

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**209405Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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## PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)  
Center for Drug Evaluation and Research (CDER)

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<b>Date of This Review:</b>	March 13, 2020
<b>Application Type and Number:</b>	NDA 209405
<b>Product Name and Strength:</b>	(b) (4) (levonorgestrel/ethinyl estradiol) tablet, 0.1 mg/0.02 mg
<b>Product Type:</b>	Multiple Ingredient Product
<b>Rx or OTC:</b>	Prescription (Rx)
<b>Applicant/Sponsor Name:</b>	Exeltis USA Inc (Exeltis)
<b>Panorama #:</b>	2019-36530689
<b>DMEPA Safety Evaluator:</b>	Chad Morris, PharmD, MPH
<b>DMEPA Team Leader:</b>	Briana Rider, PharmD, CPPS
<b>DMEPA Deputy Director:</b>	Danielle Harris, PharmD

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/s/  
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