OFFICE OF CLINICAL PHARMACOLOGY ADDENDUM

NDA: 022474

Brand Name
Ella

Generic Name
Ulipristal Acetate

Reviewer
Hyunjin Kim, Pharm.D., M.S.

Team Leader
Myong-Jin Kim, Pharm.D.

OCP Division
Division of Clinical Pharmacology 3

OND Division
Division of Reproductive and Urologic Products (DRUP)

Sponsor
HRA Pharma

Relevant IND
049381

Submission Type, Code
Original, 1S

Formulation; Strength
Tablet; 30 mg

Indication
Emergency contraceptive for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure

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1 Executive Summary
The Clinical Pharmacology review of original NDA 022474 (DARRTS, 07/09/2010) stated that the NDA 022474 was acceptable provided that 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 was reached on 08/12/2010. 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 022474 acceptable.

1.2 Phase IV Commitments
An in vivo drug-drug interaction trial of ulipristal acetate with CYP3A4 inducer should be conducted.

The sponsor agreed to conduct the study described under Section 1.2 with the following timelines (DARRTS, 08/12/2010).
   o Final Protocol Submission: 02/13/2011
   o Trial Completion: 02/13/2013
   o Final Report Submission: 08/13/2013

4 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page
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/s/

HYUNJIN KIM
08/12/2010

CHONGWOO YU
08/12/2010
Signing on behalf of Dr. Myong Jin Kim

EDWARD D BASHAW
08/12/2010