CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216285Orig1s000

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 MEMORANDUM

CLINICAL STUDIES

NDA/BLA #:	216285
Drug Name:	(b) (4) (drospirenone) chewable tablets, 3.5 mg
Indication(s):	Prevention of pregnancy
Applicant:	Exeltis USA, Inc.
Date(s):	Submitted: 8/30/2021 PDUFA: 6/30/2022
Review Priority:	Standard
Biometrics Division:	Division of Biometrics IV
Statistical Reviewer:	Yun Tang, Ph.D.
Concurring Reviewers:	Daphne Lin, Ph.D., Deputy Director
Medical Division:	Division of Urology, Obstetrics and Gynecology (DUOG)
Clinical Team:	Ioanna Comstock, M.D., Clinical reviewer Gerald D. Willett, M.D., Clinical team leader
Project Manager:	Jeannie Roule

Keywords: NDA review

MEMORANDUM

The Applicant is submitting a New Drug Application (NDA) for [redacted] (b) (4) (drospirenone) 3.5 mg chewable tablets, a progestin indicated for use by females of reproductive potential to prevent pregnancy. [redacted] (b) (4) is a new chewable tablet dosage form and a line extension of Slynd (drospirenone) 4 mg tablet (NDA 211367), which was previously approved on 23 May 2019.

No clinical efficacy data were submitted in this NDA to support the approval of [redacted] (b) (4). The Applicant cross-referenced its previously approved Slynd NDA for the effectiveness of [redacted] (b) (4) in prevention of pregnancy. As such, statistical review of NDA 216285 is not necessary. The decision on approvability of [redacted] (b) (4) is deferred to the DUOG.

Reference ID: 4983848

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/s/

YUN TANG
05/13/2022 02:47:55 PM

TSAE YUN D LIN
05/13/2022 08:21:31 PM