CLINICAL PHARMACOLOGY MEMORANDUM

NDA 208352	Submission Date: 07/02/2015
Brand Name	Amphora Gel
Generic Name	Lactic Acid, Citric Acid, Potassium Bitartrate
OCP Division	Division of Clinical Pharmacology 3
OND Division	Division of Bone, Reproductive, and Urologic Products
Sponsor	Evofem, Inc.
Submission Type	Original NDA
Dosing Route / Regimen	Vaginal gel, 5 g gel used no earlier than 1 hour before sexual intercourse
Indication	Prevention of pregnancy

The Applicant submit a New Drug Application (NDA) for Amphora gel™ (88 mg lactic acid, 50 mg citric acid, 20 mg potassium bitartrate in a 5 g dose), an non-hormonal contraceptive spermicidal gel, for the prevention of pregnancy. It is proposed that Amphora gel exerts its contraception efficacy by maintaining the acidic vaginal environment in the presence of semen and immobilizing the sperm.

In support of this NDA, the Applicant conducted a single pivotal Phase 3 study (AMP001) evaluating the contraceptive efficacy and safety of Amphora gel in preventing pregnancy in adult females over 18 years of age compared to Conceptrol® Vaginal Gel. In addition, the Applicant provided the published literature references to demonstrate the spermicidal effect after treatment with Amphora gel 0–30 minutes and 8–10 hours prior to coitus.

No Clinical Pharmacology studies were conducted during the development of Amphora gel. Therefore, no such studies were submitted for review. Additionally, labeling review was not conducted in this review cycle.

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MYONG JIN KIM
04/22/2016