OFFICE OF CLINICAL PHARMACOLOGY REVIEW

NDA	205223
Submission Date	02/05/2018
Drug	NUVESSA™ (METRONIDAZOLE VAGINAL GEL 1.3%)
OCP Reviewer	Zhixia (Grace) Yan, Ph.D.
OCP Team Leader	Philip Colangelo, Ph.D.
OCP Division	DCP4
OND Division	DAIP
Sponsor	CHEMO RESEARCH SL
Submission Type	Efficacy supplement for post marketing study
Formulation	Vaginal gel: 65 mg of metronidazole in 5 grams of gel (1.3%) in a prefilled applicator
Indication	Treatment of bacterial vaginosis in non-pregnant females 12 years of age and older
Dosage and Administration	A single-dose, pre-filled disposable applicator administered once intravaginally at bedtime

Background

NUVESSA™ (metronidazole vaginal gel 1.3%) was approved in U.S. for the treatment of bacterial vaginosis (BV) in nonpregnant women on March 24, 2014. To fullfil the post marketing requirement (PMR) 2123-001, the Applicant conducted a study to evaluate the safety of NUVESSA single dose in the treatment of bacterial vaginosis in females 12 to <18 years of age (Study MG1401). No PK assessment was performed in this study.

Recommendation

The Office of Clinical Pharmacology, Division of Clinical Pharmacology 4 has reviewed the application. No new Clinical Pharmacology information was submitted. This application is acceptable from a clinical pharmacology perspective.

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/s/

ZHIXIA YAN
07/20/2018

PHILIP M COLANGELO
07/20/2018