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

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 Thomas Permutt, Ph.D. Division Director
Medical Division:	Division of Metabolism and Endocrinology Products (DMEP)
Clinical Team:	Ilan Irony, M.D. Mary Parks, M.D. Division Director
Project Manager:	Lina Aljuburi, Pharm D.

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

Table of Contents

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.

2.

Appears This Way
On Original

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Lee-Ping Pian
3/2/2007 04:04:01 PM
BIOMETRICS

Todd Sahlroot
3/5/2007 08:08:40 AM
BIOMETRICS

Appears This Way
On Original