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APPLICATION NUMBER:

201281Orig1s000

PHARMACOLOGY REVIEW(S)

REV-NONCLINICAL-05 (Review Noted (NAI))
NDA-201281
ORIG-1
Supporting Document 23
Resubmission/Class 1
Submit Date: 11/30/2011 - FDA Received Date: 11/30/2011

Class 1 resubmission of NDA 201281, linagliptin plus metformin HCl FDC tablets. The resubmission addresses CMC issues in the original NDA review. No nonclinical data were included in the resubmission. The pharmacology/toxicology approval recommendation and labeling recommendations from the original NDA review remain unchanged.

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/s/

DAVID B CARLSON
01/26/2012
Pharmtox approval recommendation (unchanged from original NDA review recommendation)

TODD M BOURCIER
01/26/2012

Memorandum

PHARMACOLOGY/TOXICOLOGY MEMO TO FILE

Date:	15 November, 2011
NDA #	201280 201281
Sponsor:	Boehringer Ingelheim
Drug:	Tradjenta® (Linagliptin) Jentadueto® (Linagliptin + Metformin FDC)
Reviewer:	David B. Carlson, Ph.D.

Boehringer Ingelheim's drug linagliptin, a DPP4 inhibitor, was recently reviewed for treatment of type 2 diabetes mellitus as both a monotherapy and a fixed dose combination with metformin. The initial pharmacology/toxicology reviews of rabbit embryofetal development studies were completed during the IND phase and results were further reviewed and summarized in the NDA reviews. During the course of labeling discussions it became apparent that the pharmacology/toxicology reviews for NDA 201280 and NDA 201281 inadvertently listed an incorrect rabbit strain. This memo serves as an amendment to the original pharmacology/toxicology reviews to clarify that Himalayan rabbits, not New Zealand White rabbits, were used in the pivotal embryofetal development studies with linagliptin.

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/s/

DAVID B CARLSON
11/15/2011
Correction regarding rabbit strain -- no change in pharmtox conclusions or recommendations

TODD M BOURCIER
11/16/2011
Correction memo

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