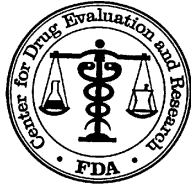


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

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STATISTICAL REVIEW(S)



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION CLINICAL STUDIES

NDA/Serial Number: 201-280 / SN 000
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Indication(s): Treatment of patients with type 2 diabetes mellitus
Applicant: Boehringer Ingelheim Pharmaceuticals Inc
Date(s): Submitted July 2, 2010
Review Priority: Standard

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Keywords: clinical studies, cardiovascular safety, meta-analysis

¹ At the time of filing of this review, the trade name under review is Tardjenta, but DMEPA has not reached a decision on the adequacy of such trade name.

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