

OFFICE OF CLINICAL PHARMACOLOGY ADDENDUM

NDA: 022474	Submission Dates: 10/15/2009, 1/19/2010, 4/05/2010, 05/11/2010, 06/29/2010, and 08/12/2010
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

Table of Contents

1	Executive Summary	2
1.1	Recommendation	2
1.2	Phase IV Commitments	2
2	Final Agreed Upon Package Insert Labeling	3

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).

- *Final Protocol Submission: 02/13/2011*
- *Trial Completion: 02/13/2013*
- *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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22474	ORIG-1	LABORATOIRE HRA PHARMA	Ella , Ulipristal Acetate

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/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