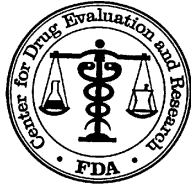# CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

201280Orig1s000

<u>STATISTICAL REVIEW(S)</u>

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
Drug Name:	Tardjenta [1] (Linagliptin, BI 1356)
Indication(s):	Treatment of patients with type 2 diabetes mellitus
Applicant:	Boehringer Ingelheim Pharmaceuticals Inc
Date(s):	Submitted July 2, 2010
Review Priority:	Standard
Biometrics Division:	Division of Biometrics VII
Statistical Reviewer:	Xiao Ding, Ph.D.
Concurring Reviewers:	Mat Soukup, Ph.D.
	Aloka Chakravarty, Ph.D.
Medical Division:	Division of Metabolism and Endocrinology Products (DMEP)
Clinical Team:	Medical Officer: Somya (Verma) Dunn, M.D.
	Medical Team Leader: Ilan Irony, M. D.
Project Manager:	Raymond Chiang, M.S. (DMEP)

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.

Table of Contents

Table of Tables

Table of Figures

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.

fastcase®
Smarter legal research.