG); molecular weight (MW)

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