# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

**22-044**

# STATISTICAL REVIEW(S)

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

# STATISTICAL REVIEW AND EVALUATION

## CLINICAL STUDIES

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|---|---|
| **NDA/Serial Number:** | 22-044 |
| **Drug Name:** | Janumet (Sitagliptin Phosphate/Metformin Hydrochloride Fixed Dose Combination Tablet) 50/500 and 50/1000 mg/mg sitagliptin/metformin |
| **Indication(s):** | An adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus who are not adequately controlled on metformin or sitagliptin alone or in patients already being treated with the combination of sitagliptin and metformin |
| **Applicant:** | Merck & Co., Inc. |
| **Date(s):** | Received 05/31/06; user fee (10 months) 03 /31/07 |
| **Review Priority:** | Standard |
| **Biometrics Division:** | Division of Biometrics 2 |
| **Statistical Reviewer:** | Lee-Ping Pian, Ph.D. |
| **Concurring Reviewers:** | Todd Sahlroot, Ph.D. Biometrics Team Leader<br>Thomas Permutt, Ph.D. Division Director |
| **Medical Division:** | Division of Metabolism and Endocrinology Products (DMEP) |
| **Clinical Team:** | Ilan Irony, M.D.<br>Mary Parks, M.D. Division Director |
| **Project Manager:** | Lina Aljuburi, Pharm D. |

**Keywords:** New Drug Application (NDA) review, clinical studies

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# 1. EXECUTIVE SUMMARY

## 1.1 Conclusions and Recommendations

The statistical review provides labeling comments only. The efficacy review for this NDA can be referenced to the statistical review for Januvia (NDA 21-995). Specifically, the original statistical review concerned protocol 020, a multinational, double-blind, randomized, parallel group Phase III study to evaluate the safety and efficacy of MK-0431 100 mg in patients with type 2 diabetes mellitus (T2DM) who have inadequate glycemic control on metformin therapy.

# 2. LABELING COMMENTS

1. The second study (protocol 015) should not be included in the clinical studies section. The study was a cross-over PD assessment of 24-hour plasma glucose values in 28 patients after 4 weeks of treatment. It was not reviewed as a well controlled clinical study.

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/s/

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