

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

022474Orig1s007

Trade Name: ella tablets, 30 mg.

Generic Name: ulipristal acetate

Sponsor: Laboratoire HRA Pharma

Approval Date: March 10, 2015

Indication: This supplemental new drug application provides for updated nonclinical and clinical information. Specifically, new language was added (1) to discuss the impact of use of hormonal contraception shortly after taking ella and the impact of ella on hormonal contraceptive effectiveness, (2) to update the labeling with results of a postmarketing study in adolescents, and (3) to update labeling with the results of carcinogenicity studies

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APPROVAL LETTER



NDA 022474/S-007

SUPPLEMENT APPROVAL

Laboratoire HRA Pharma
c/o Pacific-Link Regulatory Consulting
Attention: Richard Lowenthal, MSc, MBA
President
8195 Run of the Knolls Court
San Diego, CA 92127

Dear Mr. Lowenthal:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 9, 2014, received, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for **ella** (ulipristal acetate) tablets, 30 mg.

We acknowledge receipt of your amendments dated October 22, 2014 and January 20, 2015.

This “Prior Approval” supplemental new drug application provides for updated nonclinical and clinical information. Specifically, new language was added (1) to discuss the impact of use of hormonal contraception shortly after taking **ella** and the impact of **ella** on hormonal contraceptive effectiveness, (2) to update labeling with results of a postmarketing study in adolescents, and (3) to update labeling with the results of carcinogenicity studies.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling, with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jennifer Dao, Regulatory Project Manager, at (301)796-8189.

Sincerely,

{See appended electronic signature page}

Audrey Gassman, M.D.
Deputy Director
Division of Bone, Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

AUDREY L GASSMAN
03/10/2015