OFFICE OF CLINICAL PHARMACOLOGY REVIEW

NDA: 022573  Submission Dates: 11/26/09; 04/28/10; 06/5/10; 12/16/10, 12/21/10
Brand Name  TRADENAME
Generic Name  Norethindrone and Ethinyl Estradiol chewable tablets and ferrous fumarate chewable tablets
Reviewer  Christian Grimstein, Ph.D.
Team Leader  Myong-Jin Kim, Pharm.D.
OCP Division  Division of Clinical Pharmacology 3
OND Division  Division of Reproductive and Urologic Products (DRUP)
Sponsor  Warner Chilcott Company, LLC.
Submission Type  Original/505(b)(1)
Formulation and Strength  Chewable tablets, Cycle Days 1-24: EE 0.025 mg + NE 0.8 mg; Cycle Days 25-28: ferrous fumarate (placebo)
Indication  Prevention of pregnancy

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1 Executive Summary
The Clinical Pharmacology review of NDA 022573 (DARRTS, 09/01/2010) stated that the NDA 022573 was acceptable provided that an agreement is reached between the sponsor and the Division regarding the language in the package insert labeling. The agreement on the language in the package insert labeling between the sponsor and the Division was reached on 12/21/2010. The highlights of the prescribing information and Clinical Pharmacology relevant sections of the final agreed upon package insert labeling are included in Section 2 of this addendum.

1.1 Recommendation
The Division of Clinical Pharmacology 3, Office of Clinical Pharmacology finds the NDA 022573 acceptable.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CHRISTIAN GRIMSTEIN
12/21/2010

MYONG JIN KIM
12/22/2010