

NDA 022474/S-011

SUPPLEMENT APPROVAL

Laboratoire HRA Pharma
c/o Ann Robbins LLC
Regulatory US Agent
6430 Sun Eagle Lane, Unit 301
Bradenton, FL 34210

Dear Ms. Robbins:

Please refer to your supplemental new drug application (sNDA) dated and received, May 22, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ella (ulipristal acetate) tablet, 30 mg.

This Prior Approval supplemental new drug application provides for revisions to the following:

HIGHLIGHTS OF PRESCRIBING INFORMATION

- WARNINGS AND PRECAUTIONS
- DOSAGE AND ADMINISTRATION
- DRUG INTERACTIONS

FULL PRESCRIBING INFORMATION (PI)

- DOSAGE AND ADMINISTRATION (sections 2.1, 2.2, and 2.3)
- WARNINGS AND PRECAUTIONS (sections 5.5)
- ADVERSE REACTIONS (section 6.2)
- DRUG INTERACTIONS (section 7.1)
- USE IN SPECIFIC POPULATIONS (sections 8.3)
- CLINICAL PHARMACOLOGY (section 12.2)
- PATIENT COUNSELING INFORMATION (section 17)

Revisions were also made to Patient Information Leaflet to reflect all of the changes in the PI and to reduce redundancy.

The edits reflect clarification of instructions for initiation and resumption of a progestin-containing hormonal contraception (COCs, progestin-only pill, and non-oral progestin-containing contraception) no sooner than five days after ella intake to apply to women using ulipristal acetate for a known or suspected contraceptive failure.

Changes to the Dosing and Administration section were based on the results of your study HRA2914-5016 entitled; *“A Prospective, Randomized, Parallel-group Study to*

Assess the Effects on Ovarian Activity of ellaOne® (ulipristal acetate 30 mg single dose) Taken After Three Consecutive Days of Missed Combined Oral Contraceptive Pills” and from an investigator sponsored study (HRA2914-5017) published by Edelman, et al., from 2018.

Results from these two studies support revisions that clarify instructions in the Dosing and Administration section to inform healthcare providers and patients on how to initiate and resume hormonal contraception products after ella use.

APPROVAL & LABELING

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

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 FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert) 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 *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 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.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

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 Jeannie Roule, Chief, Project Management Staff (Acting), at 301-796-3993.

Sincerely,

{See appended electronic signature page}

³ For the most recent version of a guidance, check the FDA guidance web page at

<https://www.fda.gov/media/128163/download>.

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

Audrey Gassman, M.D.
Deputy Director
Division of Urology, Obstetrics, and Gynecology
Office of Rare Diseases, Pediatrics,
Urologic and Reproductive Medicine
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

AUDREY L GASSMAN
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