CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209405Orig1s000

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 #:	NDA 209405
Drug Name:	EV402 (levonorgestrel / ethinyl estradiol (b) (4) tablets)
Indication(s):	Prevention of Pregnancy
Applicant:	Exeltis USA, Inc
Date(s):	Received Date: May 30, 2019 PDUFA Goal Date: March 30, 2020
Review Priority:	Standard
Biometrics Division:	Division of Biometrics IV
Statistical Reviewer:	Weiya Zhang, Ph.D.
Biometrics Team Leader:	Mahboob Sobhan, Ph.D.
Medical Division:	Division of Urology, Obstetrics, and Gynecology
Clinical Team:	Anandi Kotak, M.D., Clinical Reviewer Gerald Willett, M.D., Clinical Team Leader
Project Manager:	Nikia Morris

Keywords: Clinical studies, NDA review

Memorandum

The applicant initially submitted NDA 209405 under 505(b)(2) on January 7, 2019 for the indication of prevention of pregnancy. The initial submission resulted in a refusal to file due to incomplete datasets and associated data definition files. The applicant resubmitted the NDA on May 30, 2019. This NDA included three bioavailability studies and two Phase 1 safety studies. Based on FDA review of these studies, an approval was granted on March 30, 2020.

There were no clinical efficacy data submitted in this application, and therefore, no statistical review was necessary. This memorandum completes statistical reviewer's work assignment.

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/s/

WEIYA ZHANG
03/31/2020 10:47:16 AM

MAHBOOB SOBHAN
03/31/2020 02:21:26 PM